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World Health Organization

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Agenda item 5 **CX/NFSDU 23/43/5 Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVs-R FOR PERSONS AGED 6 – 36 MONTHS (AT STEP 4)
Comments in reply to CL 2022/74/OCS-NFSDU

Comments of Australia, Canada, Chile, China, Costa Rica, Cuba, Egypt, Guatemala, India, Malaysia, New Zealand, Panama, Peru, Philippines, Saudi Arabia, South Africa, Syrian Arab Republic, Thailand, United Arab Emirates, United Kingdom, Uruguay, USA, HKI, ICUMSA, International Council of Grocery Manufacturers Associations (ICGMA), International Special Dietary Food Industries (ISDI)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/74/OCS-NFSDU issued in December 2022. 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 presented in table format.

Annex I

GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
Canada would like to thank the Government of Ireland, of the United States of America and of Costa Rica for chairing the electronic working group and preparing this report on NRVs-R for older infants and young children. Canada also suggest that discussions should take place in the Physical working Group concerning the use of INL 98 values vs AI values. The step process does not differentiate between the two types of value.	**Canada**
c. NRVs-R for persons aged 6–36 months for vitamin B12, iodine, vitamin B6, riboflavin, niacin and vitamin C (CX/NFSDU 23/43/, Appendix II, Part C. China has comments on the NRVs-R of iodine and vitamin C for older Infants. We recommend that the DRI values of other countries and regions should be fully considered in Step 2, such as Iodine Dietary intake Reference Values (DIRVs) for older Infants shown in Table 3. p11, the AI of iodine is 110 ug in MOH, and 130 ug in IOM, and 130ug in Japan NIHN, all the above data are quite different from the 70 ug referred in this report based on EFSA. The same phenomenon also occurs in vitamin C NRV-R for older Infants, that is, the AI of vitamin C is 30 mg in MOH, and 50 mg in IOM, and 140mg in Japan NIHN, as well as the INL98 of vitamin C is 30 mg in FAO/WHO, all the above data are quite different from the 20 mg referred in this report based on EFSA.	**China**
Cuba welcomes the opportunity to express its comments on circular letter CL 2022/74/OCS-NFSDU, which are as follows: Comments on the General Principles for the Establishment of NRVs-R for Persons Aged 6-36 Months Comments: a. The General Principles for the Establishment of Nutrient Reference Values for Persons Aged 6-36 Months (Appendix II, Part A). Although we argued that this section should not have a preamble, we agree with both the preamble and the definitions. It is very useful that each country can adapt them. b. Pilot step-by-step procedure on the preliminary draft of the General Principles for the Establishment of Nutrient Reference Values (NRVs-R) for Persons Aged 6-36 Months. (Appendix II, Part B) We agree with the use of the report. The FAO 2021 report was used to identify the DIRVs established by FAO/WHO and the RASBs for vitamins, minerals and proteins considered for older infants and young children. c. NRVs-R for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C	**Cuba**

COMMENT	MEMBER / OBSERVER
We also agree with having differentiated reference values for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C for infants and young children.	
New Zealand appreciates the substantive work that the Chairs have done to revise the General Principles and conduct a pilot for a number of nutrients. 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. New Zealand supports a step-wise process which recognises the FAO/WHO as the primary source for NRVs-R. This is considered of critical importance to ensure that globally relevant values are selected for the purposes of Codex. We support an approach whereby we are quickly able to determine where the FAO/WHO values are similar to those derived by RASBs and where no further work is required, and that enables a case-by-case review of those nutrients where substantive differences exist. We welcome the consideration of the work conducted as part of the review of the Standard for Follow-up Formula which considered nutrient requirements for infants and toddlers. We would like to make one point of clarification regarding paragraph 26 of the Agenda paper. NRVs-R would not be used in the Standard for Follow-up Formula (CXS 156-1987) unless Codex or a national or regional authority elected to do so as there are no current permissions for nutrient declarations. Thank you for the opportunity to provide feedback on the CL.	**New Zealand**
The Philippines expresses its support to the proposed Draft General Principles for Establishing NRVs for Persons Aged 6-36 months. Likewise, we support the revised pilot stepwise approach on the application of the proposed Draft General Principles and the proposed draft NRVs-R for persons aged 6-36 months for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C derived from this approach. It is relevant for regional or national competent authority to consider such principles in establishing their own reference values for this specific age group for labeling purposes.	**Philippines**
Syria supports what was mentioned under 1. “Governments may establish NRVs-R that take into account country or region-specific factors that affect nutrient absorption, utilization, or requirements” and request to maintain this text in the final document. Syria does not support setting rules for establishing NRVs-R in the absence of reliable scientific evidence and supporting the adoption of WHO/FAO opinion based on the best available scientific evidence and working effectively to close the gap in references, also Syria does not support establishing a limited positive list of references.	**Syrian Arab Republic**
Thailand agrees with the Proposed draft General Principles for Establishing Nutrient Reference Values for Persons Aged 6 to 36 Months (CL 2022/74/OCS-NFSDU).	**Thailand**
UAE appreciates the chair of the eWG for the clarification regarding the calculation of the NRVs proposed and for the new proposed values based on this approach. The new approach is taking the median values compared to the mean while comparing it with the FAO/WHO RNI. UAE supports the revised method which represents a good approach to initiate discussion on the establishment of these values.	**United Arab Emirates**

COMMENT	MEMBER / OBSERVER
UAE also considers it essential to review the long-term impact of proposed NRVs for specific nutrients. Based on scientific rationale and latest developments regarding the nutritional status of the 6-12- and 12-36-months population, deviation from the values established through this method should be possible. Accordingly, UAE is providing rationales that should be taken into consideration in these discussions and lead to slightly different proposed values for specific nutrients, for example Vitamin B12 and iodine.	
The United States thanks Ireland for its leadership in progressing the work and generally supports the draft General Principles. The United States welcomes further discussions during the Physical Working Group session, in particular, the areas of appropriate data and review of the data to determine strength and quality of evidence need more consideration. The work of WHO and/or the Joint Expert Meeting on Nutrition (JEMNU) should be one of the main sources of data for consideration but should not be taken to the exclusion of data from the Recognized Authoritative Scientific Bodies (RASBs). The table providing an overview of the types of data and relative strength of evidence has been removed and the United States suggests that it be added back as it provides an important reference for the General Principles. The paper for this agenda item (CX/NFSDU 23/43/5), in Appendix II Part B, outlines a stepwise approach to considering data sources and determining NRVs-R for persons 6-36 months. The United States has provided new proposed text for Steps 1-4 and believes that Step 4 needs further discussion and refinement during the PWG. With regard to Step 4, the United States suggests that all suitable data sources be included without rounding, and that all suitable data sources be used to set a value using the median of the values from all data sources.	**USA**

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

PREAMBLE para 1. Australia does not support the amended text intended to clarify that the NRVs-R are for use in the labelling of pre-packaged for special dietary uses (FSDU) for persons aged 6 -36 months. Australia notes at CCNFSDU41 there was a EWG recommendation with a note as follows: RECOMMENDATION 2 The NRVs-R for older infants and young children be located in the Guidelines on Nutrition Labelling and apply to FSDU. Application of these NRVs-R to general foods require further discussion at plenary. Note: While the majority of the eWG were in favour of applying these NRVs-R to general foods, a minority wanted these limited to FSDU only. One CM wanted application of NRVs-R to general foods for young children but not older infants. The discussion at plenary (paras 144 - 146 REP20/NFSDU) indicated there was differing views with some members noting in their countries there are already products targeted at young children that are not FSDU and that these foods would benefit from NRVs for the purpose of labelling to guide appropriate choices by consumers. The Committee agreed the general principles would be included in the Guidelines on Nutrition Labelling and that once the NRVs-R were established consideration should be given to how they were presented in order to clarify to which foods these would apply to. Therefore, Australia considers further discussion at CCNFSDU43 on the application of NRVs-R to general foods is required before agreement can be reached on this amended text.	**Australia**

