



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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NRVs-R for persons aged 6 – 36 months

Comments in reply to CL 2024/51-NFSDU

Comments by Argentina, Australia, Azerbaijan, Brazil, Canada, Colombia, Costa Rica, Guatemala, Japan, Kenya, Malaysia, New Zealand, Paraguay, Peru, Philippines, Senegal, Sierra Leone, South Africa, United Arab Emirates, United Kingdom, Uruguay, USA and Helen Keller International, ICUMSA, International Special Dietary Food Industries

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2024/51-NFSDU issued in July 2024. 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 Annex

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

GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
<p>Australia thanks the Chair and Co-Chairs for their continued work on establishing NRVs-R for persons aged 6-36 months, and for their thorough consideration of feedback received in the EWG consultations.</p> <p>Australia supports the progression of the General principles for the establishment of NRVs-R for persons aged 6-36 months and notes the draft includes only a few aspects requiring further consideration and agreement, namely; the definition of 'adequate intake' and how to consider the combined NRVs-R values for the age group 6-36 months.</p> <p>Australia does not support Approach 1 which limits the Stepwise Process to using data from FAO/WHO and data published by RASBs over the past ten years.</p> <p>Australia continues to support Approach 2 which allows the Stepwise Process to use data from FAO/WHO and ALL data published by RASBs regardless of the date of publication.</p> <p>Australia supports further discussion on restricting consideration of RASB data to more recently available publications. While it is noted that in the pilot nutrients this makes little difference to the NRVs-R established using the Stepwise Process, we cannot be confident that this will always be the result. Considering all data published by RASBs, regardless of the date of publication, ensures the derived NRVs-R always reflect the best available evidence.</p> <p>Australia is of the view that restricting the evidence to data published by RASBs over the past ten year period may significantly reduce the amount of available data, possibly overlooking valuable older studies that are still relevant. This potentially increases bias towards recent findings, where newer studies may not have undergone the same level of scrutiny and replication as older, well-established research. Further, Approach 1 presents risk to the integrity of the Stepwise Process whereby it favours and introduces an over-reliance on data from RASBs which undertake regular updates but these may not reflect the best available evidence or scientific rigour. The resulting data may also not fully represent all relevant factors and it may be influenced by specific interests. There is also the risk of precedent setting for general NRVs-R future data requirements and related expectations which should be considered further.</p>	Australia
<p>Azerbaijan expresses its gratitude to Chair (Ireland) and co-Chairs (USA and Costa Rica) for their leadership in guiding the electronic Working Group in developing the proposed draft General principles for the establishment of NRVs-R for persons aged 6-36 months. Azerbaijan recognizes the immense value of the work undertaken and the transparent, evidence-based approach to the development of these principles.</p>	Azerbaijan
<p>Brazil appreciates the excellent work made by Ireland, Costa Rica and United States of America and thanks the opportunity to provide the following comments.</p>	Brazil
<p>Canada agrees with the revisions and supports the adoption of the revised draft Stepwise Process to establish NRVs-R for persons aged 6-12 months, 12-36 months and 6-36 months, as they provide consistency and clarity on how to implement Section 3 of the draft General Principles on how to derive the NRVs-R. Canada also supports not including a definition of "recent" in the Stepwise Process, as this allows for flexibility in the future so the most appropriate DIRV data from RASBs can be used.</p> <p>Canada supports the proposed Approach 1 (to interpret "recent" in the application of the draft Stepwise Process to propose NRVs-R for all nutrients listed in ToR B) in principle, however is concerned that "recent" is not being applied to FAO/WHO values as the general principles state: Relevant daily intake reference values provided by FAO/WHO that are based on a recent review of the science should be taken into consideration as primary sources in establishing NRVs-R. Canada agrees with restricting RASB data to more recently available publications, as</p>	Canada

<p>comparison of the NRVs-R from using the two approaches shows that there is very little variation in the resulting NRVs-R values for most nutrients. Limiting the data to more recent publications also aligns with the draft General Principles. To address the concern regarding “recent” also being applied to FAO/WHO data, the committee may wish to validate the FAO/WHO data by comparing it to the RASB data (with the proposed interpretation of “recent” applied) and determining if there is considerable variation.</p> <p>As mentioned above, Canada agrees in principle with the proposed NRVs-R for persons aged 6-12 months and 12-36 months, however found some errors and inconsistencies, summarized in the bullets below. Additionally, as previously raised in our response to CP2 and confirmed by the EWG Chair and Co-Chairs, the NRVs-R for zinc will need to be updated with FAO/WHO data which is expected shortly.</p> <p>Canada does not support the proposed NRVs-R for the combined 6-36 months (established using Approach 1 and Option3 (mean value) for the combined values, as discussed in Agenda Item 4.1 - Part A), since Canada continues to support the EWG’s previous recommendation to select the higher value of the proposed NRVs-R for older infants and young children, while not exceeding the UL for either age group. Contrary to what was mentioned in the agenda paper, Option 3 (mean approach) does not ensure that the needs of all children are covered. Option 1 (highest value, not exceeding the UL) is also consistent with the one used in Canada.</p> <p>Canada agrees that as part of the process to finalize the NRVs-R for persons aged 6-12 months, 12-36 months and 6-36 months, the values should be rounded to be consistent with the NRVs-R for the general population and also to avoid giving the impression that the NRVs-R are very precise.</p> <p>Identified errors and inconsistent application of rounding rules with the proposed NRVs-R, which were not corrected in the revised document published on September 4, 2024:</p> <ul style="list-style-type: none"> • Page 20: For vitamin E for young children, the NCM recommendation is classified as 2h, however there is no 2h in the key. • Page 31: The median for folate for older infants of recent RASBs is 80 mcg (the explanation is wrong). This should be corrected to state that Step 3b.1 applies. • Page 32: For the combined aged group, it appears that Japan’s values were considered, when they should not be, since data is based on folic acid. • Pages 9 and 35-37: For pantothenic acid, inconsistencies between the values reported in the summary tables and the work tables (young children A1 and A2, combined values option 2 A1 and A2). • Pages 9,11, 50 and 51: For all age groups, issues with rounding for copper due to use of both micrograms and milligrams without converting to one consistent unit. <p>Canada does not support selecting the mean value of the proposed NRVs-R for older infants and young children. Canada continues to support the EWG’s previous recommendation to select the higher value of the proposed NRVs-R for older infants and young children, while not exceeding the UL for either age group, since this meets the requirements of all children aged 6-36 months without exposing anyone to an excessive intake. Since the UL is taken into consideration, there is no risk that this vulnerable age group exceeds their needs, which was the concern raised by those not supporting using the population coverage approach (highest value), that many countries like Canada use.</p>	
i. Costa Rica supports accepting the definition of adequate intake currently in square brackets in Section 2 of Appendix I.	Costa Rica
Japan's response to the first EWG Consultation Paper was ‘We are also prepared to provide updated data, if necessary, as differences have also arisen between the data in the FAO report and some of the current values in the Dietary Reference Intakes for Japanese.’ As it was	Japan

<p>proposed in the Part B document (CX/NFSDU 24/44/4) to use data published by FAO/WHO and RASBs in the past 10 years, the Dietary Reference Intakes for Japanese (2020), which are published in 2019, will be shared as information. The date should be replaced by the Dietary Reference Intakes for Japanese (2020) at a time convenient to the secretariat.</p> <p>https://www.mhlw.go.jp/content/10900000/001150922.pdf</p>	
<p>Kenya supports the adoption of a revised step wise approach, with step 4 only maintaining option 3 of using the mean in calculating NRV-R values. Kenya also supports adoption of the NRV-R values derived using the step wise approach as presented in the annexes.</p> <p>Justification: The stepwise approach as presented provides a clear scientific basis, including clarity of the data that may be used to compute the NRV-R for 6-36-month-old persons.</p>	Kenya
<p>Malaysia can support to use Approach 1 when applying the Stepwise Process (consideration of data from FAO/WHO & 'more recent RASBs' only) as in line with the Section 3 general principles for establishing NRVs-R, which states "relevant DIRVs that reflect recent independent review of the science from RASBs can be considered"</p> <p>Malaysia supports the proposed definition of Adequate intake in the Section 2 of the General principles for the establishment of NRVs-R for persons aged 6 – 36 months since it is in line with the definition made by FAO/WHO.</p> <p>Malaysia also supports Option 3: [The combined NRV-R value for persons aged 6-36 months should be determined by calculating the mean value of the two age groups 6-12 months and 12-36 months.] in the Section 3.2 of the General principles for the establishment of NRVs-R for persons aged 6 – 36 months. This is due to the fact that the NRVs-R for person aged 6-36 months will only be used for labelling purposes, and the values of all three options do not differ significantly.</p>	Malaysia
<p>New Zealand appreciates the substantive work that the Chairs have done to revise the General Principles and derive NRVs-R using the Stepwise process. We look forward to some fruitful discussion on the General Principles and NRVs-R within the physical working group. Our comments to this CL relate to the draft General Principles and step-wise process. We will provide comments on the specific NRVs-R for the pilot nutrients in the pWG.</p> <p>We support the derivation of NRVs-R that will provide Codex with a set of NRVs-R that are the most globally relevant and scientifically sound. In doing so it is important to consider that the main purpose of these values is 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>Thank you for the opportunity to provide feedback on the CL.</p>	New Zealand
<p>Paraguay is grateful for the opportunity to share our comments regarding this document, which deals with such an important and necessary issue as the NRVs-R.</p>	Paraguay
<p>In response to the stepwise process for establishing the NRVs-R for persons aged 6–36 months and the NRVs-R for older infants and young children and for the combined age range of 6–36 months (Appendix I, CX/NFSDU 24/44/4, Part B), the following comments are submitted:</p> <ul style="list-style-type: none"> It is noted that member countries should be able to view the evidence included in the review and the process for grading the evidence by the FAO/WHO expert working group. The general principles state that "the 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 for establishing the NRVs-R". The expression "taken into consideration" implies that the values should be considered or evaluated in the context of new evidence. The principles also state the following regarding the new relevant DIRVs from the RASBs: "Relevant daily intake reference values that reflect recent 	Peru

independent assessments of the science and that come from Recognized Authoritative Scientific Bodies...could also be taken into consideration". An updated process is therefore supported:

Step 1: Identify new or updated Daily Intake Reference Values (DIRVs) from FAO/WHO for older infants and young children and assess for establishing NRVs-R.

Step 1a: Assess the derivation of new or updated DIRVs from FAO/WHO based on the rigour of the scientific methods, the underlying data quality and strength of evidence.

Step 1b: Compare new or updated DIRVs from FAO/WHO to earlier DIRVs from FAO/WHO and the relevant NRVs from the RASBs.

Step 1c: If the derivation of the new or updated DIRV from FAO/WHO is the same as or higher than the relevant DIRVs from the RASBs, in terms of the rigour of the scientific methods, the underlying data quality and strength of evidence, then select the new DIRV from FAO/WHO as the recommended NRV-R. If not, then go to Step 2*.

*According to Note 1 of Step 2, the new FAO/WHO data would then replace the older FAO/WHO data.

- The commission agrees that DIRVs from RASBs that are based on a recent independent review of the science should be taken into consideration, with higher priority given to values where evidence has been evaluated by a systematic review. However, as outlined in our proposed Step 1, we believe that DIRVs from RASBs should also be taken into consideration along with new or updated DIRVs from FAO/WHO and the values from both FAO/WHO and the RASBs should be evaluated according to the factors outlined in the general principle: rigour of scientific methods, underlying data quality and strength of evidence. If new or updated DIRVs from FAO/WHO are evaluated in the context of DIRVs from RASBs and rank the same or higher in terms of rigour of scientific methods, underlying data quality and strength of evidence, the new or updated DIRV from FAO/WHO should be selected as the NRV-R. To align with the proposed Step 1, the following edit to Step 2 is suggested:

Step 2: Aligned with General Principle 3.1, when new or updated DIRVs have not been selected by FAO/WHO for establishing NRVs-R or when updated DIRVs have not been established by FAO/WHO for vitamins and minerals, relevant DIRVs that reflect a recent independent review of the science from RASBs can be considered, with higher priority given to values where evidence has been evaluated by a systematic review.

- The commission agrees with Step 3 of the process as it is in line with the general principles. This approach is also consistent with the weighting of the evidence by other authoritative groups. This method is also outlined as the appropriate scientific methodology for developing DIRVs, as published in the FAO "Review of derivation methods for dietary intake reference values for older infants and young children; FAO request for scientific advice to develop general principles for the establishment of Codex nutrient reference values for older infants and young children". We also agree with the use of the median rather than the mean, as it is less prone to the effect of outliers.

