CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Items 4 **CRD34**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-fourth Session

Dresden, Germany

(Comments by European Union)

AGENDA ITEM 4 NRVS-R FOR PERSONS AGED 6 – 36 MONTHS

European Union Competence
European Union Vote

A. Draft General Principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months (CX/NFSDU 24/44/4, Part A

Recommendation 1
The definition for Adequate Intake outlined below be adopted. [Adequate intake (AI) is a reference value for a specified population based on observed or experimentally determined approximations or estimates of nutrient intakes by a group (or groups) of presumably healthy people with no known evidence of deficiency.]

The European Union (EU) supports recommendation 1.

Recommendation 2
[NRV-Rs shall be derived for persons aged 6-12 months and 12-36 months from suitable data sources identified in 3.1 and the appropriate basis described above. The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.]

The EU partially supports recommendation 2.

Regarding the first sentence that was added *("NRV-Rs shall be derived for persons aged 6-12 months and 12-36 months from suitable data sources identified in 3.1 and the appropriate basis described above.")*, the EU is open to consider this text to clarify that 3 sets of values are derived. However, the wording for deriving the different data sets should be comparable. Therefore, "should" should be used instead of "shall" and the wording referring to section 3.1 should be rephrased to be clearer:

> "NRV-Rs **should**~~shall~~ be derived for persons aged 6-12 months and 12-36 months from suitable data sources identified **according to** section ~~in~~ 3.1 and the appropriate basis described above."

Regarding the second sentence ("*The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.*"), the EU prefers option 2 described in Appendix II CX/NFSDU 24/44/4, Part A, the lowest value, as for example, in the EU such a combined NRV-R value likely would be used for labelling of Processed Cereal Based Foods and Baby Foods. The majority of consumption of such products lies at the beginning of the age range and not at the end. Therefore, a value derived by using the lower value would be more appropriate for this situation. Furthermore, in jurisdictions where labelling is provided per fixed quantities, e.g. per 100 g or ml, and not per portion, even if a lower quantity of a nutrient is contained per 100g, after selecting either option 1 or 2, young children would consume higher amounts of this food, bigger portion sizes, due to higher energy requirements, and would therefore consume in absolute amounts also higher amounts of the nutrients as compared to older infants.

Recommendation 3
The Updated Revised Stepwise Process outlined in Appendix II be adopted

The EU considers it crucial that the stepwise process reflects the agreed draft General Principles, the stepwise process should not contradict the draft General principles, being as close as possible to the concepts and wording there.

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.

The EU supports this step 1, but suggests adding "that are based on a recent review of the science" to better align with the text in the draft General Principles, as it is not clear why this text part was omitted:

> *"Identify new or updated daily intake reference values (DIRVs) from FAO/WHO* ***that are based on a recent review of the science*** *for older infants and young children and select for establishing NRVs-R."*

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.

The EU generally supports this step 2, but suggests adding "also" to better align with the text in step 1 that is referred to here as well as the text in the draft General Principles, as it is not clear why this text part was omitted:

> *"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* ***also*** *be considered, with higher priority given to values where evidence has been evaluated by a systematic review."*

The EU considers that the draft General Principle in section 3.1 does not seem to have been implemented in the current stepwise process proposal:

> *"[…] Higher priority should be given to values in which the evidence has been evaluated through a systematic review."*

This is a principle that ensures that higher data quality values are given priority. The EU would like to receive clarification about how this principle has been applied and notes that if this principle was omitted, a sentence of clarification should be introduced to acknowledge this.

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:

A. To be applied when DIRVs informed by relevant physiological evidence are available

DIRVs informed by relevant physiological evidence from the target group are selected to establish NRVs-R for persons aged 6~~–36~~ **12 months and 12-36 months**. In cases where this includes the FAO/WHO DIRV, this is selected for the establishment of NRVs-R for persons aged 6~~–36~~ **12 months and 12-36 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~~ **12 months and 12-36 months**. **In the absence of DIRVs informed by relevant physiological evidence, go to Step 3 B.**

B. To be applied when ~~there are no~~ DIRVs informed by relevant ~~physiological evidence~~ extrapolation from other age groups are available

DIRVs informed by extrapolation of DIRVs from other age groups are selected to establish NRVs-R for persons aged 6~~–36~~ **12 months and 12-36 months**. Suitable DIRVs are selected by considering how the original DIRVs established for these other age groups are derived.

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~~ **12 months and 12-36 months**.

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~~ **12 months and 12-36 months**.

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~~ **12 months and 12-36 months**.

C. To be applied when there are no DIRVs informed by either relevant physiological evidence or extrapolation from other age groups available

DIRVs informed by estimates of nutrient intake from the target group or interpolation, are selected to establish NRVs-R for persons aged 6~~–36~~ **12 months and 12-36 months**.