3.2 Appropriate Basis for Establishing NRVs-R Australia supports reference to the 2021 FAO report so to provide clarity on the nature of the evidence that should inform establishing NRVs-R.	
PREAMBLE para 1. Canada believes that the NRVs for children should apply to all pre-packaged foods targeted to young children such as infant cereals as the information on the label can help caregivers in selecting healthier version of foods. We would ask clarification from the Committee if canned baby foods and processed cereal-based foods are considered FSDUs as per Codex. The standard for Canned Baby Foods and the Standard for Processed Cereal-base foods are silent on the issue while the Advisory List of Nutrient Compounds (CAC/GL 10-1979) includes these two standards as FSDU. Relevant daily intake reference values that reflect recent independent review of the science, from recognized authoritative scientific bodies ~~could~~ should also be taken into consideration. Higher priority should be given to values in which the evidence has been evaluated through a systematic review. ` a) Concerning the revised General Principles, Canada supports the revisions proposed but have the following suggested edit:	**Canada**
Chile welcomes the opportunity to comment on the work done by the chair and co-chairs for the NRVs-R. In this respect, we agree with the general principles established. We also agree with the revised “step-by-step procedure” algorithm for implementing the draft general principles. We emphasise that it seems reasonable, transparent, appropriate and feasible to implement. We believe that the work reasonably addresses and resolves the concerns presented beforehand. In any case, we believe that the “step-by-step procedure” that has been used to establish the NRVs-R, either this one or including any adjustments that may be made, should be contained in the final text of the general principles, either in an appendix or in a section of the same document, explaining the procedure so that it can be carried out.	**Chile**
Costa Rica appreciates the work done and in this regard, I would like to mention the following: The revised method is a good approach to start the discussion on the establishment of these values. However, it is considered essential to review the long-term impact of the proposed NRVs for specific nutrients.	**Costa Rica**
GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVs-R The use and application of reference values in relation to the DIRV, INL_{98}, UL and AI for micronutrients is considered appropriate, taking into account the nutritional reality of the country.	**Ecuador**

DEFINITIONS 2. Definitions Egypt proposes to add the definitions of (NRVs) and (NRVs-R) as follow: Nutrient Reference Values (NRVs) A set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims. Nutrient reference values – requirements (NRVs-R) Which refer to NRVs that are based on levels of nutrients associated with nutrient requirements. NRVs-R are established for vitamins, minerals and protein. Reference: Codex Nutrient Reference Values Specially for Vitamins, Minerals and protein.2019 **3.2 Appropriate Basis for Establishing NRVs-R** Page 36 in this reference "Review of derivation methods for older infants and young children" of Niacin NE means niacin equivalents; 1 mg NE = 1 mg niacin +60 mg tryptophan Egypt Comment: the Niacin equivalents footnote should be corrected as follow: 1 mg niacin equivalents (NE) = 1 mg niacin 60 mg tryptophan Reference: Codex nutrient reference values 2019 Rational:Use of the plus can lead to misinterpretation of the equivalency.	**Egypt**
3.3 Consideration of Upper Levels of Intake GUATEMALA agrees with the principles established in the wording	**Guatemala**
PREAMBLE para 1. Comment: For clarity include ‘of nutrients’ in the sentence --- healthful dietary intake of nutrients. Rationale: For clarity include – “of nutrients” **3.2 Appropriate Basis for Establishing NRVs-R** Comment: This section needs better explanations and clarity. Rationale: • Nutrient Reference Values–Requirement: refers to NRVs that are based on levels of nutrients associated with nutrient requirements for the general population. In healthy population estimated average requirement (INL 50 or EAR) is recommended as the unit of nutrient requirements. • INL98=RDA=INL 50+2SD is a nutrient reference value for healthy individuals, which when applied as a metrics for public health nutrition purpose can introduce a risk of excess intake, since each individual may not actually require that much.	**India**

• The FAO2021 report clearly indicates that for older infants and young children (6-12 mo and 12-36 mo), the most common derivation is based on extrapolation from adult/ young infants considering their reference body weights/energy intake. • The derivation of NRV-R for older infants is by allometric scaling up from DIRV young infants (Breast milk intake) and for young children by allometric scaling down from DIRV adult requirements. • The above derivations contribute to discrepancies. • Since internationally accepted WHO growth standards (MGRS) are available for the group 6-36 mo extrapolated INL50/INL98/ NRVs should be close across the regions.	
Malaysia supports the Proposed Draft General Principles for Establishing Nutrient Reference Values for Persons Aged 6 to 36 Months in the Guidelines on Nutrition Labelling (CXG 2-1985) (Part A), the proposed pilot stepwise approach (Part B) and the proposed values of NRVs-R for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C (Part C) as in document CX/NFSDU 23/43/5. However, Malaysia is of the opinion that a combined set of NRVs-R for both older infants and young children should be established since it is for labelling purposes which provides guidance to consumers on the food label. It does not require a further separation of the age groups.	**Malaysia**
Individual Nutrient Level 98 (INL98) INL98 - 98 should be subscript throughout the document. This would align with the General Principles. Definitions Recognized Authoritative Scientific Body (RASB) This first sentence has been altered from the general population principles and it is unclear why it has been reframed when the meaning should apply consistently across the two documents. The wording as drafted for the general population was purposefully written that way to indicate that the FAO and WHO are also considered recognised and authoritative in their work NRVs. **3.2 Appropriate Basis for Establishing NRVs-R** The NRVs-R should be based on Individual Nutrient Level 98 (INL98) i**nformed by relevant evidence (2021 FAO report[5]). Where the INL98 cannot be determined, the AI should be used.** Where there is an absence of, or an older, established INL98 for a nutrient, it may be more appropriate to consider the use of other daily intake reference values or ranges that have been more recently established by recognized authoritative scientific bodies. **The rigor of scientific methods, and quality and strength of evidence used to establish these values should be reviewed on a case-by-case basis.** As seen in the pilot process different RASBs do not use the terms consistently for AI and INL98. In the iodine example, EFSA are the only RASB to use physiological data and have derived an AI for both infants and young children. It is proposed that the first sentence could be amended to state the following: "NRVs-R should be based on Individual Nutrient Level 98 (INL98), higher priority should be given to values derived from relevant physiological evidence from the target age group (REF:2021 FAO) This would enable the text to more accurately reflect the process undertaken in the pilot. With this amendment the second sentence should be deleted, the rationale is detailed in the next comment This is an unnecessary addition to this set of principles and deviates from the General Population. As indicated in the previous comment the terminology is not consistent across RASBs.	**New Zealand**