- We support the selection of Option 1 in Step 4 for determining the combined NRV-R for 6–36 months, as this ensures that the highest nutrient requirements of the population are reasonably met, as long as the lowest UL is not exceeded. This approach manages potential risks of both toxicity and deficiency. In cases where the combined NRV-R exceeds the lowest UL, it is recommended to use the UL of the most sensitive population, as it would be appropriate and safe.

- We agree with Step 5 of the process, as it is in line with the general principles. With regard to the Summary Tables of NRVs-R for Older Infants and Young Children and for the combined age range of 6–36 months, Appendix II CX/NFSDU 24/44/4 Part B (for comments at Step 3), the following comments are submitted:

- We support the use of Approach 1 (consideration of data from FAO/WHO and more recent RASBs only) as it is in line with the general principles, which state that "relevant DIRVs that reflect a recent independent review of the science from RASBs can be considered".

<ul style="list-style-type: none"> • For vitamin D, supplementation studies and dose-response modelling have generally concluded that a vitamin D intake of 10 µg/day in infants aged 6–12 months and 10–15 µg/day in children aged 1–3 years is adequate for obtaining a serum concentration of 25(OH)D of 50 nmol/L, considering minimal exposure to sunlight. Recent recommendations by IOM, EFSA and the Nordic Council of Ministers are higher than 5 µg. This is likely due to the determination that a target serum concentration of 25(OH)D of 50 nmol/L is indicative of vitamin D sufficiency, as well as the more recent availability of data to generate dose-response models. In this context, we recommend considering the RASB values as more up-to-date than the 2004 DIRVs from FAO/WHO and recalculating the NRV values accordingly. • In the case of pantothenic acid, since only the DIRVs from FAO/WHO and IOM were considered for young children, while the DIRVs from all the RASBs were considered for older infants, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs. This should be reviewed before a final agreement is reached. • In the case of copper, since only the EFSA DIRVs were taken into consideration for older infants, while only the IOM and Japanese NIH values were taken into consideration for young children, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs. This should be reviewed before a final agreement is reached. • In the case of magnesium, with Approach 1, since the RASB values were considered for older infants rather than for young children, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs. This should be reviewed before a final agreement is reached. • We support the selection of Option 1 for determining the combined NRVs-R for vitamins for 6–36 months, as this ensures that the highest nutrient requirements of the population are reasonably met, as long as the lowest UL is not exceeded. This approach manages potential risks of both toxicity and deficiency. • We support the selection of Option 1 for determining the combined NRVs-R for minerals and proteins for 6–36 months, as this ensures that the highest nutrient requirements of the population are reasonably met, as long as the lowest UL is not exceeded. This approach manages potential risks of both toxicity and deficiency. 	
<p>The Philippines appreciates the extensive work conducted by the Electronic Working Group on Draft General Principles for Establishing Nutrient Reference Values for Persons Aged 6-36 months led by Ireland and co-chaired by USA and Costa Rica. The Philippines expresses its support to the proposed definition of Adequate Intake and deletion of the brackets in Section 2 of the Proposed Draft. This definition is consistent with the definition of adequate intake as reflected in the Philippine Dietary Reference Intake 2015 (PDRI 2015) and adopted as local regulation.</p> <p>Consistent with principle of establishing NRVs-R for adults, we support Option 3- Combined NRV-R value for persons aged 6-36 months should be determined by calculating the mean value of the two age groups 6-12 months and 12-36 month, and deletion of the brackets and stricken out statements (Option 1 and Option 2) in Section 3.2.</p> <p>The Philippines supports the revised stepwise process using Approach 1 outlining the process to establish NRVs-R for persons aged 6-12 months, 12-36 months, and 6-35 months. The stepwise process is a valuable framework emphasis on using updated FAO/WHO data where available. This aligns with the Philippines' regulatory practices, implementing evidence-based guidelines and international standards based on the latest science.</p>	Philippines
Sierra Leone accepts the proposal for NRVs-R for all nutrients for older infants, young children 6 - 36 months	Sierra Leone
CL 2024/51-NFSDU Request for comments on the General Principles for the Establishment of NRVs-R for Persons Aged 6 - 36 Months and the NRVs-R for Persons Aged 6 - 36 Months Regarding the invitation to submit comments on the General Principles for the Establishment of NRVs-R for Persons Aged 6 - 36 Months and the NRVs-R for Persons Aged 6 - 36 Months: a- CX/NFSDU 24/44/4, Part A, the draft General principles for the establishment of NRVs-R for persons aged 6 – 36 months; and, b- Regarding CX/NFSDU 24/44/4, Part B NRVs-R to use	United Arab Emirates

<p>Approach 1 when applying the Stepwise Process; and the proposals for NRVs-R for all nutrients for older infants, young children, and the combined age range 6 – 36 months. United Arab Emirates, UAE consider the following:</p> <p>a- Regarding CX/NFSDU 24/44/4, Part A.</p> <ul style="list-style-type: none"> - Adequate intake (AI) is a reference value for a population based on observed or experimentally determined approximations or estimates of nutrient intakes by a group (or groups) of presumably healthy people with no known evidence of deficiency. - UAE supports Option 1 (determining the combined NRV-R by selecting the highest value of the proposed NRVs-R for older infants and young children), as long as the lowest upper limit is not exceeded. This approach manages both the potential risks of toxicity and deficiency. The General Principles state that ideally the NRVs-R should be based on the INL98, which is defined as “the daily intake reference value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in the population aged from 6 to 36 months”. Taking the highest value ensures the nutrient requirements of most individuals in the combined 6–36-month population are reasonably met, as long as the lowest upper level of intake is not exceeded. Further, the ages of 12-36 months are a critical period for growth and development, and by choosing the mean value (option 3) for the combined value, it may not be adequate for children in this age range for which the nutrient recommendations were derived to support the incremental mass gain of these growing children. - UAE supports the need to determine three sets of NRVs-R: 1) 6-12 months, 2) 12-36 months, and 3) a combined value for 6-36 months. The revised Codex Standard for Follow-up Formula for Older Infants and Products for Young Children has set two parts of nutrient compositional requirements for products intended for two distinct age ranges (6-12 months and 12-36 months). Therefore, it is necessary to have separate NRVs-R for the two age ranges for these two distinct products for labelling purposes. On the other hand, complementary foods may be formulated for and intended for use by the combined age range 6-36 months, thus combined NRVs-R is needed for these products. Therefore, we believe three sets of NRVs-R must be derived. <p>b- Regarding CX/NFSDU 24/44/4, Part B NRVs-R.</p> <ul style="list-style-type: none"> - UAE supports use of Approach 1 (consideration of data from FAO/WHO & ‘more recent RASBs’ only) as in line with the General Principles, which state “relevant DIRVs that reflect recent independent review of the science from RASBs can be considered”. As outlined above, UAE supports use of Option 1 (highest value taken for the combined NRV-R). 	
<p>The United States applauds the significant progress made on the general principles and supports having a productive discussion to resolve the minor remaining areas for consideration and advance the general principles to the Codex Alimentarius Commission for final adoption.</p> <p>It is the U.S. view that these elements in principle 3.2 are fundamental and should apply to all recent systematic reviews used to establish NRVs-R, including new or updated reviews from both FAO/WHO and relevant RASBs.</p> <p>The United States is concerned that the stepwise process is more complex than necessary and is not as scientifically rigorous as possible, and therefore has proposed edits to simplify the steps and improve the scientific rigor such that all relevant data are used to establish NRVs-R.</p>	USA
<p>Helen Keller Intl commends the EWG on the development of these general principles and agrees they reflect the discussions held thus far, and that the general principles are ready to advance to the CAC for final adoption.</p>	Helen Keller International
<p>Only English version was reviewed. The revised text is an improvement on the original.</p>	ICUMSA

SPECIFIC COMMENTS	
PART A. DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR PERSONS AGED 6 TO 36 MONTHS	
COMMENT	MEMBER / OBSERVER
New Zealand supports the progress made to the General Principles.	New Zealand
1. PREAMBLE	
Guatemala supports the preamble and definitions as currently worded in CX/NFSDU 24/44/4, Part A, Appendix I. We also support the inclusion of the proposed definition of Adequate Intake.	Guatemala
ISDI supports the general principle as worded.	International Special Dietary Food Industries
2. DEFINITIONS AS USED IN THESE PRINCIPLES	
Australia supports the inclusion of the FAO/WHO definition for 'Adequate Intake' and supports the removal of the square brackets.	Australia
Brazil agrees with the definition of Adequate Intake presented in section 2 of the principles, which takes into account the ongoing FAO/WHO work to update nutrient intake values for infants and young children from birth through 3 years of age.	Brazil
Peru agrees with the definition of Adequate Intake (AI) and notes that member countries should be able to view the evidence included in the review and the process for grading the evidence by the FAO/WHO expert working group	Peru
Uruguay agrees to accept the definition of Adequate Intake (AI) currently in square brackets: [Adequate Intake (AI) is a reference value for a specified population based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of presumably healthy people with no known evidence of deficiency], as it is in line with definitions from FAO/WHO and other international literature.	Uruguay
ISDI supports the general principle as worded. ISDI supports the inclusion of the proposed definition of Adequate intake	International Special Dietary Food Industries
Argentina proposes removing the square brackets and keeping the definition of Adequate Intake as it stands.	Argentina
Having carefully reviewed the previous documents, such as the CX/NFSDU 24/44/4, Part A; CX/NFSDU 23/43/5; REP23/NFSDU etc. Azerbaijan considers this version the most appropriate, especially compared to previous versions, as it provides a clear and practical basis for setting nutrient intakes for older infants and toddlers. However, it should be noted that there is no explicit reference to the specific age group of 6-36 months in the current definition. Azerbaijan believes that including this age group in the definition of Adequate Intake would improve clarity and ensure consistency with other definitions in the document that already refer to this population, and that such an adjustment would contribute to a more consistent application of the principles in all relevant definitions.	Azerbaijan

<p>Canada supports removing the square brackets from the definition of Adequate Intake (AI). Canada supports aligning the definition of AI with that of the FAO/WHO, as it is very consistent with the definition of other Recognized Authoritative Scientific Bodies (RASBs), like the National Academies of Science, Engineering and Medicine (NASEM).</p>	<p>Canada</p>
<p>Colombia does not accept the definition of Adequate Intake as currently stated in square brackets.</p> <p>We suggest:</p> <p>Option 1.</p> <p>Changing the word “adequate” to “recommended”, to refer to the concept to be included in the Draft General Principles for Establishing Nutrient Reference Values for Persons Aged 6–36 Months, with the following proposed wording:</p> <p>[Recommended Intake (RI) is a reference value for a specified population based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of presumably healthy people with no known evidence of deficiency.]</p> <p>Option 2.</p> <p>Consulting international standards in order to adopt a global definition of Adequate Intake (AI). The following definition is proposed:</p> <p>Adequate Intake (AI): Recommended average intake level based on observed estimates of nutrient intake or experimentally determined approximations of nutrient intake or estimates of nutrient intake by a group or groups of apparently healthy people, for whom it is assumed to be adequate, according to criteria of adequacy established for each nutrient. AI is established instead of RDA when there is not enough evidence to establish EAR and thus to calculate RDA.</p> <p>First of all, it is important to remember that when establishing the recommendations for energy and nutrient intake, different reference values are defined, such as: Estimated Average Requirement (EAR), Recommended Dietary Allowance (RDA), Energy Requirement (ER) and Adequate Intake (AI), among others.</p> <p>In this vein, Adequate Intake (AI) is understood to be the “Recommended average intake level based on observed estimates of nutrient intake or experimentally determined approximations of nutrient intake or estimates of nutrient intake by a group or groups of apparently healthy people, for whom it is assumed to be adequate, according to criteria of adequacy established for each nutrient. AI is established instead of RDA when there is not enough scientific evidence to establish EAR and thus to calculate RDA”.</p> <p>The earlier definition coincides with that of various regulations such as those of EFSA, Canada and Colombia (Resolution 3803 of 2016).</p> <p>Based on the earlier information, there would be a lot of confusion if the same term (“Adequate Intake”) were used to define a different concept than the one that is already laid down in different regulatory standards.</p>	<p>Colombia</p>
<p>Kenya agrees with the definition and supports its adoption.</p> <p>Justification: The definition has been used extensively in FAO/WHO documents providing a common understanding and application of the term.</p>	<p>Kenya</p>
<p>New Zealand supports the revised definition that was provided by the FAO and WHO.</p>	<p>New Zealand</p>
<p>Paraguay understands that the proposed definition is the FAO/WHO definition, and the square brackets can be removed.</p>	<p>Paraguay</p>
<p>Establishing a definition for Adequate Intake (AI) on the General Principles for Establishing Nutrient Reference Values (NRV) specific for persons aged 6-36 months is essential as it provides a practical, science-based framework for ensuring appropriate nutrient intake during a critical phase of early development. It supports public health efforts, accommodates diverse dietary patterns, and serves as a bridge until a more precise data becomes available. The Philippines support the definition "Adequate intake (AI) is a reference value for a specified</p>	<p>Philippines</p>