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~~ **12 months and 12-36 months**.

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~~ **12 months and 12-36 months**.

The EU supports for the proposed Approach 1 where "recent" is included in the application of the draft Stepwise Process to propose NRVs-R. Limiting the data to more recent publications is better aligned with the draft General Principles.

The EU reference to the abbreviation “DIRVs” to better align with the text in step 1 and 2. Furthermore, it is not clear what “along with existing data from FAO/WHO” refers to, therefore “data” should be replaced by “DIRVs”:

> *“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 **DIRVs**~~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:

> *“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 **also** be considered, with higher priority given to values where evidence has been evaluated by a systematic review.”*

The EU would like to receive clarification what “this assessment” in the sentence “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.” refers to. The EU considers that the original text in the draft General Principles is clearer. The EU understands that for the establishment NRVs, when deriving those from DIRVs coming from RASBs, the derivation of DIRVs from RASBs should be reviewed on a case-by-case basis, considering

- 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.

This means, values that have been established with a higher rigour of scientific methods, with better underlying data quality, with a higher strength of evidence used to establish these values and which involved the most recent independent review of the science should be given priority over other DIRVs from RASBs. The EU understands that the added step 4 might provide for consideration of all elements listed above.

The EU considers that the following sentence is not aligned with the draft General Principles, but contradicts them:

> *“DIRVs are selected based on the totality of this evidence as NRVs-R in the following priority order:”*

Taking the “rigor of scientific methods” as the only determining factor, here by determining the priority, to select among the DIRVs from RASBs to derive NRVs from contradicts the draft General Principles and rephrased text in the stepwise process “shall take into account the following elements: the rigour of scientific methods, the underlying data quality, the strength of evidence used to establish these values and the most recent independent review of the science.” The EU considers that always a case-by-case assessment is applied allowing for further scrutiny and some refinements when needed, e.g. when DIRVs vary broadly across RASBs

(indicating large uncertainties regarding actual requirement or adequate intake) and/or when there are safety concerns. However, if the newly introduced step 4 is maintained, the concerns of the EU are addressed, and step 3 is generally supported by the EU, while the text in step 3 should refer to step 4 to clarify that art of the criteria from the draft General Principles listed in step 3 are accounted for in step 4.

The EU does not support the following principle in step 3:

> *"In cases where this includes the FAO/WHO DIRV, this is selected for the establishment of NRVs-R for persons aged 12 months and 12-36 months.".*

The EU understands that the stepwise process is terminated in case new or updated daily intake reference values (DIRVs) from FAO/WHO for older infants and young children are identified and is then selected for establishing NRVs-R. Step 2 only starts, in case the DIRVs from FAO/WHO are not considered to be sufficient to establish NRVs. Therefore, older DIRVs from FAO/WHO that were deemed to be not appropriate to set NRVs in a previous step should not be automatically used to derive NRVs. Despite the approach from FAO/WHO being informed by physiological evidence at the time, this may today be scientifically outdated.

Regarding the calculation of one NRV-Rs value from several values from the different RASBs, the EU considers that the calculation of the median is not the appropriate mathematical tool, but the mean value would be appropriate. Even if one DIRV is clearly higher or lower than other DIRV values, it cannot be assumed that this differing value is of a lesser quality and should therefore be less considered. Only rigour of scientific methods; the underlying data quality; the strength of evidence used to establish these values; the most recent independent review of the science is mentioned in the draft General Principles as criteria that shall be considered, not whether a DIRV is differing from others or not.

Step 4

All proposed NRV-Rs established in Step 3, are reviewed on a case-by-case basis. Proposed NRVs-R for all nutrients for persons 6-12 months and 12-36 months are checked considering scientific rigor of the methods, underlying data and data quality, and all available evidence. If necessary, proposed NRVs-R are amended/adjusted.

The EU strongly supports the introduction of step 4, however, would like to receive some clarification about the meaning of *"all available evidence".* The EU understands that this would allow for additional relevant evidence, in particular more and most recent evidence to be considered in order to revise, if needed, the outcome of step 3. The EU understands that in this step, a case-by-case assessment of all NRV-Rs established in step 3 is performed, looking again at the derivation of values from recognized authoritative scientific bodies, taking into account the rigour of scientific methods, the underlying data quality, the strength of evidence used to establish these values and the most recent independent review of the science. The EU considers that this should not be limited to the specific cases as outlined in CRD6, but go beyond, in cases were issues with the values derived from step 3 are identified. This step ensures that the text under 3.2 of the draft General Principles is considered in the stepwise process:

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

The EU does not fully understand why a lack of scientific data was evoked in part C. of CRD 6, leading to the conclusion that all available data would need to be used and that therefore Approach 2 would be more appropriate to establish the global NRVs-R as this approach takes account of all data on nutrient intakes.