Furthermore, an AI would be considered within the following sentence as it is another DIRV. If the general principles were to be strictly interpreted then this be difficult to consider when a RASB has established an AI based on physiological data. New Zealand would prefer that this text is reviewed to more closely align with the recent FAO 2021 report and utilise the term derivation which is more appropriate for these purposes and alignment with the principles for the General Population. Proposed alternative text to align with the General Population: "The derivation of these values should be reviewed on a case-by case basis [taking into account the strength and quality of evidence underpinning the DIRV]." The proposed alternative text would also work better in navigating the pilot process. We have inserted square brackets around the text which considers the strength and quality of evidence. The FAO report prioritises different methods for derivation rather than judgement on the strength and quality of evidence. As indicated in the Chairs' agenda paper, most RASBs have not evaluated the strength and quality of evidence in this manner, which may be partly due to the paucity of data available and timing with which this work was undertaken. It is anticipated that when the WHO finalise their review of NRVs for this age group that systematic reviews will be undertaken along with assessments of the strength and quality of the evidence. At this time the text we have placed in square brackets would be of relevance.	
GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R We thank the chair of the eWG for the clarification regarding the calculation of the NRVs proposed and for the new proposed values based on this robust approach. The new approach excludes additional RASB recommendations with lower scientific rigor and is also taking the median values compared to the mean while comparing it with the FAO/WHO RNI. We believe that the revised method represents a good approach to initiate discussion on the establishment of these values. However, we consider it essential to review the long-term impact of proposed NRVs for specific nutrients. Based on scientific rationale and latest developments regarding the nutritional status of the 6-12 and 12-36 months population, deviation from the values established through this method should be possible. On that basis, we are putting forward some elements of information and rationales that should be taken into consideration in these discussions and lead to slightly different proposed values for specific nutrients.	**Panama**
PREAMBLE para 2. Establishment of Nutrient Reference Value (NRVs) specific for persons aged 6-36 months should consider important factors that affect nutrient absorption, utilization and requirements. The Philippines supports the statement: "Governments may also consider to establish separate NRVs-R for specific segment of persons aged 6-36 months" without the brackets.	**Philippines**
Saudi Arabia support the proposed draft "General Principles for Establishing Nutrient Reference Values (NRVs-R)for Persons Aged 6 –36 Months", the revised plot stepwise approach on the application of that draft and the proposed NRVs-R mentioned in (Appendix II, Part C).	**Saudi Arabia**
South Africa is in support of the revised proposed draft general principles for establishing nutrient reference values for persons aged 6 to 36 months (Appendix ll- Part A)	**South Africa**
Response to question a. The general principles for establishing nutrient reference values (NRVs-R) for persons aged 6 –36 months (CX/NFSDU 23/43/5, Appendix II, Part A);	**United Kingdom**

The UK support the position agreed at CCNFSDU42 that the original text in Annex 1 of the General Principles for the establishment of NRVs for the General Population of Guidelines on Nutrition Labelling (CXG 2-1985) should be retained as far as possible. The UK support the decision of the EWG to include further text to clarify that these NRVs-R are for use in the labelling of pre-packaged foods for special dietary uses (FSDU) intended for persons aged 6–36 months. The UK support the decision of the EWG Chairs to keep text relating to future decisions on the NRV-Rs for different age groups to be kept in square brackets which can be revised accordingly. The UK support the reference in the preamble which supports governments to use the NRVs-R and the general principles in establishing their own NRVs-R to take into account specific country or region considerations. UK look forward to further discussion and consideration of the proposed general principles for establishing nutrient reference values (NRVs-R) for persons aged 6 –36 months at CCNFSDU43.	
GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVs-R As expressed in the responses to the consultation documents of the Electronic Working Group (in which Uruguay participates) we do not support removing the definition of Acceptable Macronutrient Distribution Range (AMDR). While we acknowledge that the AMDR is not relevant for establishing the NRVs-R for vitamins, minerals and proteins, the AMDR is a factor to be considered in the production of dietary guidelines for the target population of these principles and should be considered for future establishment. Therefore, we prefer to include the definition and not to close this possibility.	**Uruguay**
The United States supports the amendments to the Preamble, Definitions, and General Principles for Establishing NRVs-R based on the discussion provided in Consultation Paper 2 and CX/NFSDU 23/43/5. The United States offers the following editorial comments to Part A. Definitions Recognized Authoritative Scientific Body (RASB) RASB be bolded for consistency with the other definitions. **3.2 Appropriate Basis for Establishing NRVs-R** The NRVs-R should be based on Individual Nutrient Level 98 (INL98) informed by relevant evidence ~~(2021~~ (e.g. 2021 FAO report[5]). Where the INL98 cannot be determined, the AI should be used. Where there is an absence of, or an older, established INL98 for a nutrient, it may be more appropriate to consider the use of other daily intake reference values or ranges that have been more recently established by recognized authoritative scientific bodies. The rigor of scientific methods, and quality and strength of evidence used to establish these values should be reviewed on a case-by-case basis.	**USA**
PREAMBLE para 2. For the last sentence – “Governments may also consider whether to establish [separate or combined] NRVs-R for specific segments of persons aged 6-36 months.” – Helen Keller suggests that the square brackets [separate or combined] be removed as this will allow national governments the decision of which approach to take for their own NRVs. **DEFINITIONS** Helen Keller Int'l agrees with this section. **3.1 Selection of suitable data sources to establish NRVs-R** Helen Keller Int'l agrees with this section. **3.2 Appropriate Basis for Establishing NRVs-R** Helen Keller agrees with this section, including the removal of ‘Selection of Nutrients’ from the heading for the reasons noted by the Chairs; the inclusion of ‘informed by physiological evidence’; retaining INL98 as the primary basis for NRVs-R; the addition of ‘The rigour of scientific methods, and quality and strength of evidence used to establish these values should be reviewed on a case-by-case basis.’. **3.3 Consideration of Upper Levels of Intake** Helen Keller Int'l agrees with this section.	**HKI**
ICGMA has no further comments on the latest draft of GP and supports the latest version.	**ICGMA**

DEFINITIONS Format of reference numbers should be the same for all numbers (1 and 2 are different to 3, 4, 5)	**ICUMSA**

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

Australia supports the use of the stepwise approach as providing clear and consistent guidance on for determining NRVs-R. We note the intention is not to include the stepwise approach in the general principles. However, for clarity and consistency, Australia considers there would be value in having the stepwise approach included as part of the draft general principles.	**Australia**
Step 4: More clarity should be given concerning step 4a and 4b. In step 4a, it is stated that "If the FAO/WHO DIRV and the RASBs DIRVs are similar, the FAO/WHO DIRV is selected for the establishment of NRVs-R for persons aged 6 – 36 months" whereas the footnote states "The median of the FAO/WHO and RASBs DIRVs is the same as the FAO/WHO DIRV", similar does not mean the same. Therefore, we recommend that "same" be used instead of "similar". For 4a and 4b, an edit is proposed as the process involves comparing the FAO value to the median of the RASB values. See suggested edit for 4a and 4b. **Step 4a:** If the FAO/WHO DIRV and the median of the RASBs DIRVs are ~~similar~~the same[1], the FAO/WHO DIRV is selected for the establishment of NRVs-R for persons aged 6 – 36 months. **Step 4b:** If the FAO/WHO DIRV and the median of the RASBs DIRVs are *not* ~~similar~~the same[1], the median of the DIRVs from the FAO/WHO and the RASBs is selected for the establishment of NRVs-R for persons aged 6 – 36 months. ~~[1]The median of the FAO/WHO and RASBs DIRVs is the same as the FAO/WHO DIRV (when rounded up).~~ We recommend deleting footnote 1 and instead adding an overarching statement addressing rounding rules in all situations: when RASBs have DIRVs for boys and girls, when the age range is different than 1-3 years and for steps 4a and 4b.	**Canada**
Step 1: the FAO 2021 report was used to identify the DIRVs established by FAO/WHO and the RASBs for vitamins, minerals and proteins considered for older infants and young children. We consider it appropriate, having carried out in steps the criteria for the establishment and definition of reference values, to place emphasis again on taking into account the nutritional realities of the country and the scientific evidence concerning the specific population of the country.	**Ecuador**
Egypt agrees with PART B but we would like to ask for an explanation for using "median" instead of "average" in calculation of NRVs	**Egypt**
GUATEMALA agrees with the steps of the pilot plan for the establishment of NRVs-R.	**Guatemala**