population based on observed or experimentally determined approximations or estimates of nutrient intakes by a group (or groups) of presumably healthy people with no known evidence of deficiency.” This definition is consistent with the definition of AI in the PDR1 2015 and is adopted into a local regulation by the FDA Philippines that is “Adequate Intake is the daily nutrient intake level that is based on observed or experimentally determined approximation of the average nutrient intake by a group (or groups) of apparently healthy people that is assumed to sustain a defined nutritional state.”	
South Africa agrees with the definition of Adequate Intake currently in square brackets and proposes the removal of square brackets	South Africa
Adequate intake (AI) is a reference value for a population based on observed or experimentally determined approximations or estimates of nutrient intakes by a group (or groups) of presumably healthy people with no known evidence of deficiency.	United Arab Emirates
The UK note that definitions have already been agreed for: Daily Intake Reference Value (DIRV), Individual Nutrient Level 98 (INL98), and Upper Level of Intake (UL). The UK supports the conclusion of the EWG Chair and Co-Chairs for the use of the FAO/WHO definition of Adequate Intake (AI).	United Kingdom
Section 2. Definitions – The United States supports the proposed definition of “Adequate Intake” (AI) as it aligns with the definition set by the FAO/WHO.	USA
Helen Keller Intl supports the proposed definition of ‘Adequate Intake’.	Helen Keller International
- UAE supports Option 1 (determining the combined NRV-R by selecting the highest value of the proposed NRVs-R for older infants and young children), as long as the lowest upper limit is not exceeded. This approach manages both the potential risks of toxicity and deficiency.	United Arab Emirates
3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R	
3.1 Selection of suitable data sources for establishing NRVs-R Guatemala supports Section 3.1 of the general principles as drafted.	Guatemala
3.1 Selection of suitable data sources for establishing NRVs-R The commission agrees with the wording of Section 3.1.	Peru
3.1 Selection of suitable data sources to establish NRVs-R ISDI supports Section 3.1 of the general principles as worded.	International Special Dietary Food Industries
3.2 Appropriate Basis for Establishing NRVs-R Australia does not support the basis for establishing NRVs-R for the entire age group 6-36 months in square brackets (i.e. Option 3). Australia continues to support Option 1 as this most appropriately manages both the potential risks of nutrient toxicity and deficiency	Australia
3.2 Suitable basis for establishing NRVs-R Colombia does not support determining the combined NRV-R by calculating the mean value of the two age groups. It is suggested that Codex consider separating the values for the two age groups.	Colombia

<p>It is not statistically relevant to calculate an average of reference values that come from populations with different characteristics, in this case, infants aged 6–12 months and young children aged 12–36 months.</p> <p>Independent reference values have been established for these two age groups precisely due to the differences identified in the distribution curve of the requirements for each of the nutrients.</p>	
<p>3.2 Suitable basis for establishing NRVs-R</p> <p>Guatemala agrees with the general principle that the reference values or ranges recently established by the Scientific Bases for Risk Assessment may be more appropriate for consideration when there is either no DIRV or only an older DIRV from FAO/WHO for a nutrient. We also support the consideration of factors such as the rigour of scientific methods, the underlying data quality, strength of evidence, and the most recent independent review of the science used to derive the NRVs-R from the Scientific Bases for Risk Assessment.</p> <p>However, Guatemala does not admit determining the combined NRV-R by calculating the mean value of the two age groups. Guatemala asks the working group to reconsider choosing the higher value of the proposed NRVs-R for older infants and young children when determining a combined NRV-R, as long as it does not exceed the UL, where available. Guatemala believes that this is the best way to ensure that the nutrient needs of the combined population are met, thus avoiding deficiency and at the same time the potential risk of toxicity, taking into account the ULs.</p> <p>Guatemala disagrees with the concern that choosing the higher NRV-R in the case of nutrients that have no defined UL would drive excessive intake of a nutrient to the point of toxicity or adverse events. In some cases, a UL has not been set for a nutrient because no adverse events have been identified that could serve as a basis for deriving an upper limit. Additionally, as the combined age range only spans 30 months, and the difference between the NRVs-R for the two age ranges is not large, it is also highly unlikely that nutrients consumed at the recommended NRV-R, even at the higher NRV-R, by either age group, would result in risk of adverse events or toxicity. However, chronically consuming a nutrient at levels below the NRV-R could increase the risk of deficiency. Therefore, taking the higher NRV-R would be the more conservative approach for balancing deficiency with toxicity. Guatemala would like to ask for clarification on the concern that, for countries that label foods based on a fixed quantity rather than a per serving basis, choosing the higher NRV-R would drive higher consumption of these foods in older infants.</p>	<p>Guatemala</p>
<p>3.2 Suitable basis for establishing NRVs-R</p> <p>Peru does not agree with Option 3 and considers that Option 1 is the best way to ensure that the nutrient requirements of the combined population are met, thus preventing deficiency while also avoiding the potential risk of toxicity, taking into account the ULs.</p> <p>Peru is not concerned that choosing the higher NRV-R in the case of nutrients that have no defined UL could lead to excessive intake of a nutrient to the point of producing toxicity or adverse events. In some cases, a UL has not been set for a nutrient because no adverse events have been identified that could serve as a basis for deriving an upper limit. Additionally, as the combined age range only spans 30 months, and the difference between the NRVs-R for the two age ranges is not large, it is also highly unlikely that nutrients consumed at the recommended NRV-R, even at the higher NRV-R, by either age group, would result in risk of adverse events or toxicity. However, chronically consuming a nutrient at levels below the NRV-R could increase the risk of deficiency.</p> <p>Therefore, taking the higher NRV-R would be the right approach. We ask for clarification on the concern that, for countries that label foods based on a fixed quantity rather than a per serving basis, choosing the higher NRV-R would drive higher consumption of these foods in older infants.</p> <p>Peru agrees with the general principle that the reference values or ranges recently established by the Recognized Authoritative Scientific Bodies (RASBs) may be more appropriate for consideration when there is no DIRV from FAO/WHO for a nutrient or when there is only an older</p>	<p>Peru</p>

<p>one. We also support the consideration of factors such as the rigour of scientific methods, the underlying data quality, strength of evidence, and the most recent independent review of the science used to derive the NRVs-R from the RASBs.</p>	
<p>3.2 Appropriate Basis for Establishing NRVs-R</p> <p>The General Principles state that ideally the NRVs-R should be based on the INL98, which is defined as “the daily intake reference value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in the population aged from 6 to 36 months”. Taking the highest value ensures the nutrient requirements of most individuals in the combined 6–36-month population are reasonably met, as long as the lowest upper level of intake is not exceeded.</p> <p>Further, the ages of 12-36 months are a critical period for growth and development, and by choosing the mean value (option 3) for the combined value, it may not be adequate for children in this age range for which the nutrient recommendations were derived to support the incremental mass gain of these growing children.</p>	<p>United Arab Emirates</p>
<p>3.2 Appropriate Basis for Establishing NRVs-R</p> <p>Nevertheless, the derivation of these values from from FAO/WHO or from recognized authoritative scientific bodies, shall take into account the following elements: the rigour of scientific methods, the underlying data quality, the strength of evidence used to establish these values and the most recent independent review of the science.</p> <p>The United States notes that principle 3.2 for the establishment NRVs-R includes, among other considerations, that the rigor of scientific methods, the underlying data quality, the strength of evidence and the most recent independent reviews of the science shall be taken into account when deriving values from Recognized Authoritative Scientific Bodies (RASBs).</p> <p>It is the U.S. view that these elements in principle 3.2 are fundamental and should apply to all recent systematic reviews used to establish NRVs-R, including new or updated reviews from both FAO/WHO and relevant RASBs. Therefore, the United States suggests a minor edit in bold to the fourth sentence of General Principle 3.2:</p> <p>“Nevertheless, the derivation of these values from FAO/WHO or from recognized authoritative bodies shall take into account the following elements: the rigour of scientific methods, the underlying data quality, the strength of evidence used to establish these values and the most recent independent review of the science.”</p>	<p>USA</p>
<p>3.2 Suitable basis for establishing NRVs-R</p> <p>Uruguay considers that Option 1 is the most appropriate option for determining the combined NRV-R value for persons aged 6–36 months, i.e. it should be determined by selecting the higher value of the proposed NRVs-R for older infants and young children, as long as it does not exceed the maximum intake (UL) for older infants or young children, where available. In the case that the higher value exceeds the lower UL (for either of the two age groups) the average of both groups should be used. This is understood to be the most appropriate option, taking into account the essential nature of the nutrients at this stage, since this would ensure that the needs of both groups are met. In contrast, Options 2 and 3 would result in the failure to meet the needs of some persons within the combined age range.</p>	<p>Uruguay</p>
<p>Nevertheless, the derivation of these values from recognized authoritative scientific bodies, shall take into account the following elements: the rigour of scientific methods, the underlying data quality, the strength of evidence used to establish these values and the most recent independent review of the science.</p> <p>ISDI agrees with the general principle and that reference values or ranges recently established by RASBs may be more appropriate to consider when there is not, or there is an older, FAO/WHO DIRV for a nutrient. We also support the consideration of elements including rigour of</p>	<p>International Special Dietary Food Industries</p>

<p>scientific methods, the underlying data quality, the strength of the evidence, and the most recent independent review of the science when deriving NRVs-R from RASBs.</p>	
<p>[The combined NRV-R value for persons aged 6–36 months should be determined by selecting the higher value of the proposed NRVs-R for older infants and young children as long as it does not exceed the UL for older infants and/or young children, where available.]</p> <p>We propose to delete the brackets and stricken out statements (Option 1 and 2) in Section 3.2. We are of the opinion that Option 3, wherein the combined NRV-R value for persons aged 6-36 months should be determined by calculating the mean value of the two age groups 6-12 months and 12-36 months, could be considered to address the issues on excessive intake or lower than optimal intake. This is in adherence to the Philippines' local regulation adopting the PDRI 2015. Though a single value NRVs-R for 6-36 months are to be established based on the proposed principles, the Philippines may opt to use a separate locally established nutrient reference values (PDRI) for older infants (6-12 months old) and for young children (1-3 years old). We believe that it is necessary to account for differences in physiological requirements for each nutrient specific for these two age groups.</p>	<p>Philippines</p>
<p>[The combined NRV-R value for persons aged 6–36 months should be determined by selecting the higher value of the proposed NRVs-R for older infants and young children as long as it does not exceed the UL for older infants and/or young children, where available.]</p> <p>The United States does not support the recommendation to establish the combined NRVs-R for persons 6 – 36 months using option 3, the mean value. Rather, the United States supports option 1, which ensures a population coverage approach by selecting the higher value from the two population groups. In cases where the higher value exceeds the upper limit for one of the age groups, then the United States would recommend using the mean for these instances. The United States therefore proposes removing the strikethrough from option 1, and deleting options 2 and 3.</p>	<p>USA</p>
<p>The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups: 6–12 months and 12–36 months.]</p> <p>Argentina agrees with this criterion.</p>	<p>Argentina</p>
<p>NRV-R combined values for persons aged 6-36 months</p> <p>Brazil believes that separate food label NRVs-R should be established for specific age segments, namely 6 to 12 months and 12 to 36 months, as the nutritional needs vary between these groups. None of the three options—using the highest value, the lowest value, or the mean value of the two age groups—would adequately address the concerns raised by members of the Electronic Working Group (EWG). Using the highest value may be inappropriate if the food is primarily targeted at the younger age group (6 to 12 months, Older Infants), as the specified requirements would exceed what is necessary. Additionally, the potential risk of excessive nutrient intake in this vulnerable age group, where no UL has been established, must be considered.</p> <p>Conversely, using the lowest value could result in an amount below the requirements for those at the upper end of the age range. When the difference between the values of the two age groups is significant, using the mean value may also be unsuitable.</p>	<p>Brazil</p>
<p>The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.]</p> <p>Kenya supports adoption of Option 3. Justification: The 3rd option, which is applying mean calculation, provides a better value as opposed to the choice of either an upper or lower value. Mean has also been used in establishing NRV-R of the general population.</p>	<p>Kenya</p>

<p>The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.]</p> <p>The New Zealand position throughout this work has been that the purpose and use of the combined value of the NRV-R for the 6 - 36 month age group should be determined, prior to establishing which approach is warranted.</p> <p>For the NRVs-R to provide the overall objective of providing caregivers with labelling information to understand the relative contribution of the product to overall dietary intakes and compare products, there needs to be some consistency in how the individual and combined values are to be applied. This is particularly important for the food products that are within a standard that covers the wider age range.</p> <p>It is our view that the following questions should be addressed, prior to establishing the most appropriate value.</p> <p>Will these NRV-s R be presented as up to national or regional authorities to determine whether to have two NRVs-R for the two age groups, or a single combined value 6-36 months, or will all three be considered to be appropriate to be chosen by the manufacturer and will there be guidance as to how to select the appropriate value?</p> <p>If the highest value is always selected, this may be inappropriate if the food is intended for older infants as the requirements specified will be much higher than necessary. Furthermore, many of the Standards have mandatory nutrient requirements which may have been set to meet the requirements of either infants or young children.</p> <p>Without knowledge of how these values are to be used or presented for use within the Guidelines, it is difficult to comment on which approach is most suitable.</p> <p>New Zealand supports recommendation iii to clarify how the combined NRVs-R for persons aged 6-36 months should be used. As noted in the agenda paper, it is our understanding that many products that are formulated using these standards are typically targeted to younger infants.</p>	<p>New Zealand</p>
<p>The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups: 6–12 months and 12–36 months.]</p> <p>Having analysed the comments presented in the EWG, understanding that neither Options 1 and 2 might meet the needs of this age group, it is our view that Option 3 (the combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups: 6–12 months and 12–36 months) would be a better option.</p>	<p>Paraguay</p>
<p>Position: Senegal approves the work carried out by the EWG and supports option 3, which is the combined value of the NRVs-R for children aged 6 to 36 months. This value should be determined by selecting the mean value of the NRVs-R proposed for older infants and young children.</p> <p>Justification: Senegal considers option 3 to be the most appropriate as it offers greater flexibility and good micronutrient coverage. The mean value is more suitable for obtaining the optimum physiological benefit.</p> <p>Governments can establish the NRVs-R for food labelling by taking into account factors specific to the country or to the region that influence absorption, use and nutrient requirements.</p>	<p>Senegal</p>
<p>The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.]</p>	<p>South Africa</p>

<p>South Africa is in support of applying option 3 ONLY for use in nutrients that DO NOT have an upper limit (UL). However, we believe that Option 1 is most favourable in meeting the requirements of infants and young children for nutrients that have an UL.</p> <p>Rationale:</p> <p>We are of the view that Option 1 is pragmatic in terms of meeting the requirements for persons with the highest requirement if the lowest upper limits are not exceeded. This approach manages both the potential risks of toxicity and deficiency. It upholds the principles of application on a case-by-case basis. Our concern still remains in circumstances whereby there are no ULs for some nutrients as one is unable to determine the safety of these nutrients. Therefore, option 3 for these nutrients may be more suitable until UL's are derived.</p>	
<p>The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.]</p> <p>UAE supports use of Approach 1 (consideration of data from FAO/WHO & 'more recent RASBs' only) as in line with the General Principles, which state "relevant DIRVs that reflect recent independent review of the science from RASBs can be considered".</p> <p>As outlined above, UAE supports use of Option 1 (highest value taken for the combined NRV-R).</p>	<p>United Arab Emirates</p>
<p>The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.]</p> <p>The UK supports the conclusion of the EWG Chair and Co-Chairs in choosing Option 3 whereby the combined NRV-R value for persons aged 6-36 months is determined by selecting the mean value of the proposed NRVs-R for older infants and young children. The UK notes that clarification on how these combined NRVs-R for persons aged 6–36 months should be used will be outlined in relevant text that relates to where the three sets of NRVs-R are presented in CXG 2-1985</p>	<p>United Kingdom</p>
<p>The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.]</p> <p>The United States does not support the recommendation to establish the combined NRVs-R for persons 6 – 36 months using option 3, the mean value. Rather, the United States supports option 1, which ensures a population coverage approach by selecting the higher value from the two population groups. In cases where the higher value exceeds the upper limit for one of the age groups, then the United States would recommend using the mean for these instances.</p>	<p>USA</p>
<p>The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.]</p> <p>Helen Keller Intl does not support the recommendation from the EWG Chair and Co-Chairs that the mean value of the proposed NRVs-R for older infants and young children be used as the combined NRV-R value for persons aged 6-36 month. Instead, option 1 is preferred: selection of the higher value of the proposed NRVs-R for older infants and young children if it does not exceed the UL for older infants and/or young children. In cases where this value does exceed the UL, then the mean value could be used. Helen Keller Intl highlights the importance of including guidance and clarification on how these combined NRVs-R for persons aged 6–36 months should be used.</p>	<p>Helen Keller International</p>
<p>The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.]</p> <p>ISDI does not support determining the combined NRV-R by calculating the mean value of the two age groups. ISDI asks the working group to reconsider selecting the higher value of the proposed NRVs-R for older infants and young children when determining a combined NRV-R, as long as it does not exceed the UL, where available. ISDI believes this is the best way to ensure the nutrient requirements of the combined</p>	<p>International Special Dietary Food Industries</p>

<p>population are met, thereby preventing deficiency while also avoiding the potential risk of toxicity by taking ULs into account.</p> <p>ISDI disagrees with the concern that choosing the higher NRV-R in the case of nutrients that have no defined UL would drive excessive intake of a nutrient to the point of toxicity or adverse events. In some cases, an UL has not been set for a nutrient because no adverse events have been identified that could be a basis for deriving an upper limit. Additionally, as the combined age range spans only 30 months, and the difference between NRVs-R for the two age ranges is not large, it is also highly unlikely that nutrients consumed at the recommended NRV-R, even at the higher NRV-R by either age group, would result in risk of adverse events or toxicity. However, chronically consuming a nutrient at levels below the NRV-R could increase the risk of deficiency. Therefore, taking the higher NRV-R would be the most conservative approach to balancing deficiency with toxicity.</p> <p>ISDI also notes the concern raised that consumers of these foods would more typically be at the lower end of the age range. As the combined NRV-Rs would be used in situations where the food is intended to be consumed by a population covering both age ranges, ISDI still feels it would be most relevant to derive NRVs-R that ensures the nutrient requirements of the combined population are met, regardless of the proportion of consumers from each age group.</p> <p>ISDI would like to ask for clarification on the concern that, for countries that label foods based on a fixed quantity versus per portion, choosing the higher NRV-R would drive higher consumption of these foods in older infants.</p>	
<p>3.3 Consideration of maximum intake levels</p> <p>Guatemala supports Section 3.3 of the general principles as drafted.</p>	<p>Guatemala</p>
<p>3.3 Consideration of maximum intake levels</p> <p>Peru agrees with the wording of Section 3.3.</p>	<p>Peru</p>
<p>3.3 Consideration of Upper Levels of Intake</p> <p>ISDI supports Section 3.3 of the general principles as worded.</p>	<p>International Special Dietary Food Industries</p>
<p>SPECIFIC COMMENTS</p>	
<p>PART B: REVISED STEPWISE PROCESS</p>	
<p>COMMENT</p>	<p>MEMBER / OBSERVER</p>
<p>Argentina agrees with the revised stepwise process for establishing NRVs-R for persons aged 6–36 months and NRVs-R for older infants and young children.</p>	<p>Argentina</p>
<p>Overall, Azerbaijan supports the endorsement of the Stepwise Process, as it provides consistency and clarity. However, Azerbaijan believes that the Stepwise Process still requires further refinement, particularly for nutrients such as pantothenic acid and copper, as mentioned in the eWG. The limited available data for these nutrients may result in NRVs-R that are either misleading or unbalanced. To ensure the Stepwise Process can be confidently applied to all nutrients, it is essential that these data gaps are addressed first.</p>	<p>Azerbaijan</p>
<p>Brazil has no objections to the steps outlined in the general principles. We support using Approach 1 when applying the Stepwise Process: utilizing data from FAO/WHO and data published by RASBs within the past 10 years.</p> <p>Steps 1 and 2</p>	<p>Brazil</p>

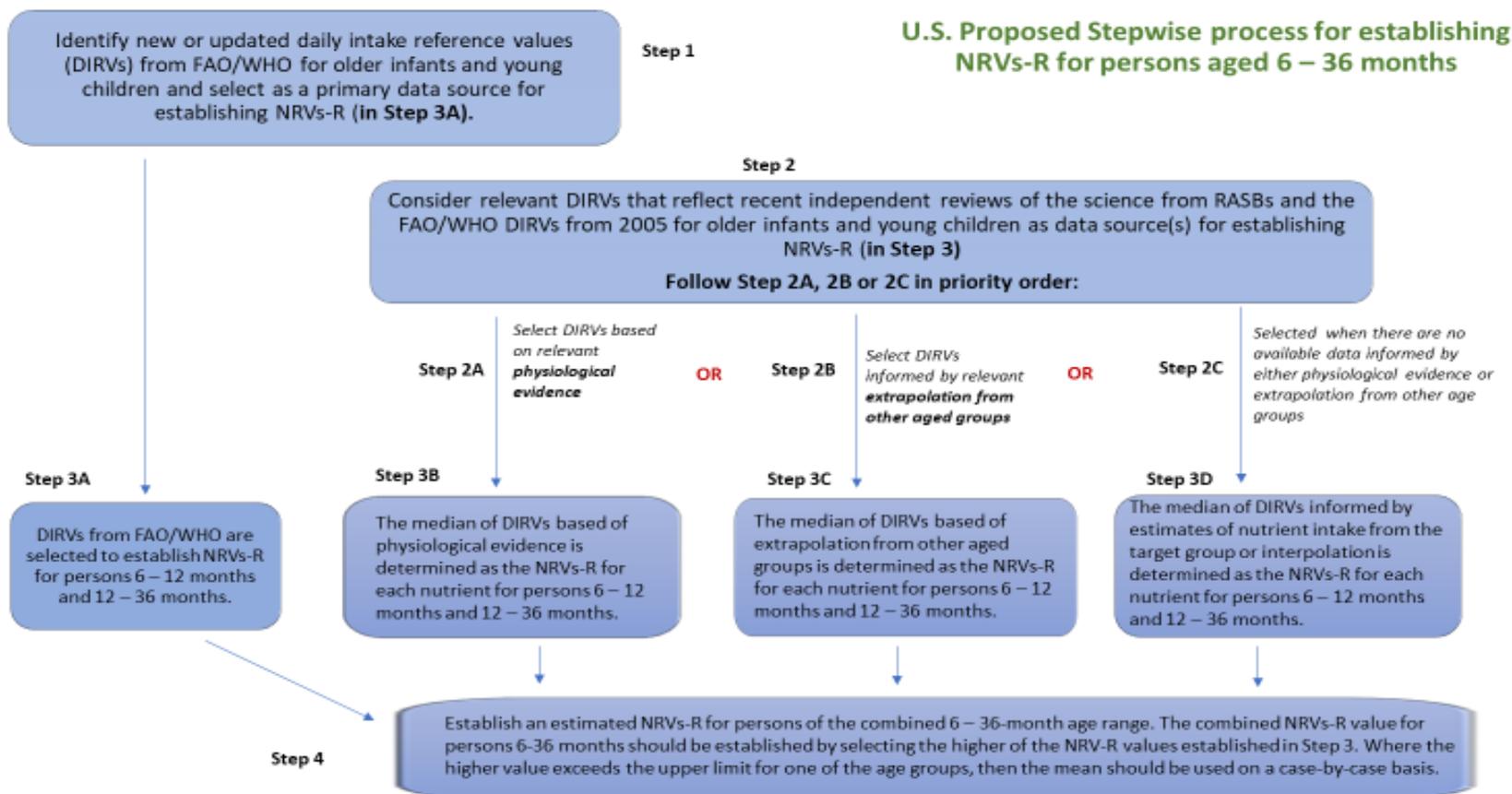
<p>We agree that new or updated DIRVs from FAO/WHO for older infants and young children should be identified and considered as primary sources in establishing NRVs-R. Relevant DIRVs reflecting recent independent reviews of the science by RASBs should also be considered, with higher priority given to values supported by evidence evaluated through systematic reviews, along with existing FAO/WHO data. Therefore, we support the proposed texts for steps 1 and 2.</p> <p>We acknowledge that the additional instructions in step 3 are based on the FAO/WHO report (2021) and aim to facilitate the implementation of the criteria for deriving NRVs-R values. However, when applying the stepwise process to all nutrients, inconsistencies were observed for some, such as vitamin D, vitamin B12, pantothenic acid, copper, and magnesium. This suggests that the text of Step 3 should be further explored to better align with the principles outlined in section 3.2.</p>	
<p>Colombia does not support determining the combined NRV-R by calculating the mean value of the two age groups.</p> <p>It is not statistically relevant to calculate an average of reference values that come from populations with different characteristics, in this case, infants aged 6–12 months and young children aged 12–36 months.</p> <p>Independent reference values have been established for these two age groups precisely due to the differences identified in the distribution curve of the requirements for each of the nutrients.</p>	Colombia
<p>Pilot Stepwise process New Zealand appreciates the substantive amount of work that the Chairs have done to revise the Stepwise process to accommodate an alternative approach. However, the Committee and EWG has already put in a considerable amount of work into the confirmation of the RASBs, Stepwise process and review of each requirement, for the two age groups.</p> <p>The development of these NRVs-R was intended to be an efficient process as a continuation of the work for the general population, with an FAO report available to assess the methods used and expedite the process. We continue to support Approach 2.</p> <p>To revise the process to now exclude RASBs undermines the efforts and progress made since this work was initiated in 2018. The selected RASBs have been agreed as relevant to this work for many years. The longer we take to complete the work, the less 'recent' all authoritative bodies work become which may then necessitate their removal from consideration without any sound basis.</p> <p>It has been repeatedly stated that there is limited data available to set NRVs-R for this age group, therefore there is limited benefit in placing a focus on 'recent' publications. Particularly as the stepwise process already prioritises physiological evidence from the target age group at Step 3A. New data for establishing nutrient requirements does not appear to be a research priority, and the absence of new data is part of the reason why many authoritative bodies have not revised their nutrient requirements, or why limited number of nutrients are reviewed.</p> <p>We are very concerned that too much effort is being placed on editing the stepwise process particularly where there are limited impacts to the majority of nutrients.</p> <p>When the work for the general population was conducted, WHO undertook a stocktake of dietary intake reference values used in national guidelines globally. As may be expected the WHO/FAO values were most frequently used globally, followed by the US Institute of Medicine values. While the most recent reviews have been undertaken in Europe and the Nordic countries, these reviews also take into account contextual factors which may not be relevant to all regions.</p> <p>We strongly urge the Committee to move forward with this work.</p>	New Zealand