Step 4a: We support the revised approach which prioritises the FAO/WHO DIRV where values are similar **Step 4b:** While we acknowledge that the pilot process seems to have worked relatively well with the nutrients that have been considered we note that there may be greater deviation for the remaining nutrients which may warrant consideration of the methods for derivation or physiological endpoints that are being used to derive the values. As such a simple median of all DIRVs may not be appropriate for Steps 4b and 4c and we should consider the methods that underpin the DIRV. If a median value is selected this could result in the potential for needing to review the DIRVs and recalculate median values as new DIRVs are published by RASBs. As such we would consider that the principle of reviewing these nutrients on a case by case may be necessary. This approach was taken in the work within the Follow-up Formula standard which was referenced under 14/36/7. We would only recommend this to be done where are substantive differences and a high level assessment was taken. We would not wish this to be an onerous process as we see this work as an interim measure while new data is collated for this age group and the WHO work on NRVs is ongoing.	**New Zealand**
South Africa is in support of the revised proposed pilot stepwise approach on the proposed draft general principles for establishing nutrient reference values (NRVS-R) for persons aged 6-36 months (Appendix ll-Part B).	**South Africa**
Response to question B - Pilot stepwise approach on the application of the General principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months (CX/NFSDU 23/43/5, Appendix II, Part B); The UK support the use of the FAO 2021 report “Review of Derivation Methods for Dietary Intake Reference Values (DIRVs) for Older Infants and Young Children” and the DIRVs established by FAO/WHO in the proposed pilot stepwise approach on the proposed draft General principles for establishing nutrient reference values (NRV-Rs) for persons aged 6 – 36 months. The UK support the EWGs application of the revised pilot stepwise approach (provided for in the General principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months) for the draft NRV-Rs for vitamin B12, iodine, vitamin B6, riboflavin, niacin and vitamin C which are included in part C of Appendix II. The UK agree with the position of the Chair of the EWG that the stepwise process may need adjustment depending on the nutrient and each nutrient needs to be treated on a case-by case basis. The UK look forward to hearing the outcome of the discussion of the PWG, seeing the results of using the pilot stepwise approach of the General principles for establishing nutrient reference values (NRVs-R) for the remaining nutrients and to discussing the further considerations which may be needed to amended the pilot step wise approach at CCNNFSDU43.	**United Kingdom**
Uruguay generally agrees with the approach taken to establish the NRVs; however, there is concern that for some nutrients there is a considerable difference between the values, and a more thorough evaluation of the methods used to derive the values is needed.	**Uruguay**
In general, the United States supports the proposed stepwise approach and has offered plain language edits for easier comprehension of the process. The United States supports using the 2021 FAO Report to identify DIRVs, RASBs, and methods. To simplify and focus on the conceptual approach, the United States suggests referencing the 2021 FAO Report as a citation in the Stepwise approach rather than including it in each step. The U.S. comments on the proposed stepwise approach align with the approach outlined in CX/NFSDU 14/36/7 with the following exceptions: • Selecting RASBs and identifying DIRVs are combined into one step instead of two.	**USA**

• DIRVs from FAO/WHO and RASBs are equally considered unless deemed potentially unsuitable • Use the median of all suitable DIRVs rather than in some cases defaulting to FAO/WHO when DIRVs from RASBs are similar. Basing the NRV on an older FAO/WHO DIRV may not capture the totality of evidence reported by RASBs. The United States proposes replacing the original text with the following text for Steps 1-4. **Step 1: Identify DIRVs from FAO/WHO and accepted RASBs for vitamins and minerals for older infants and young children.** ~~Using the 2021 FAO report, DIRVs established by FAO/WHO and the RASBs for the vitamins, minerals and protein under consideration for older infants and young children, were identified.~~ The "accepted RASBs" are from the 2021 FAO report. **Step 2: Compare the DIRVs from FAO/WHO and accepted RASBs based on the scientific rigour of derivation method.** ~~The scientific rigour of the derivation methods used to establish these DIRVs (outlined in the 2021 FAO report) were used to identify nutrients where DIRVs are based on INL98/AI informed by relevant physiological evidence (Category 1 in 2021 FAO report).~~ **Step 3: Identify DIRVs from FAO/WHO and accepted RASBs derived with strongest scientific rigour and exclude less scientifically rigorously derived DIRVs.** ~~Potentially unsuitable DIRVs (Category 3 in 2021 FAO report) are excluded due to the lower scientific rigour of such values~~. **Step 4:** ~~Where~~ Recommend the ~~scientific rigour of~~ most appropriate NRV-R based on the ~~derivation methods of the DIRVs established by the FAO/WHO and any of the RASBs are of similar ranking (Category 2 in the 2021 FAO report), the~~ median ~~and range~~ of ~~these RASB~~ all suitable DIRVs ~~are compared with the~~ [CC1] from FAO/WHO ~~DIRV (if included) to provide an overview of the potentially suitable DIRVs~~and accepted RASBs.	
Helen Keller Int'l agrees with this section. We congratulate the Chairs for the creation of this stepwise approach, and appreciate the clear, understandable format in which this has been presented. This is highly beneficial for those reviewing this piloted approach and would also be beneficial for national governments who may consider establishing NRVs-R for specific segments of persons aged 6-36 months. We note that on page 9 of CX/NFSDU 23/43/5 it states that “The stepwise process is not proposed to be included in the General Principles.” but would suggest their inclusion (once finalized, noting they may be revised after application to a wider range of nutrients as noted) for transparency and the benefit of national governments.	**HKI**
ICGMA considers important to clarify the relevant switch from “average” to “median” in the calcula-tions mentioned in Steps 2 & 4, to ensure proper information of the Codex members and observers. ICGMA would also welcome clarification on the derivation methodology in relation to the Nordics values. ICGMA hopes for all changes in calculations from previous draft to be articulated during the Physical Working Group. Established values have been in place for a long time and understanding if they have properly served that population health is essential and evident in the prevalence of deficiencies. ICGMA re-quests to include at the end of the step process and before establishing a value, a step for consider-ation of the prevalence of nutrient deficiencies and the long-term impact of the NRVs to be estab-lished, in order to adapt the values for optimal health.	**ICGMA**
ISDI thanks the chair of the eWG for the clarification regarding the calculation of the NRVs proposed and for the new proposed values based on this robust approach. The new approach excludes additional RASB recommendations with lower scientific rigor and is also taking the median values compared to the mean while comparing it with the FAO/WHO RNI. ISDI believes that the revised method represents a good approach to initiate discussion on the establishment of these values.	**International Special Dietary Food Industries**

However, ISDI considers it essential to review the long-term impact of proposed NRVs for specific nutrients. Based on scientific rationale and latest developments regarding the nutritional status of the 6-12 and 12-36 months population, deviation from the values established through this method should be possible. On that basis, ISDI is putting forward some elements of information and rationales that should be taken into consideration in these discussions and lead to slightly different proposed values for specific nutrients.	