<p>As with the General Population, it may be of benefit to the Committee to agree to a number of the nutrients, particularly where there is no discrepancy in the NRVs derived using either Step wise process. During the work for the NRVs-R for the general population, a comparison of the global DIRVs against the WHO/FAO value was conducted, where there was a difference of greater than 15%, further work was conducted to determine which was the most suitable.</p> <p>We would like to note that the following NRVs-R are the same for both age groups regardless of the stepwise approach used: vitamin A, Vitamin D, Vitamin K, Thiamine, Niacin, Pantothenic acid, calcium, selenium, potassium and protein.</p>	
<p>The Philippines acknowledges the application of the draft revised stepwise process in providing consistency and clarity in the derivation of NRVs-R for 6-36 months age group. We support the recommendation to adopt Approach 1: The Stepwise Process is applied using data from FAO/WHO and data published by RASBs over the past 10 years which prioritizes data from more recent RASBs over this period. This approach ensures that the NRVs-R reflect the latest scientific evidence to generate reference values for optimal nutrition of older infants and young children. Likewise, we concur with the recommendation to adopt Approach 1 with data within the past 10 years as a reasonable threshold period to allow for generation of new evidence and to ensure utilization of more recent data of RASBs. Lastly, use of the revised Stepwise approach is consistent with the draft general principles.</p> <p>If FAO/WHO updated requirements for calcium, Vitamin D, and Zinc are to be expected shortly, we are supportive of aligning the proposed NRVs-R for 6-36 months based on independent recent review of nutrient values and as provided in Approach 1.</p> <p>While the Philippines affirms the global approach as proposed in this draft, we emphasize the need for flexibility in applying these standards at the national level. Local dietary patterns and prevalent nutritional deficiencies should be considered when implementing the Proposed NRVs-R for older infants (6-12 months) and young children (12-36 months). We reiterate our previous stand supporting the statement that encourages national governments to consider establishing NRVs-R that take into account country or region-specific factors that affect nutrient absorption, utilization, or requirements. This is in consideration of the values in Iodine and Vitamin A which are quite lower compared to locally established reference values (Philippine Dietary Reference Intake). This is to also consider the problem in iodine deficiency disorder in vulnerable groups of the population.</p>	Philippines
<p>The United States supports the utilization of a stepwise process to facilitate establishing NRVs-R for persons aged 6 – 12 months, 12 – 36 months, and 6 – 36 months. The United States notes that the General Principles indicate that they are to be used to establish NRVs-R for persons 6 – 36 months and does not indicate the intention of the committee to set values for persons 6 – 12 months, 12 – 36 months, and the combined ages of 6 – 36 months. The United States therefore suggests that at the start of the stepwise process it be made clear that the steps are intended to be used to set NRVs-R for persons 6 – 12 months, 12 – 36 months, and a combined value for persons 6 – 36 months.</p> <p>The United States is concerned that the stepwise process is more complex than necessary and is not as scientifically rigorous as possible, and therefore has proposed amendments to simplify the steps and improve the scientific rigor such that all relevant data are used to establish NRVs-R. The United States is of the view that Steps 1 and 2 are about selecting appropriate data sources and that those data sources identified in Steps 1 and 2 are used in Step 3 to establish NRVs-R for persons 6 – 12 months and 12 – 36 months. The U.S. suggested amendments to the current stepwise process are below.</p> <p><u>Stepwise Process: To be used to establish NRVs-R for persons 6-12 months, 12-36 months and 6-36 months for selected nutrients.</u></p>	USA

The United States suggests the following edit to make clear that the steps are intended to be used to set NRVs-R for persons 6-12 months, 12-36 months, and a combined value for persons 6-36 months:

Step Process: To be used to establish NRVs-R for persons 6-12 months, 12-36 months and 6-36 months for selected nutrients.

The United States has prepared a schematic flow diagram below to demonstrate the decision points based on U.S. suggested edits to the stepwise process. The United States notes the only substantive change from the current stepwise process is that the 2005 FAO/WHO DIRVs are treated similarly to those of the recognized authoritative scientific bodies (RASBs) and when selected are included in establishing NRVs-R using the median of the data set



<p>ii) NRVs-R for persons aged 6–36 months, Revised Stepwise Process CX/NFSDU 24/44/4, Part B, Appendix I. Uruguay has reviewed the draft stepwise process and agrees to its application. We support adopting Approach 1 when the draft stepwise process is applied, by means of which the latest RASB data are used, taking a 10-year period as reference. A comparison of the two approaches (1 and 2) shows that, for most nutrients, very similar NRV-R values are set. We agree with the NRVs-R for all the nutrients set by applying the stepwise process using Approach 1 presented in Summary Table 1, Appendix I, for older infants and young children. It is considered appropriate to use rounded values, as is done for the general population.</p>	<p>Uruguay</p>
<p>Step 1: Identify new or updated daily intake reference values from FAO/WHO for older infants and young children and select for establishing NRVs-R.</p> <p>Colombia supports updating the reference values, but suggests the following wording:</p> <p>Step 1: Identify new or updated Daily Intake Reference Values (DIRVs) from FAO/WHO for older infants and young children and assess the establishment of NRVs-R.</p> <p>Step 1a: Assess the derivation of new or updated DIRVs from FAO/WHO based on the rigour of the scientific methods, the underlying data quality and strength of evidence.</p> <p>Step 1b: Compare new or updated DIRVs from FAO/WHO to earlier DIRVs from FAO/WHO and the relevant NRVs from the RASBs.</p> <p>Step 1c: If the derivation of the new or updated DIRV from FAO/WHO is the same as or higher than the relevant DIRVs from the RASBs, in terms of the rigour of the scientific methods, the underlying data quality and strength of evidence, then select the new DIRV from FAO/WHO as the recommended NRV-R. If not, then go to Step 2*.</p> <p>*According to Note 1 of Step 2, the new FAO/WHO data would then replace the older FAO/WHO data.</p> <p>Member countries should be able to view the evidence included in the review and the process for grading the evidence by the FAO/WHO expert working group.</p> <p>The general principles state that “the 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 for establishing the NRVs-R”. The expression “taken into consideration” implies that the values should be considered or evaluated in the context of new evidence.</p> <p>The principles also state the following regarding the new relevant DIRVs from the RASBs: “Relevant daily intake reference values that reflect recent independent assessments of the science and that come from Recognized Authoritative Scientific Bodies...could also be taken into consideration”.</p>	<p>Colombia</p>
<p>To be applied when DIRVs informed by relevant physiological evidence <u>extrapolation from other age groups</u> are not available</p> <p>It is noted that member countries should be able to view the evidence included in the review and the process for grading the evidence by the FAO/WHO expert working group. The general principles state that: “The relevant daily intake reference values provided by FAO/WHO that are based on a recent review of the science should be taken into account as primary sources for establishing the NRVs-R”. The expression “taken into consideration” implies that the values should be considered or evaluated in the context of new evidence. The principles also state that the new relevant DIRVs from the Scientific Bases for Risk Assessment “that reflect a recent independent review of the science...could also be taken into consideration”. Guatemala therefore supports an updated process:</p>	<p>Guatemala</p>

<p>Step 1: Identify new or updated Daily Intake Reference Values (DIRVs) from FAO/WHO for older infants and young children and assess for establishing NRVs-R.</p> <p>Step 1a: Assess the derivation of new or updated DIRV from FAO/WHO based on the rigour of the scientific methods, the underlying data quality and strength of evidence.</p> <p>Step 1b: Compare new or updated DIRVs from FAO/WHO with earlier DIRVs from FAO/WHO and the relevant DIRVs from the Scientific Bases for Risk Assessment.</p> <p>Step 1c: If the derivation of new or updated DIRVs from FAO/WHO is the same as or higher than the relevant DIRVs from the Scientific Bases for Risk Assessment, in terms of the rigour of the scientific methods, the underlying data quality and strength of evidence, then select the new DIRV from FAO/WHO as the recommended NRV-R. If not, then go to Step 2*.</p> <p>*According to Note 1 of Step 2, the new FAO/WHO data would then replace the older FAO/WHO data.</p>	
<p>Step 1: Identify new or updated daily intake reference values (DIRVs) for nutrients from FAO/WHO for older infants and young children and select for establishing NRVs-RNRVs-R for ages 6 – 12 month and 12 – 36 months..</p> <p>In line with the comments above, the United States suggests the following edit to step 1:</p> <p>Step 1: Identify new or updated daily intake reference values (DIRVs) for nutrients from FAO/WHO for older infants and young children and select for establishing NRVs-R for ages 6 – 12 month and 12 – 36 months.</p>	USA
<p>Step 1: Identify new or updated daily intake reference values (DIRVs) from FAO/WHO for older infants and young children and select for establishing NRVs-R.</p> <p>ISDI notes Member countries should have visibility to evidence included in review and process of grading the evidence by the FAO/WHO expert working group. The general principles state, “Relevant daily intake reference values provided by FAO/WHO that are based on a recent review of the science should be taken into consideration as primary sources in establishing NRVs-R.” The language “taken into consideration” infers that the values should be considered or assessed in the context of new evidence. The principles also state that new relevant DIRVs from RASBs “that reflect recent independent review of the science...could also be taken into consideration.” Therefore, ISDI supports an updated process:</p> <p>Step 1: Identify new or updated daily intake reference values (DIRVs) from FAO/WHO for older infants and young children and assess for establishing NRVs-R.</p> <p>Step 1a: Evaluate derivation of the new or updated FAO/WHO DIRV based on rigour of scientific methods, the underlying data quality, and the strength of evidence.</p> <p>Step 1b: Compare the new or updated FAO/WHO DIRVs to the earlier FAO/WHO DIRV and relevant DIRVs from RASBs.</p> <p>Step 1c: If derivation of the new or updated FAO/WHO DIRV are the same or higher than relevant DIRVs from RASBs on the elements of rigour of scientific methods, the underlying data quality, and the strength of the evidence, then select the new FAO/WHO DIRV as the recommended NRV-R. If not, then go to step 2*.</p> <p>*As per Step 2 note 1, the new FAO/WHO data would then replace the older FAO/WHO data</p>	International Special Dietary Food Industries
<p>Step 2: Aligned with General Principle 3.1, when updated DIRVs have not been established by FAO/WHO for the nutrients, relevant DIRVs that reflect recent independent assessments of the science from RASBs can be considered, with higher priority given to values where evidence has been evaluated by a systematic review.</p>	Colombia

<p>Aligned with the proposal for Step 1, the following wording is suggested for Step 2:</p> <p>Step 2: Aligned with General Principle 3.1, when new or updated DIRVs have not been selected by FAO/WHO for establishing NRVs-R or when updated DIRVs have not been established by FAO/WHO for vitamins and minerals, relevant DIRVs that reflect recent independent assessments of the science from RASBs can be considered, with higher priority given to values where evidence has been evaluated by a systematic review.</p> <p>Colombia agrees that DIRVs from RASBs that are based on a recent independent review of the science should be considered, with higher priority given to values where evidence has been evaluated by a systematic review.</p> <p>However, as indicated in the proposal of Step 1, it is considered that DIRVs from RASBs should also be considered along with new or updated DIRVs from FAO/WHO and that the values from both FAO/WHO and the RASBs should be evaluated according to the factors outlined in the general principle: rigour of scientific methods, underlying data quality and strength of evidence. If new or updated DIRVs from FAO/WHO are evaluated in the context of DIRVs from RASBs and rank the same or higher in terms of rigour of scientific methods, underlying data quality and strength of evidence, the new or updated DIRV from FAO/WHO should be selected as the NRV-R.</p>	
<p>Step 2: Aligned with General Principle 3.1, when updated DIRVs have not been established by FAO/WHO for the nutrients, relevant DIRVs that reflect recent independent assessments of the science from RASBs can be considered, with higher priority given to values where evidence has been evaluated by a systematic review.</p> <p>Guatemala agrees that the DIRVs from the Scientific Bases for Risk Assessment that are based on recent independent review of the science should be taken into consideration, with higher priority given to values where evidence has been evaluated by a systematic review. However, as indicated in the proposed Step 1, we believe that the DIRVs from the Scientific Bases for Risk Assessment should also be taken into consideration along with new or updated DIRVs from FAO/WHO and the values from both FAO/WHO and the Scientific Bases for Risk Assessment should be evaluated according to the factors outlined in the general principle: rigour of scientific methods, underlying data quality and strength of evidence. If new or updated DIRVs from FAO/WHO are evaluated in the context of the DIRVs from the Scientific Bases for Risk Assessment and rank the same or higher in terms of rigour of scientific methods, underlying data quality and strength of evidence, the new or updated DIRV from FAO/WHO should be selected as the NRV-R. To align with the proposed Step 1, Guatemala suggests the following edit to Step 2:</p> <p>Step 2: Aligned with General Principle 3.1, when new or updated DIRVs have not been selected by FAO/WHO for establishing NRVs-R or when updated DIRVs have not been established by FAO/WHO for vitamins and minerals, relevant DIRVs that reflect a recent independent review of the science from the Scientific Bases for Risk Assessment can be considered, with higher priority given to values for which the evidence has been evaluated by a systematic review.</p>	Guatemala
<p>Step 2: Aligned with General Principle 3.1, when updated DIRVs have not been established by FAO/WHO for the nutrients<u>nutrients</u>, relevant DIRVs that reflect recent<u>recent</u> independent review of the science from RASBs can be considered<u>and the older (2005) values from FAO/WHO are considered and appropriate data</u> In line with the general U.S. comments regarding the stepwise process, the United States suggests the following edits to step 2:</p> <p>Step 2: Aligned with General Principle 3.1, when updated DIRVs have not been established by FAO/WHO for the nutrients, relevant DIRVs that reflect recent independent review of the science from RASBs and the older (2005) values from FAO/WHO are considered and appropriate data sources are selected for establishing NRVs-R, with higher priority given to values where evidence has been evaluated by a systematic review. Selection of appropriate data shall consider the rigor of scientific methods, underlying data quality, strength of the evidence and the totality of the evidence with priority given to DIRVs based on physiological evidence, then DIRVs based on extrapolation and last DIRVs based on other evidence (i.e average intakes).sources are selected for establishing NRVs-R, with higher priority given to values where evidence has been</p>	USA

<p>evaluated by a systematic review. <u>Selection of appropriate data shall consider the rigor of scientific methods, underlying data quality, strength of the evidence and the totality of the evidence with priority given to DIRVs based on physiological evidence, then DIRVs based on extrapolation and last DIRVs based on other evidence (i.e average intakes).</u></p>	
<p>Step 2: Aligned with General Principle 3.1, when updated DIRVs have not been established by FAO/WHO for the nutrients relevant DIRVs that reflect recent independent review of the science from RASBs can be considered, with higher priority given to values where evidence has been evaluated by a systematic review.</p> <p>ISDI agrees that DIRVs from RASBs that are based on recent independent review of the science should be taken into consideration, with higher priority given to values where evidence has been evaluated by a systematic review. However, as outlined in our proposed Step 1, we believe DIRVs from RASBs should also be taken into consideration alongside new or updated DIRVs from FAO/WHO and values from both FAO/WHO and RASBs should be evaluated based elements outlined in the General Principle: rigour of scientific methods, the underlying data quality, and the strength of the evidence. If the new or updated DIRVs from FAO/WHO are evaluated in the context of DIRVs from RASBs and ranked the same or higher on the elements of rigour of scientific methods, the underlying data quality, and strength of the evidence, the new or updated DIRV from FAO/WHO should be selected as the NRV-R. To align with the proposed Step 1, ISDI suggests the following edit to Step 2:</p> <p>Step 2: Aligned with General Principle 3.1, when new or updated DIRVs by FAO/WHO are not selected for establishing NRVs-R OR when updated DIRVs have not been established by FAO/WHO for the vitamins and minerals, relevant DIRVs that reflect recent independent review of the science from RASBs can be considered, with higher priority given to values where evidence has been evaluated by a systematic review.</p>	<p>International Special Dietary Food Industries</p>
<p>Step 3: In the absence of updated Daily Intake Reference Values from FAO/WHO, the establishment of the NRVs-Rs should involve consideration, on a case-by-case basis, of the derivation of DIRVs more recently established by RASBs along with existing data from FAO/WHO. This assessment shall take account of the rigour of scientific methods, the underlying data quality and strength of evidence used to obtain the DIRVs in these data sources. DIRVs are selected based on the totality of this evidence as NRVs-R in the following priority order:</p> <p>It is suggested to clarify the term “relevant physiological evidence” and to indicate the specific evidence to which it refers, or else to delete from the text the paragraphs that mention this term.</p>	<p>Colombia</p>
<p>Step 3: In the absence of updated Daily Intake Reference Values from FAO/WHO, the establishment of the NRVs-Rs should involve consideration, on a case-by-case basis, of the derivation of DIRVs more recently established by RASBs along with existing data from FAO/WHO. This assessment shall take account of the rigour of scientific methods, the underlying data quality and strength of evidence used to obtain the DIRVs in these data sources. DIRVs are selected based on the totality of this evidence as NRVs-R in the following priority order:</p> <p>Guatemala agrees with Step 3 of the process because it is in line with the general principles. This approach is also consistent with the weighting of the evidence by other authoritative groups. This method is also outlined as the appropriate scientific methodology for the development of DIRVs, as published in the “Review of derivation methods for dietary intake reference values for older infants and young children; FAO request for scientific advice to develop general principles for the establishment of Codex nutrient reference values for older infants and young children”. Guatemala also agrees with the use of the median rather than the mean, as it is less prone to the effect of outliers.</p>	<p>Guatemala</p>
<p>Step 3 When new or recent DIRVs from FAO/WHO are identified in Step 1 those values are selected and used to establish NRVs-R. In the absence of updated daily intake reference values (DIRVs) DIRVs from FAO/WHO, DIRVs identified and selected in Step 2 are used to establish NRVs-R in the establishment of the NRVs-R should involve consideration following priority order: DIRVs informed by relevant physiological evidence, on a case-by-case basis, of the derivation of DIRVs more recently established informed by RASBs along with existing data-relevant extrapolation from FAO/WHO. This assessment shall take account of the rigour of scientific methods other age groups, the underlying data quality and strength of evidence used to derive the DIRVs in these data sources. DIRVs are selected based on the totality absence of this evidence as NRVs-R in the following priority order: latter, DIRVs informed from other evidence.</p>	<p>USA</p>

<p>In line with the general U.S. comments regarding the stepwise process, the United States suggests step 3 to be edited as follows:</p> <p>Step 3: When new or recent DIRVs from FAO/WHO are identified in Step 1 those values are selected and used to establish NRVs-R. In the absence of updated DIRVs from FAO/WHO, DIRVs identified and selected in Step 2 are used to establish NRVs-R in the following priority order: DIRVs informed by relevant physiological evidence, DIRVs informed by relevant extrapolation from other age groups, and in the absence of the latter, DIRVs informed from other evidence.</p>	
<p>Step 3: In the absence of updated daily intake reference values (DIRVs) from FAO/WHO, the establishment of the NRVs-R should involve consideration, on a case-by-case basis, of the derivation of DIRVs more recently established by RASBs along with existing data from FAO/WHO. This assessment shall take account of the rigour of scientific methods, the underlying data quality and strength of evidence used to derive the DIRVs in these data sources. DIRVs are selected based on the totality of this evidence as NRVs-R in the following priority order:</p> <p>ISDI agrees with Step 3 of the process as being in line with the General Principles. This approach is also consistent with the weighting of evidence by other authoritative groups. This method is also outlined as the appropriate scientific methodology for developing DIRVs as published in the FAO "Review of derivation methods for dietary intake reference values for older infants and young children; FAO request for scientific advice to develop general principles for the establishment of Codex nutrient reference values for older infants and young children". ISDI also agrees with the use of the median vs the mean as it is less prone to the effect of outliers.</p>	<p>International Special Dietary Food Industries</p>
<p>DIRVs informed by relevant physiological evidence from the target group are selected for establishing NRVs-R for persons aged 6–36 months. In cases where this includes the DIRV from FAO/WHO, this is selected for establishing NRVs-R for persons aged 6–36 months. In cases where this does not include the DIRV from FAO/WHO, the median of the DIRVs from the RASBs is determined and selected for establishing NRVs-R for persons aged 6–36 months. <u>In the absence of DIRVs informed by relevant physiological evidence, go to Step 3B.</u></p> <p>We understand that it gives greater clarity to the paragraph, and we agree to add the sentence in bold.</p>	<p>Paraguay</p>
<p>To be applied when DIRVs informed by relevant physiological evidence extrapolation from other age groups are not available</p> <p>We agree with the proposed sentence.</p> <p>B. To be applied when relevant DIRVs informed by extrapolation to other age groups are available.</p>	<p>Paraguay</p>
<p><u>B. To be applied when New or recent DIRVs informed by relevant physiological evidence from FAO/WHO are available used to establish NRVs-Rs for the nutrients for persons 6 – 12 months and persons 12 – 36 months.</u></p> <p>In line with the general U.S. comments regarding the stepwise process and the edits suggested to step 3, the United States recommends step 3A read as follows:</p> <p>Step 3A: New or recent DIRVs from FAO/WHO are used to establish NRVs-Rs for the nutrients for persons 6 – 12 months and persons 12 – 36 months.</p>	<p>USA</p>
<p>DIRVs informed by relevant physiological evidence from the target group are selected to establish NRVs-R for persons aged 6–36 months. In cases where this includes the FAO/WHO DIRV, this is selected for the establishment of NRVs-R for persons aged 6–36 months. In cases where this does not include the FAO/WHO DIRV, the median of the DIRVs from the RASBs is determined and selected to establish NRVs-R for persons aged 6–36 months. <u>In the absence of DIRVs informed by relevant physiological evidence, go to Step 3 B.</u></p> <p>With the U.S. suggested edit to step 3A, this paragraph is no longer relevant to the step and the United States would recommend deleting it.</p>	<p>USA</p>
<p><u>B. To be applied when no new or recent DIRVs from FAO/WHO are available but DIRVs informed by relevant physiological evidence are available from data sources selected in Step 2. NRVs-R are established using the median of the DIRVs based on physiological</u></p>	<p>USA</p>