APPENDIX II PART C Proposed draft NRVs-R for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C

Australia considers the stepwise approach adopted to establish NRVs-R for persons aged 6 -36 months as detailed in Appendix II Part B provides consistency and clarity for the derivation of draft NRVs-R. We therefore support the proposed draft NRVs-R as presented in Appendix II, Part C	**Australia**
Vitamin B12 (µg) 0.5 Costa Rica doesn´t consider the proposed value of 0.5µg to be appropriate, and in effect supports a value of 0.7µg, Justification: The EFSA AI has increased in recent years from 0.5 µg in 2013 to 1.5 µg. Costa Rica recognizes the efforts that many countries are making to fortify with vitamin B12 and folate, however, deficiency of this vitamin is still prevalent in the population of older infants and young children, especially in developing countries. Food insecure people who do not have resources and therefore cannot consume animal products are at greater risk, and the more frequent folate fortification programs may mask the development of folate deficiency. Younger infants are at greater risk because vitamin B12 concentrations in breast milk may be markedly lower in women with B12 deficiency. In addition, if older infants do not transition well to supplemental foods with adequate B12, they are at increased risk. As a result, 0.7 µg is a valid NRV value for older infants. Thiamine (mg) 70 Although the proposed value is aligned with EFSA recommendations, the value for older infants is however lower than the U.S AI which is based on a median level in breast milk from 2 groups of women categorized as having low iodized salt intake. In this regard, Costa Rica would like to raise the following considerations that could be taken into account during the debate: In the WHO Global scorecard on median iodine status for school age children and women of reproductive (WRA) age worldwide, several countries around the globe report insufficiency as determined by urinary iodine concentration (UIC) an imperfect indicator of iodine intake. The WHO defines adequate iodine intake in adults as a median UIC value ≥ 100 µg/L. However, the scientific basis for this threshold is weak. The WHO shared in this document that «estimates based on populations other than school aged children (SAC) should be interpreted with caution.» This brings into question an even greater proportion of countries as the median UIC in many populations for WRA are very close to this threshold.	**Costa Rica**

The one balance study cited in the U.S. DRI was performed on 1 month old infants and extrapolated up. The infant retained 7.3 µg/kg/day and excreted 12.7 µg/kg/day. The extrapolated retained mass for a 6 month old weighing 8 kg is 58.4 µg per day. With the rapid increase in white matter for this age group, 70 µg seems too low to cover 98% of the population. Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. Washington, DC: The National Academies Press, 2001. "The median concentration of iodine in human milk for all women was 146 µg/L for 14 days to 3.5 years postpartum. Based on an average milk excretion of 0.78 L/day (Chapter 2) and an average concentration of 146 µg/L, the mean amount of iodine secreted in human milk is 114 µg/day. Therefore, Costa Rica considers that the proposed NRV of 70 µg for older infants is too high. Vitamin C (mg) 20 Costa Rica agrees that the recommendation is consistent with the agreed method for obtaining the derived NRV; however, the proposed NRV is much lower than the FAO/WHO recommendations. Vitamin C (mg) 24 Costa Rica does not see the decrease of the Vitamin C value from 28 mg to 24 mg in young children as appropriate and in its effect would like to propose that the value of 28 mg as a minimum be maintained, with 30 mg as the preferred option. Justification: FAO/WHO data indicate 30 mg. In the same vein, most individual DIRVs in countries such as Australia, New Zealand, Japan, Nordic countries are higher than 24 mg.	
Although the use and application of reference values in relation to the DIRV, INL_{98}, UL and AI for micronutrients is considered adequate, in Ecuador there is no scientific evidence for any deficiency in B-complex vitamins (B12, B6, riboflavin, niacin); however, iodine and vitamin C supplementation is being performed, especially in pregnant women; likewise, we hope that micronutrient requirements will be implemented for the entire life cycle.	**Ecuador**
Vitamin B12 (µg) 0.5 Egypt suggests the value of 0.7µg for NRVs-R of vitamin B12for older infants. Rational: Based on the assumption that human milk contains enough vitamin B12 for optimum health, an EAR between 0.3 and 0.6µg/day seems reasonable giving an RNI of between 0.4 and 0.7µg/day. It would seem appropriate to use the lower RNI figure of 0.4µ/day for infants aged 0–6 months and the higher RNI figure of 0.7µ/day for infants aged 7–12 months Reference : "FAO/WHO Vitamin and mineral requirements in human nutrition Second edition 2004" Thiamine (mg) 70 Egypt suggests the value of 80µg for NRVs-R of iodine for older infants. Vitamin C (mg)	**Egypt**

Egypt proposes that the NRVs-R values of vitamin C to be a range as follow: Older Infants: 20mg -30mg Young Children: 24mg- 30mg Rational: Many countries have a problem of iron deficiency anaemia;vitamin C has a key physiologic role in facilitating the absorption of non-heme iron from the diet.Its action is twofold: (1) the prevention of the formation of insoluble and unabsorbable iron compounds and (2) the reduction of ferric to ferrous iron, which seems to be a requirement for the uptake of iron into the mucosal cells.	
Guatemala requests the modification of two NRVs for older infants, for which it indicates the following: VITAMIN B12 FOR OLDER INFANTS: We support 0.7 mcg, not the proposed 0.5 mcg. Vitamin B12 deficiency is prevalent in underdeveloped and developing countries among older infants and young children despite efforts to fortify with vitamin B12 and folate in many countries, as demonstrated by biochemical analyses. • People suffering from food insecurity who lack the necessary resources to be able to consume animal products are at greater risk, and the more frequent folate fortification programmes may mask the development of vitamin B12 deficiency. • Younger babies are at greater risk because vitamin B12 concentrations in breast milk may be significantly lower in women with vitamin B12 depletion. In addition, if older infants do not make a good transition to complementary foods with adequate B12, they are at greater risk. • It appears that the proposed value extrapolates upwards from infants aged 0-6 months, indicating a relationship to the amount of breast milk consumed not extrapolated from the young children population where some RASBs have developed DIRVs for B12 for older infants. • B12 is a water-soluble vitamin and no adverse effects have been identified that could serve as a basis for deriving an upper limit (IOM and EFSA). As a result, we believe that 0.7 µg is a preferred value of the NRV for older infants. IODINE NRV FOR OLDER INFANTS: We support 80 µg of iodine as NRV for older infants, to be considered in comparison with the proposed 70 µg. • Although the proposed value is in line with EFSA recommendations, the value for older infants is lower than the AI in the USA, which is based on an average level in breast milk from two groups of women categorised as having low iodised salt intake. • There is current concern with most of the populations that develop iodine deficiency. Dairy farmers have long used iodine as an agent for cleaning cows' udders, but are moving away from its use, replacing it with other cleaning agents. This practice used to ensure a range of iodine levels in milk that have greatly diminished. This is added to the use of non-iodised salt to reduce costs or the lowering of salt consumption for health benefits (when salt is a vehicle for iodine intake). This has led to deficiencies in a percentage of the population in many countries. • As infants begin the transition to complementary foods, iodine intake may be affected by lower levels in their diet.	**Guatemala**

• We note that even for breastfed infants, the iodine content of breast milk depends on the mother's iodine intake. Therefore, if a breastfeeding mother does not continue to take vitamin supplements or specific complementary foods, her food choices may reduce her iodine status and affect infant intake. • In the WHO global scorecard on average iodine status for school-aged children and women of reproductive age (WRA) worldwide, several countries around the world report inadequacy as determined by urinary iodine concentration (UIC), an imperfect indicator of iodine intake. WHO defines adequate iodine intake in adults as a mean value of UIC ≥ 100 µg/L. However, the scientific basis for this threshold is weak. WHO shared in this document that "estimates based on populations other than school-aged children (SAC) should be interpreted with caution". This calls into question an even larger proportion of countries, as the median UIC for WRA in many populations is very close to this threshold. • The thyroid hormone is particularly important for the myelination of the central nervous system, which is most active in the perinatal period and during foetal and early postnatal development. The brain reaches 90% of its adult weight by the age of 2 years. Therefore, white matter formation depends on iodine adequacy. Iodine deficiency does not present clinically until enlargement of the thyroid gland occurs. This means that the deficiency may have developed but has not yet manifested. It is not yet clear whether low deficiency can have neurological implications that are fully reversible with iodine supplementation. • The only balance study cited in the DRI for the USA was conducted in 1-month-old infants and extrapolated. The infant retained 7.3 µg/kg/day and excreted 12.7 µg/kg/day. The retained mass extrapolated for a 6-month-old child weighing 8 kg is 58.4 µg per day. With the rapid increase in white matter for this age group, 70 µg seems too low to cover 98% of the population. We would like to raise these elements of concern for consideration during the discussions. We consider the proposed NRV of 70 µg for older infants to be too low and hope to discuss this issue further during PWG and CCNFSDU. In view of the above, we consider that 80 µg for older infants would be more appropriate for their health.	
Comment: Indian RDA's are higher than the Codex NRV-R values. Rationale: • Indian EAR's for this age groups are also based on extrapolation from adults and energy requirements. For older infants' both INL50 and INL98 have been derived for vitamins B12 and B6while for iodine, vitamins B1, B2, Niacin and vitamin C only INL98 is provided. For young children both INL50/INL98 (EAR and RDA's) have been computed and provided for these nutrients. • Indian RDA's may fit into the Step 4b: If the FAO/WHO DIRV and the RASBs DIRVs are not similar, the median of the DIRVs from the FAO/WHO and the RASBs is selected for the establishment of NRVs-R for persons aged 6 – 36 months. Thus we can agree and adopt this NRV-R for older infants (6-12 mo) and young children (1-3 years). Reference: FAO 2021. Review of Derivation Methods for Dietary Intake Reference Values for Older Infants and Young Children Thiamine (mg) 70 Comment: The proposed NRVs of 70 mcg for Iodine for Older Infants is too low Rationale: • Although the proposed value is aligned with EFSA recommendations, the value for older infants is however lower than the U.S AI which is based on a median level in breast milk from 2 groups of women categorized as having low iodized salt intake and high. There is current concern with most populations developing iodine deficiency. Milk producers have long used iodine as an agent to clean the udders of cows but are moving away from using it and replacing with other cleaning agents. This practice used to allow for a range of iodine levels in milk which have diminished greatly. In addition, the use of non-iodized salt to reduce costs or decrease	**India**

of salt consumption for health benefits (when salt is a vehicle for iodine intake). This has led to deficiencies in a percentage of population in many countries. • As infants begin to transition to complementary foods, iodine intakes could be impacted by lower levels in their diet. We note that even for children that are breastfed, iodine content of human milk is dependent upon maternal iodine intake. Therefore, if a breastfeeding mother does not continue to take vitamin supplements or specific complementary foods, her food choices may reduce her iodine status and impact infant intake. • Thyroid hormone is particularly important for myelination of the central nervous system, which is most active in the perinatal period and during fetal and early postnatal development. The brain reaches 90% of adult weight by age 2 years. White matter formation is therefore dependent on iodine adequacy. Iodine deficiency does not clinically present until enlargement of the thyroid gland occurs. This means deficiency could have developed but has not presented yet. It is yet unclear if low deficiency can have neurological implications that are entirely reversible with supplementation of iodine. • The one balance study cited in the U.S. DRI was performed on 1 month old infants and extrapolated up. The infant retained 7.3 mcg/kg/day and excreted 12.7 mcg/kg/day. The extrapolated retained mass for a 6-month-old weighing 8 kg is 58.4 mcg per day. With the rapid increase in white matter for this age group, 70 mcg seems too low to cover 98% of the population. Reference: Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. Washington, DC: The National Academies Press, 2001. “The median concentration of iodine in human milk for all women was 146 µg/L for 14days to 3.5 years postpartum. Based on an average milk excretion of 0.78 L/day (Chapter 2) and an average concentration of 146µg/L, the mean amount of iodine secreted inhuman milk is 114µg/day. Vitamin C (mg) 20 Comment: The proposed NRV of 20 for Vitamin C is much lower than the recommendations by Koletzko 2012, LSRO breastmilk minimums also. Rationale: The NRV should be 50 mg/day for Vitamin C to align with Koletzko and DRI. Or 30 mg/day to at least be aligned with minimum breast milk contribution 6 mg/100 kcal (1.2.). References:Koletzko B, Bhutta ZA, Cai W, et al. Compositional Requirements of Follow-Up Formula for Use in Infancy: Recommendations of an International Expert Group Coordinated by the Early Nutrition Academy. Annals of Nutrition & Metabolism2012; 11:1-11. Raiten DJ, Talbot JM, Waters JH, eds. Life Sciences Research Office (LSRO) Report: Assessment of Nutrient Requirements for Infant Formulas, JNutr (Supplement). 1998; 128: 2059S-2078S.	
Vitamin B12 (µg) Vitamin B12 for Older Infant: We support 0.7µg, not the proposed 0.5µg • We also note that the EFSA AI has increased in recent years, not decreased, from 0.5 µg in 2013 to 1.5 µg today.	**Panama**

• Prevalence of B12 deficiency exists in under-developed and developing countries in older infant and young children despite efforts to fortify B12 and folate in many countries and as evidenced by biochemical analysis. • Food insecure individuals who do not have adequate resources to consume animal products are at greater risk and folate fortification programs which are more prevalent can mask development of B12 deficiency. • Younger infants are at greater risk because vitamin B12 concentrations in breastmilk can be distinctly lower in vitamin B12-depleted women. Additionally, if the older infants do not transition well to complementary foods with adequate B12, they are at greater risk. • It appears the proposed value is extrapolated up from infants 0-6 months which indicates a relationship to the amount consumed from human milk not extrapolated down from the toddler population where some RASB have developed DIRVs for B12 for older infants. • B12 is a water-soluble vitamin and no adverse effects have been identified that could be a basis for deriving an upper limit (IOM and EFSA). As a result, we believe 0.7 µg is a preferred value for the NRV for older infants. Iodine NRVs for Older infant: In order to set the best NRV possible for iodine, we believe important to have a better understanding of current iodine intake and also regarding of levels of retention vs. excretion. We note the following key points of concern: • Although the proposed value is aligned with EFSA recommendations, the value for older infants is however lower than the U.S AI which is based on a median level in breast milk from 2 groups of women categorized as having low iodized salt intake. We would like to bring forward the following considerations for further discussions: • There is current concern with most populations developing iodine deficiency. Milk producers have long used iodine as an agent to clean the udders of cows but are moving away from using it and replacing with other cleaning agents. This practice used to allow for a range of iodine levels in milk which have diminished greatly. In addition, the use of non-iodized salt to reduce costs or decrease of salt consumption for health benefits (when salt is a vehicle for iodine intake). This has led to deficiencies in a percentage of population in many countries. • As infants begin to transition to complementary foods, iodine intakes could be impacted by lower levels in their diet. • We note that even for children that are breastfed, iodine content of human milk is dependent upon maternal iodine intake. Therefore, if a breastfeeding mother does not continue to take vitamin supplements or specific complementary foods, her food choices may reduce her iodine status and impact infant intake. • In the WHO Global scorecard on median iodine status for school age children and women of reproductive (WRA) age worldwide, several countries around the globe report insufficiency as determined by urinary iodine concentration (UIC) an imperfect indicator of iodine intake. The WHO defines adequate iodine intake in adults as a median UIC value ≥ 100 µg/L. However, the scientific basis for this threshold is weak. The WHO shared in this document that «estimates based on populations other than school	