<p><u>evidence for persons 6 – 12 months and persons 12 – 36 months</u>there are no DIRVs informed by relevant physiological evidence extrapolation from other age groups are available</p> <p>In line with the general U.S. comments regarding the stepwise process and the edits suggested to step 3, the United States recommends step 3B be simplified as follows:</p> <p>Step 3B: To be applied when no new or recent DIRVs from FAO/WHO are available but DIRVs informed by relevant physiological evidence are available from data sources selected in Step 2. NRVs-R are established using the median of the DIRVs based on physiological evidence for persons 6 – 12 months and persons 12 – 36 months.</p>	
<p>DIRVs informed by extrapolation of DIRVs from other age groups are selected to establish NRVs-R for persons aged 6–36 months. Suitable DIRVs are selected by considering how the original DIRVs established for these other age groups are derived.</p> <p>With the U.S. suggested edit to step 3B, this paragraph is no longer relevant to the step and the United States would recommend deleting it.</p>	USA
<p>B.1. If the FAO/WHO DIRV and the median of the RASBs DIRVs are the same, the FAO/WHO DIRV is selected for the establishment of NRVs-R for persons aged 6–36 months.</p> <p>B.2. If the FAO/WHO DIRV and the median of the RASBs DIRVs are not the same, a new median of the DIRVs from the FAO/WHO and relevant RASBs is calculated and selected for the establishment of NRVs-R for persons aged 6–36 months.</p> <p>B.3. If the FAO/WHO DIRV is not included, the median of the DIRVs from the RASBs is selected for the establishment of NRVs-R for persons aged 6–36 months.</p> <p>With the U.S. suggested edit to step 3B, this paragraph is no longer relevant to the step and the United States would recommend deleting it.</p>	USA
<p><u>C. To be applied when there are no new or recent DIRVs from FAO/WHO and no DIRVs informed by relevant physiological evidence are available from steps 3A and 3B. NRVs-R are established using the median of the relevant DIRVs based on extrapolation from other groups for persons 6 – 12 months and persons 12 – 36 months.</u>either relevant physiological evidence or extrapolation from other age groups available</p> <p>In line with the general U.S. comments regarding the stepwise process and the edits suggested to step 3, the United States recommends step 3C be simplified as follows:</p> <p>Step 3C: To be applied when no new or recent DIRVs from FAO/WHO and no DIRVs informed by relevant physiological evidence are available from steps 3A and 3B. NRVs-R are established using the median of the relevant DIRVs based on extrapolation from other groups for persons 6 – 12 months and persons 12 – 36 months.</p>	USA
<p>DIRVs informed by estimates of nutrient intake from the target group or interpolation, are selected to establish NRVs-R for persons aged 6–36 months.</p> <p>With the U.S. suggested edit to step 3C, this paragraph is no longer relevant to the step and the United States would recommend deleting it.</p>	USA

<p>C.1. If the FAO/WHO DIRV and the median of the RASBs DIRVs are the same, the FAO/WHO DIRV is selected for the establishment of NRVs-R for persons aged 6–36 months.</p> <p>C.2. If the FAO/WHO DIRV and the median of the RASBs DIRVs are not the same, a new median of the DIRVs from the FAO/WHO and relevant RASBs is calculated and selected for the establishment of NRVs-R for persons aged 6–36 months.</p> <p>With the U.S. suggested edit to step 3C, this paragraph is no longer relevant to the step and the United States would recommend deleting it.</p>	USA
<p>Step 4: Estimate the NRVs-R for the combined 6–36month age group according to the three options outlined below:</p> <p>As mentioned above, Brazil believes that separate food label NRVs-R should be established for specific age groups, namely 6 to 12 months and 12 to 36 months.</p>	Brazil
<p>Step 4: Estimate the NRVs-R for the combined age group from 6–36 months according to the three options outlined below:</p> <p>Colombia does not support determining the combined NRV-R. It is suggested that Codex consider separating the values for the two age groups.</p>	Colombia
<p>Step 4: Estimate<u>The Combined NRVs-R value for persons 6-36 months should be determined by selecting the higher value of the proposed NRVs-R established in step 3 for person 6 – 12 months and 12 – 36 months if it does not exceed the combined 6–36month age group UL for either older infants or young children, where available. On a case-by-case basis when the UL is exceeded for one of the age groups the mean value of the NRVs-R for the two age groups should be used to establish the NRVs-R.</u> according to the three options outlined below:</p> <p>Regarding Step 4: The United States notes the Committee needs to discuss and agree the approach for establishing NRVs for the combined aged 6 – 36 months as part of the general principles. In line with the comments regarding the Section 3.2 of the general principles, the United States supports Option 1 with a suggestion in bold concerning the upper limit (UL): The Combined NRVs-R value for persons 6-36 months should be determined by selecting the higher value of the proposed NRVs-R established in step 3 for person 6 – 12 months and 12 – 36 months if it does not exceed the UL for either older infants or young children, where available. On a case-by-case basis when the UL is exceeded for one of the age groups the mean value of the NRVs-R for the two age groups should be used to establish the NRVs-R.</p>	USA
<p><u>Step 3D: To be applied when no new or recent DIRVs from FAO/WHO are available and no DIRVs informed by relevant physiological evidence (3B) or extrapolation from other age groups (3C) are available. NRVs-R are established using the median for the relevant DIRVs based on other evidence for persons 6 – 12 months and persons 12 – 36 months.</u>Step 4: Estimate the NRVs-R for the combined 6–36month age group according to the three options outlined below:</p> <p>In line with the general U.S. comments regarding the stepwise process and the edits suggested to step 3, the United States recommends a step 3D be added as follows:</p> <p>Step 3D: To be applied when no new or recent DIRVs from FAO/WHO are available and no DIRVs informed by relevant physiological evidence (3B) or extrapolation from other age groups (3C) are available. NRVs-R are established using the median for the relevant DIRVs based on other evidence for persons 6 – 12 months and persons 12 – 36 months.</p>	USA
<p>Option 1 (selecting the higher value of the proposed NRVs-R for older infants and young children not exceeding the UL for either age group), as the NRV-R is selected for the combined age range of 6–36 months.</p> <p>Guatemala supports selecting Option 1 for determining the combined NRV-R for 6–36 months, as this ensures that the highest nutrient requirements of the population are reasonably met, as long as the lowest UL is not exceeded. This approach manages potential risks of both</p>	Guatemala

toxicity and deficiency. In cases where the combined NRV-R exceeds the lower UL, Guatemala believes it would be appropriate and safe to use the UL of the more sensitive population.	
<p>Option 1 (selecting the higher value of the proposed NRVs-R for older infants and young children that does not exceed the UL for either age group) as the NRV-R for the combined age range 6–36 months is selected.</p> <p>ISDI supports selection of Option 1 to determine the combined NRV-R for 6-36 months, as this ensures that the highest nutrient requirements of the population are reasonably met, as long as the lowest UL is not exceeded. This approach manages both the potential risks of toxicity and deficiency. In cases when the combined NRV-R exceeds the lowest UL, ISDI believes using the most sensitive population's UL would be appropriate and safe.</p>	International Special Dietary Food Industries
<p>Step 5: Consideration of ULs (where available) is given to ensure that the proposed NRVs-R do not exceed the lowest of the UL values available.</p> <p>Brazil supports step 5.</p>	Brazil
<p>Step 5: Consideration of ULs (where available) is given to ensure that the proposed NRVs-R do not exceed the lowest of the UL values available.</p> <p>Colombia agrees with Step 5 of the process. The consideration of MIs (where available) to ensure that the proposed NRVs-R do not exceed the lower value of the available MIs is in line with the general principles.</p>	Colombia
<p>Step 5: Consideration of ULs (where available) is given to ensure that the proposed NRVs-R do not exceed the lowest of the UL values available.</p> <p>Guatemala agrees with Step 5 of the process because it is in line with the general principles.</p>	Guatemala
<p>Step 5: Consideration of ULs (where available) is given to ensure that the proposed NRVs-R do not exceed the lowest of the UL values available.</p> <p>Regarding step 5: The United States is not opposed to retaining step 5, however, as UL is a consideration when FAO/WHO or the RASBs establish DIRVs, the United States is of the view that UL is only relevant to step 4 and is already considered as a part of step 4. The United States would therefore suggest that step 5 could be deleted.</p>	USA
<p>Step 5: Consideration of ULs (where available) is given to ensure that the proposed NRVs-R do not exceed the lowest of the UL values available.</p> <p>ISDI agrees with Step 5 of the process as being in line with the General Principles.</p>	International Special Dietary Food Industries
NRVS-R FOR OLDER INFANTS AND YOUNG CHILDREN AND FOR THE COMBINED AGE RANGE 6-36 MONTHS	
Argentina agrees with the tables summarizing the application of the stepwise process to all nutrients	Argentina
<p>Azerbaijan is in agreement with the use of Approach 1 for the application of the Stepwise Process for the establishment of NRVS-R of all nutrients. However, Azerbaijan would like to express a concern regarding the NRVs-R for vitamin B12, as the value of 1.2 µg for young children compared to 1.5 µg for older infants appears to be inconsistent, especially given the lack of UL (upper intake limit) data for vitamin B12. Azerbaijan believes that these values warrant further investigation, although the stepwise procedure was correctly applied and the results are in theory valid. It is important to ensure that the NRVs-R for younger children adequately reflects their nutritional needs, as vitamin B12 deficiency is still common among older infants and young children, especially in developing countries.</p>	Azerbaijan

<p>Azerbaijan respectfully disagrees with the proposed NRVs-R for calcium, vitamin D, and zinc at this time. In view of the fact that new updated data on dietary requirements will soon be published by FAO/WHO, it would be prudent to await the publication of this information before establishing final NRVs for these nutrients.</p> <p>Azerbaijan also supports the rounding of NRVs-R for 6-12 months, 12-36 months and 6-36 months as presenting values that are too precise could imply a level of precision that doesn't reflect the natural variability of NRVs-R. It also maintains consistency of values across age groups, as rounding has been used to establish NRVs-R for the general population.</p>	
<p>Summary Table 1: Proposed NRVs-R for older infants (6–12 months) and young children (12–36 months): in application of the revised stepwise process using Approach 1 (consideration of data from FAO/WHO and more recent RASBs¹ only) and Approach 2 (consideration of data from FAO/WHO + all RASBs²).</p> <p>Colombia supports the use of Approach 1 (consideration of data from FAO/WHO and more recent RASBs only).</p> <p>Approach 1 is in line with the general principles, which state that “relevant DIRVs that reflect a recent independent review of the science from RASBs can be considered” and uses data from FAO/WHO and data published by RASBs over the past 10 years, limiting RASB data to four sources publishing data within the past 10 years: NCM (2023), NASEM (2019), NIHN (2015) and EFSA (2014-2017).</p> <p>In this vein, Summary Table 1 (adopting Approach 1) would look like this in the case of iron:</p> <p>Nutrient: Iron Older Infants Approach: 1 9.3 (10%)</p> <p>Nutrient: Iron Small Children Approach: 1 5.8 (10%)</p> <p>1 A bioavailability percentage of 10% was considered.</p> <p>There is sufficient evidence to affirm that the diets of populations are of mixed origin, and that the composition and origin of the diet varies from one population to another. Therefore, to establish the NRVs-R for iron it would not be appropriate to adopt bioavailability percentages that have been established for specific populations, based on their particular nutritional and dietary profile.</p> <p>Accordingly, it is considered to be safer for different populations to use the lowest identified bioavailability percentage, which is 10% in the case of iron, and thus to adopt a single NRV-R for this nutrient.</p> <p>Proposed adjustment: It is recommended not to establish different NRVs-R for zinc according to its bioavailability percentage, and instead to select the estimated reference value using the lowest bioavailability percentage, in this case 15%.</p> <p>In this vein, Summary Table 1 (adopting Approach 1) would look like this in the case of zinc: Nutrient: Zinc Older Infants</p>	<p>Colombia</p>