aged children (SAC) should be interpreted with caution.» This brings into question an even greater proportion of countries as the median UIC in many populations for WRA are very close to this threshold. • Thyroid hormone is particularly important for myelination of the central nervous system, which is most active in the perinatal period and during fetal and early postnatal development. The brain reaches 90% of adult weight by age 2 years. White matter formation is therefore dependent on iodine adequacy. Iodine deficiency does not clinically present until enlargement of the thyroid gland occurs. This means deficiency could have developed but has not presented yet. It is yet unclear if low deficiency can have neurological implications that are entirely reversable with supplementation of iodine. • The one balance study cited in the U.S. DRI was performed on 1 month old infants and extrapolated up. The infant retained 7.3 µg/kg/day and excreted 12.7 µg/kg/day. The extrapolated retained mass for a 6 month old weighing 8 kg is 58.4 µg per day. With the rapid increase in white matter for this age group, 70 µg seems too low to cover 98% of the population. We wish to put forward these elements of concern for considerations during the discussions. We consider that the proposed NRVs of 70 µg for Older Infants is too low and looks forward further discussing this matter during PWG and CCNFSDU. Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. Washington, DC: The National Academies Press, 2001. “The median concentration of iodine in human milk for all women was 146 µg/L for 14 days to 3.5 years postpartum. Based on an average milk excretion of 0.78 L/day (Chapter 2) and an average concentration of 146 µg/L, the mean amount of iodine secreted in human milk is 114 µg/day.” Vitamin C (mg) Vitamin C for Older Infant: Although the recommendation is consistent with the agreed method to obtain the derived NRV, We note that the proposed NRV is much lower than the recommendations by Koletzko 2012, LSRO breastmilk minimums also. The NRV should be 50 mg/day to align with Koletzko and DRI. Or 30 mg/day to at least be aligned with minimum breast milk contribution 6 mg/100 kcal (1.2.). We wish to put forward these elements of concern for considerations during the discussions and looks forward to the discussions on this matter during PWG and CCNFSDU to assess if a slightly higher level should be recommended. Bibliographic References. 1. Koletzko B, Bhutta ZA, Cai W, et al. Compositional Requirements of Follow-Up Formula for Use in Infancy: Recommendations of an International Expert Group Coordinated by the Early Nutrition Academy. Annals of Nutrition & Metabolism 2012; 11: 1-11. 2. Raiten DJ, Talbot JM, Waters JH, eds. Life Sciences Research Office (LSRO) Report: Assessment of Nutrient Requirements for Infant Formulas, J Nutr (Supplement). 1998; 128: 2059S-2078S. Vitamin C for Young children: We do not support a decrease in the recommendation from 28 mg to 24 mg.	

Most of the individual DIRVs are above 24 mg (Aus/NZ, FAO/WHO, Japan, Nordic). We note that FAO/WHO, which represents the global situation more than the others, is at 30 mg Given this, we are not aligned with the proposal of a reduction to 24 mg. We recommend keeping 28 mg at a minimum, with 30 mg as a preferred option.	
Peru considers that the proposed reference values for vitamin B6, riboflavin, thiamine and niacin should be maintained, and that the values for vitamin B12, vitamin C and iodine should be reviewed in the light of new scientific evidence, considering the different realities of developing countries, in order to define whether there is sufficient evidence to justify adjusting these values.	**Peru**
South Africa is in support of the proposed draft NRVs-R for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin, and vitamin C (Appendix ll- Part C). However, can we please verify the information on page 16 at the bottom of Table 7 of Agenda item 5 (CX/NFSDU 23/43/5) related to the niacin equivalent. Should this not read: 1mg of niacin equivalent = 1mg of niacin OR 60 mg of tryptophan?	**South Africa**
Thiamine (mg) 70 Syria requests to establish Iodine reference value NRV for older infants 90 µg as per FAO/WHO recommendation. Vitamin C (mg) 20 Syria requests to establish Vitamin C reference value NRV for older infants 30 mg as per FAO/WHO recommendation.	**Syrian Arab Republic**
Thailand agrees with the Proposed draft NRVs-R for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, and niacin.	**Thailand**
Response to question C NRVs-R for persons aged 6 – 36 months for vitamin B12, iodine, vitamin B6, riboflavin, niacin and vitamin C – The UK are aware there is some evidence and some CCNFSDU members and observers which have concerns about requirements for specific nutrients (including iodine, vitamin B12 and vitamin C) in particular population groups. Following further consideration of the NRV-Rs at the PWG the UK look forward to further discussion at CCNFSDU 43 on the draft NRV-Rs values presented in part C of Appendix II. The UK are of the view it is important that the NRV-Rs which are proposed in Part C Appendix II are reviewed based on any further revisions which are made to the requirements of the General principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months at the PWG and CCNFSDU43. The UK continues to be supportive of considering the recommendations and advice from recognised authoritative scientific bodies (RASBs)".	**United Kingdom**
Iodine: as already expressed in the response to the second EWG consultation document, we consider that the methods used by RASB, whose values differ markedly and lead to a decrease in the average, should be better studied. Given the health implications of iodine deficiency in infants, we believe that the recommended value should be analysed more thoroughly.	**Uruguay**
The United States supports that review of the proposed NRVs-R be done once the stepwise approach is finalized.	**USA**
Helen Keller Int'l agrees with this section.	**HKI**
ICGMA supports the revised NRVs shown above but seeks to further understanding on the follow-ing:	**ICGMA**

Calculations for B12, B-6, Riboflavin, Thiamine, Niacin, and Vitamin C (see pp. 11, 13-17) involving the Nordic Countries. Specifically, a 3rd data point (the higher of the two data points is counted twice) is included in the average calculation for the 1-2 and 2-5 year old children. Can the eWG explain this approach to averaging the data points for the two age brackets? Process for median selection for B12 and Iodine It appears the proposed value for B12 is extrapolated up from infants 0-6 months which indicates a relationship to the amount consumed from human milk not extrap-olated down from the toddler population where some RASB have developed DIRVs for B12 for older infants. B12 is a water-soluble vitamin and no adverse effects have been identified that could be a basis for deriving an upper limit (IOM and EFSA). On pp. 16, the Niacin equivalents footnote should be corrected to indicate 1 mg niacin OR 60mg tryptophan equals 1 mg NE. Use of the plus can lead to misinterpretation of the equivalency. Alternatively, “1 mg NE = 1 mg niacin = 60 mg tryptophan” would also better convey this equivalency. In addition, ICGMA requests that the following information regarding prevalence of the following nu-trient deficiencies be included for context and further discussion: Iodine • There is current concern with most populations developing iodine deficiency. Milk producers have long used iodine as an agent to clean the udders of cows but are moving away from using it and replacing with other cleaning agents. This practice allowed for a range of iodine levels in milk which have diminished greatly. In addition, the use of non-iodized salt to re-duce costs or decrease of salt consumption for health benefits (when salt is a vehicle for io-dine intake). This has led to deficiencies in a percentage of population in many countries. • As infants begin to transition to complementary foods, iodine intakes could be impacted by lower levels in their diet. • ICGMA notes that even for children that are breastfed, iodine content of human milk is de-pendent upon maternal iodine intake. Therefore, if a breastfeeding mother does not continue to take vitamin supplements or provide specific complementary foods, her food choices may reduce her iodine status and impact infant intake. • In the WHO Global scorecard on median iodine status for school age children and women of reproductive (WRA) age worldwide, several countries around the globe report insufficien-cy as determined by urinary iodine concentration (UIC). While UIC is not a marker of long term status it is a short-term indicator of iodine intake over the previous day or so. The RASBs such as EFSA are of the opinion that spot urine samples used to estimate urinary io-dine excretion are imprecise and often used instead of 24 hours collections. The WHO de-fines adequate iodine intake in adults as a median UIC value ≥ 100 µg/L. However, the sci-entific basis for this threshold is weak. The WHO shared in this document that «estimates based on populations other than school aged children (SAC) should be interpreted with cau-tion» This brings into question an even greater proportion of countries as the median UIC in many populations for WRA are very close to this threshold. • Thyroid hormone is particularly important for myelination of the central nervous system, which is most active in the perinatal period and during fetal and early postnatal development. The brain reaches 90% of adult weight by age 2 years. White matter formation is therefore dependent on iodine adequacy. Iodine deficiency does not clinically present until enlarge-ment of the thyroid	

gland occurs. This means deficiency could have developed but has not presented yet. It is yet unclear if low deficiency can have neurological implications that are entirely reversable with supplementation of iodine. • The one balance study cited in the U.S. DRI was performed on 1 month old infants and ex-trapolated up. The infant retained 7.3 µg/kg/day and excreted 12.7 µg/kg/day. The extrapo-lated retained mass for a 6 month old weighing 8 kg is 58.4 µg per day. With the rapid in-crease in white matter for this age group, 70 µg seems too low to cover 98% of the popula-tion. Vitamin B12 • Prevalence of B12 deficiency exists in under-developed and developing countries in older infant and young children despite efforts to fortify B12 and folate in many countries and as evidenced by biochemical analysis. • Food insecure individuals who do not have adequate resources to consume animal products are at greater risk and folate fortification programs which are more prevalent can mask de-velopment of B12 deficiency • Younger infants are at greater risk because vitamin B12 concentrations in breastmilk can be distinctly lower in vitamin B12-depleted women. Additionally, if the older infants do not tran-sition well to complementary foods with adequate B12, they are at greater risk.	
Vitamin B12 (µg) 0.5 ISDI supports 0.7µg, not the proposed 0.5µg • Prevalence of B12 deficiency exists in under-developed and developing countries in older infant and young children despite efforts to fortify B12 and folate in many countries and as evidenced by biochemical analysis. • Food insecure individuals who do not have adequate resources to consume animal products are at greater risk and folate fortification programs which are more prevalent can mask development of B12 deficiency • Younger infants are at greater risk because vitamin B12 concentrations in breastmilk can be distinctly lower in vitamin B12-depleted women. Additionally, if the older infants do not transition well to complementary foods with adequate B12, they are at greater risk. • It appears the proposed value is extrapolated up from infants 0-6 months which indicates a relationship to the amount consumed from human milk not extrapolated down from the toddler population where some RASB have developed DIRVs for B12 for older infants. • B12 is a water-soluble vitamin and no adverse effects have been identified that could be a basis for deriving an upper limit (IOM and EFSA). As a result, ISDI believe 0.7 µg is a preferred value for the NRV for older infants. Thiamine (mg) 70 ISDI puts forth 80 µg of iodine as an NRV for older infants for consideration compared to the proposed 70 µg. In order to set the best NRV possible for iodine, ISDI believes important to have a better understanding of current iodine intake and also regarding of levels of retention vs. excretion.	**International Special Dietary Food Industries**

ISDI notes the following key points of concern: • Although the proposed value is aligned with EFSA recommendations, the value for older infants is however lower than the U.S AI which is based on a median level in breast milk from 2 groups of women categorized as having low iodized salt intake. ISDI would like to bring forward the following considerations for further discussions: • There is current concern with most populations developing iodine deficiency. Milk producers have long used iodine as an agent to clean the udders of cows but are moving away from using it and replacing with other cleaning agents. This practice allowed for a range of iodine levels in milk which have diminished greatly. In addition, the use of non-iodized salt to reduce costs or decrease of salt consumption for health benefits (when salt is a vehicle for iodine intake). This has led to deficiencies in a percentage of population in many countries. • As infants begin to transition to complementary foods, iodine intakes could be impacted by lower levels in their diet. • ISDI notes that even for children that are breastfed, iodine content of human milk is dependent upon maternal iodine intake. Therefore, if a breastfeeding mother does not continue to take vitamin supplements or provide specific complementary foods, her food choices may reduce her iodine status and impact infant intake. • In the WHO Global scorecard on median iodine status for school age children and women of reproductive (WRA) age worldwide, several countries around the globe report insufficiency as determined by urinary iodine concentration (UIC). While UIC is not a marker of long term status it is a short-term indicator of iodine intake over the previous day or so. The RASBs such as EFSA are of the opinion that spot urine samples used to estimate urinary iodine excretion are imprecise and often used instead of 24 hours collections. The WHO defines adequate iodine intake in adults as a median UIC value ≥ 100 µg/L. However, the scientific basis for this threshold is weak. The WHO shared in this document that «estimates based on populations other than school aged children (SAC) should be interpreted with caution.» This brings into question an even greater proportion of countries as the median UIC in many populations for WRA are very close to this threshold. • Thyroid hormone is particularly important for myelination of the central nervous system, which is most active in the perinatal period and during fetal and early postnatal development. The brain reaches 90% of adult weight by age 2 years. White matter formation is therefore dependent on iodine adequacy. Iodine deficiency does not clinically present until enlargement of the thyroid gland occurs. This means deficiency could have developed but has not presented yet. It is yet unclear if low deficiency can have neurological implications that are entirely reversable with supplementation of iodine. • The one balance study cited in the U.S. DRI was performed on 1 month old infants and extrapolated up. The infant retained 7.3 µg/kg/day and excreted 12.7 µg/kg/day. The extrapolated retained mass for a 6 month old weighing 8 kg is 58.4 µg per day. With the rapid increase in white matter for this age group, 70 µg seems too low to cover 98% of the population. ISDI wishes to put forward these elements of concern for considerations during the discussions. ISDI considers that the proposed NRVs of 70 µg for Older Infants is too low and looks forward further discussing this matter during PWG and CCNFSDU. ISDI considers that 80 µg for Older Infants would be more appropriate. Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. Washington, DC: The National Academies Press, 2001. “The median concentration of iodine in human milk for all women was 146 µg/L for 14 days to 3.5 years postpartum. Based on an	

average milk excretion of 0.78 L/day (Chapter 2) and an average concentration of 146 µg/L, the mean amount of iodine secreted in human milk is 114 µg/day.”	