<p>Approach 1 8.4 (15%)</p> <p>Nutrient: Zinc Young Children Approach 1 8.3 (15%)</p> <p>A bioavailability percentage of 15% was considered.</p> <p>There is sufficient evidence to affirm that the diets of populations are of mixed origin, and that the composition and origin of the diet varies from one population to another. Therefore, to establish the NRVs-R for iron it would not be appropriate to adopt bioavailability percentages that have been established for specific populations, based on their particular nutritional and dietary profile.</p> <p>Accordingly, it is considered to be safer for different populations to use the lowest identified bioavailability percentage, which is 10% in the case of iron, and thus to adopt a single NRV-R for this nutrient.</p>	
<p>It is suggested to review the proposed values for magnesium.</p> <p>In the case of magnesium, with Approach 1, since the RASB values were considered for older infants rather than for young children, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs. This should be reviewed before a final agreement is reached.</p> <p>It is suggested to review the proposed values for copper.</p> <p>In the case of copper, since only the EFSA DIRVs were considered for older infants, while only the IOM and Japanese NIHN values were taken into consideration for young children, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs. A review is recommended before a final agreement can be reached.</p> <p>It is suggested to review the proposed values for pantothenic acid.</p> <p>In the case of pantothenic acid, since only the DIRVs from FAO/WHO and IOM were considered for young children, while the DIRVs from all RASBs were considered for older infants, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs. Accordingly, a review is recommended before a final agreement can be reached.</p> <p>For vitamin D, it is recommended to recalculate the RV values in the light of the RASB values, which are more up-to-date than the 2004 DIRVs from FAO/WHO.</p> <p>Supplementation studies and dose-response modelling have concluded that, in general, a vitamin D intake of 10 µg/day in infants aged 6–12 months and 10–15 µg/day in children aged 1–3 years is adequate for obtaining a serum concentration of 25(OH)D of 50 nmol/L, considering minimal exposure to sunlight.</p> <p>Recent recommendations by IOM, EFSA and the Nordic Council of Ministers are higher than 5 µg. This is likely due to the determination that a target serum concentration of 25(OH)D of 50 nmol/L is indicative of vitamin D sufficiency, as well as the more recent availability of data to generate dose-response models, so the RASB values are considered to be more up-to-date than the 2004 DIRVs from FAO/WHO.</p>	Colombia
<p>Costa Rica agrees with Points 3.1 and 3.2 of the draft general principles (Appendix I, CX/NFSDU 24/44/4, Part A) regarding the fact that more recent data from the primary source (FAO/WHO) and the RASBs are preferable. Additionally, it supports giving higher priority to values for which the evidence has been evaluated by a systematic review. Costa Rica therefore supports what was stated for the stepwise process.</p>	Costa Rica

<p>In addition, we support the use of Approach 1 (consideration of data from FAO/WHO and more recent RASBs only) as it is in line with the general principles, which state that “relevant DIRVs that reflect a recent independent review of the science from RASBs can be considered”. It also supports the use of the median rather than the mean, as it is less prone to the effect of outliers or extremes.</p> <p>ii. Costa Rica does not initially support Option 3 (MEAN), according to which the combined NRV-R value for persons aged 6–36 months is determined by selecting the mean value of the proposed NRVs-R for older infants and young children. We understand that the choice of such an option represents middle ground that could allow an agreement to be reached, but we do not think it is the most appropriate choice.</p> <p>Option 1 (HIGHEST VALUE), as long as it does not exceed the UL, where available, is considered the best way to ensure that the nutrient requirements of the population in the combined age range are met, spanning an age range of only 30 months, in which the differences between the NRVs-R for the two age ranges are not very large, thus preventing deficiency while avoiding the potential risk of toxicity when considering the ULs. There is more concern about establishing lower values that can lead to chronic consumption of nutrients at levels below the NRVs-R, due to the possibility of increasing the risk of deficiency.</p>	
<p>In the case of pantothenic acid, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs.</p> <p>In the case of copper, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs.</p> <p>In the case of magnesium, with Approach 1, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs.</p>	Costa Rica
<ul style="list-style-type: none"> • Guatemala supports the use of Approach 1 (consideration of data from FAO/WHO and more recent Scientific Bases for Risk Assessment only) as it is in line with the general principles, which state that “relevant DIRVs that reflect a recent independent review of the science from the Scientific Bases for Risk Assessment can be considered”. <ul style="list-style-type: none"> o In the case of vitamin D, supplementation studies and dose-response modelling have generally concluded that a vitamin D intake of 10 µg/day in infants aged 6–12 months and 10–15 µg/day in children aged 1–3 years is adequate for obtaining a serum concentration of 25(OH)D of 50 nmol/L, considering minimal exposure to sunlight. Recent recommendations by IOM, EFSA and the Nordic Council of Ministers are higher than 5 µg. This is likely due to the determination that a target serum concentration of 25(OH)D of 50 nmol/L is indicative of vitamin D sufficiency, as well as the more recent availability of data to generate of dose-response models. In this context, Guatemala recommends considering the values of the Scientific Bases for Risk Assessment to be more up-to-date than the 2004 DIRVs from FAO/WHO and recalculating the NRV values accordingly. o In the case of pantothenic acid, since only the DIRVs from FAO/WHO and IOM were considered for young children, while the DIRVs from all the Scientific Bases for Risk Assessment were considered for older infants, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs. This should be reviewed before a final agreement can be reached. o In the case of copper, since only the EFSA DIRV was considered for older infants, while only the IOM and Japanese NIHN values were considered for young children, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs. This should be reviewed before a final agreement can be reached. 	Guatemala

<p>o In the case of magnesium, with Approach 1, since the values of the Scientific Bases for Risk Assessment were considered for older infants rather than for young children, the stepwise process leads to a lower NRV-R for young children than for older infants, which does not seem to be the intent of the DIRVs. This should be reviewed before a final agreement can be reached.</p> <ul style="list-style-type: none"> • Guatemala supports selecting Option 1 for determining the combined NRV-R for vitamins for 6–36 months, as this ensures that the highest nutrient requirements of the population are reasonably met, as long as the lowest UL is not exceeded. This approach manages potential risks of both toxicity and deficiency. • Guatemala supports selecting Option 1 for determining the combined NRV-R for minerals and proteins for 6–36 months, as this ensures that the highest nutrient requirements of the population are reasonably met, as long as the lowest UL is not exceeded. This approach manages potential risks of both toxicity and deficiency. 	
<p>Malaysia can agree with the Summary Table 1, Appendix I because they are very similar with the NRVs-R values established for the majority of nutrients provided by the two Approaches.</p>	Malaysia
<p>In line with all the provisions of the working document, we believe that Approach 1 is suitable for these age groups</p>	Paraguay
<p>UK agrees with the recommendations on NRVs-R for persons aged 6-36 months. The UK agrees that Approach 1 should be used when applying the draft Stepwise Process so that more recent data from RASBs is used. The UK has considered the NRVs-R for all nutrients established through application of the Stepwise process using Approach 1 and presented in the Summary Table 1, Appendix I, and to be recommended as the established NRVs-R for a. Older Infants and b. Young Children. The UK supports that NRVs-R for all nutrients established through application of the Stepwise process using Approach 1 and in Option 3 (highlighted in the Summary Tables 2 and 2b, Appendix I) are recommended for the combined age range 6-36 months. The UK agrees that as part of the process when finalising the NRVs-R to be established for 6-12 months, 12-36 months and 6-36 months, values should be rounded (as was undertaken when establishing NRVs-R for the general population).The UK proposes that the UK Scientific Advisory Committee on Nutrition (SCAN) is recognised as a Recognized Authoritative Scientific Body (RASB).</p>	United Kingdom
<p>Once the Committee finalizes the General Principles and the stepwise process, the United States could support rounded NRVs-R values established by applying the stepwise process for older infants, young children, and a combined age range 6-36 months.</p>	USA
<p>Summary Table 1: Proposed NRVs-R for older infants (6-12 months) and young children (12-36 months): on application of revised Stepwise Process using Approach 1 (consideration of data from FAO/WHO & ‘more recent RASBs’¹ only) and Approach 2 (consideration of data from FAO/WHO + ‘all RASBs’²)</p> <p>ISDI supports use of Approach 1 (consideration of data from FAO/WHO & ‘more recent RASBs’ only) as in line with the general principles, which states “relevant DIRVs that reflect recent independent review of the science from RASBs can be considered”.</p>	International Special Dietary Food Industries
<p>- For vitamin D, supplementation studies and dose-response modelling have generally concluded that a vitamin D intake of 10 µg /day in infants 6-12 months and 10-15 µg /day in children 1-3 years is adequate to obtain a serum 25(OH)D concentration of 50 nmol/L, considering minimal exposure to sunlight. Recent recommendations by IOM, EFSA, and Nordic Council of Ministers are higher than 5 µg. This is likely due to determination that a target serum 25(OH)D concentration of 50 nmol/L is indicative of vitamin D sufficiency, as well as more recent availability of data to generate dose-response models. ISDI recommends in that context to consider RASBs values as more up to date than the 2004 FAO/WHO DIRV and recalculate the NRVs values accordingly.</p> <p>- For magnesium, with Approach 1, because of the RASBs values considered for older infants versus young children, the Stepwise Process leads to a lower NRV-R for young children as compared to older infants, which does not seem to be the intent of DIRVs. This should be reviewed before final agreement.</p>	International Special Dietary Food Industries

SUMMARY TABLE 2A: PROPOSED NRVS-R FOR VITAMINS ACCORDING TO OPTIONS 1, 2 & 3 FOR PERSONS AGED 6-36 MONTHS:	
Colombia does not support determining the combined NRV-R. It is suggested that Codex consider separating the values for the two age groups.	Colombia
For the combined NRVs-R value for person age 6 to 36 months, Malaysia can support the use of Approach 1 and Option 3, as the values derived by both approaches and the three options for the majority of the nutrients in Summary Tables 2 and Table 2b, Appendix I are similar.	Malaysia
Having analysed the three options outlined, Paraguay chooses Approach 1 of Option 3: the mean of the NRV-R values.	Paraguay
<p>Summary Table 2a: Proposed NRVs-R for vitamins according to Options 1, 2 & 3⁴ for persons aged 6-36 months: on application of revised Stepwise Process using Approach 1 (consideration of data from FAO/WHO & 'more recent RASBs'⁵ only) and Approach 2 (consideration of data from FAO/WHO + 'all RASBs'⁶)</p> <p>ISDI supports selection of Option 1 to determine the combined NRVs-R for vitamins for 6-36 months, as this ensures that the highest nutrient requirements of the population are reasonably met, as long as the lowest UL is not exceeded. This approach manages both the potential risks of toxicity and deficiency.</p>	International Special Dietary Food Industries
Summary Table 2b: Proposed NRVs-R for minerals and protein according to Options 1, 2 & 3⁸ for persons aged 6-36 months:	
Colombia does not support determining the combined NRV-R. It is suggested that Codex consider separating the values for the two age groups.	Colombia
For the combined NRVs-R value for person age 6 to 36 months, Malaysia can support the use of Approach 1 and Option 3, as the values derived by both approaches and the three options for the majority of the nutrients in Summary Tables 2 and Table 2b, Appendix I are similar.	Malaysia
In accordance with the answer in the table above, we agree with Option 3 of this table, with the proposed Approach 1.	Paraguay
<p>South Africa is in support of using Approach 1.</p> <p>South Africa supports the use of the NRVs-R for all nutrients established through application of the Stepwise process using Approach 1 and presented in the Summary Table 1, Appendix I, and to be recommended as the established NRVs-R for Older Infants and Young Children.</p> <p>South Africa is in support of applying option 3 ONLY for use in nutrients that DO NOT have an upper limit (UL). However, we believe that Option 1 is most favourable in meeting the requirements of infants and young children for nutrients that have an UL.</p> <p>South Africa supports that as part of the process when finalizing the NRVs-R to be established for 6-12 months, 12-36 months and 6-36 months, values should be rounded (as was undertaken when establishing NRVs-R for the general population).</p> <p>Rationale: Approach 1 allows for the use of more recent data from RASBs. Approach 1 together with option 1 is the most favoured where UL`s are available. These ULs will ensure that although some values may be higher for the infant group but will still be lower than the UL. However, Approach 1 and option 3 may be considered only where these UL`s are not available. We have noted that using option 3 for all vitamins and minerals is a compromise as it does not meet the requirements of either group.</p>	South Africa
ISDI supports selection of Option 1 to determine the combined NRVs-R for minerals and protein for 6-36 months, as this ensures that the highest nutrient requirements of the population are reasonably met, as long as the lowest UL is not exceeded. This approach manages both the potential risks of toxicity and deficiency.	International Special Dietary Food Industries