The EU notes that sometimes RASBs do not have the needed data to derive an UL, however, there is clear scientific evidence of harm to health at higher intake levels. In such cases other values than an UL are established, e.g. Health Based Guidance Values (HBGVs) or safe levels of intake. In step 6 and in the draft General Principles, only "ULs" are mentioned. In order to ensure that the levels established are safe for the very vulnerable population group, also safety-based values other than UL should be taken into account. This could either happen at step 4 or 6. The EU strongly supports including this consideration into the stepwise process. to ensure safety.

Step 5

Estimate the NRVs-R for the combined 6–36month age group ~~according to the three options outlined below:~~

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

~~Option 2: The combined NRV-R value for persons aged 6–36 months should be determined by selecting the lower value of the proposed NRVs-R for older infants and young children.~~

~~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.**

~~The three optional NRVs-R for the combined age group (6–36 months) are considered relative to the NRVs-R established for the two age groups (6–12 months and 12–36 months) and any UL where available.~~

~~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.~~

See EU comments to recommendation 2.

Step 6

Consideration of ULs (where available) is given to ensure that the proposed NRVs-R do not exceed the lowest of the UL values available.

The EU supports this step 6. However, the latest reports from EFSA with regard to ULs should be considered (selenium, iron, manganese, vitamin A, B6, E, D, folate). While only ULs are mentioned in the draft General Principles, for some nutrients there is clear scientific evidence of harm to health at higher intake levels. However, data is not sufficient to calculate an UL. In such cases, RASBs may establish Health Based Guidance Values (HBGVs). The EU considers that it is important to also consider HBGVs to ensure safety for the vulnerable population group 6 to 36 months, either at step 4 or step 6. The EU notes that for some nutrients HBGVs are relevant, e.g. EFSA's ADI for phosphorus and copper.

Recommendation 4

a) The NRVs-R listed as 'Green Light' in Tables 1 and 2 in Appendix IV be adopted for Older Infants (6-12 months) and Young Children (12-36 months).

b) The combined NRVs-R for 6-36 months listed as 'Green light' in Tables 4a and 4b in Appendix IV be adopted

c) The NRVs-R listed as 'Amber Light' in Tables 3 and 4a and 4b in Appendix IV be carried forward for deeper review by an EWG

The EU proposes not to establish values for Calcium, Zinc and vitamin D, but to await the updated values from FAO/WHO and use those. Therefore, the EU does not provide comments for these 3 nutrients.

"green" list:

The EU agrees to keep the following nutrients in the "green" list and place the other nutrients in the "amber" list:

- Vitamin A
- Thiamine
- Riboflavin
- Vitamin B6
  However, before agreeing the Vitamin B6 value, the EU considers that at step 6, the latest report from EFSA with regard to ULs should be considered.
- Niacin
- Pantothenic acid
- Iodine
- Copper
  However, before agreeing the Copper value, the EU considers that at step 6, the latest report from EFSA with regard to an ADI (Health Based Guidance Value) should be considered.

With regard to protein, the EU considers that this value has been included in the exercise very recently and would like to have additional time to consider the derivation process for the protein value. Therefore, the EU proposes to add protein to the "amber" list.

“amber list”

The EU has specific comments for values that should be, among others proposed, be grouped to the “amber” list:

- Vitamin E

NRV-Rs are expressed in mg. Different activities for various tocopherols have been considered across the evaluations from FAO/WHO and RASBs. The EU notes that most recent evidence has questioned the activity of β-tocopherol, γ-tocopherol, δ-tocopherol. In its assessment of 2015, EFSA concluded that α-tocopherol is the only bioactive form of the vitamin and set an AI for α-tocopherol only.

Also, the EU notes that the latest UL reports from EFSA for vitamin E should be considered.

Therefore, the EWG should clarify these aspects for CCNFSDU 45.

The EU notes that the Guidelines on Nutrition Labelling (CXG 2-1985) are not clear in relation to the activity of different tocopherols as the NRV-Rs refers to “vitamin E” and conversion factors specific for α-tocopherol are then provided.

- Iron

The EU would like to clarify in some additional text a definition of what the type of 10% and 15% absorption are related to. In the Guidelines on Nutrition Labelling (CXG 2-1985), it has been clarified that 15% absorption refers to a mixed diet and a 10% absorption refers to a cereal based diet.

Furthermore, the EU considers that the application of step 3a is reconsidered, as more recent assessments, including by EFSA, concluded on higher values, possibly because of additional data to estimate growth requirement and basal losses. Either the application of step 3a and the underlying RASBs data, or consideration under the additional step 4 should be reconsidered.

Also, the EU notes that the latest UL reports from EFSA for iron should be considered.

Therefore, the EWG should clarify these aspects for CCNFSDU 45.

- Magnesium

The EU considers that in the light of most recent RASBs assessments, including by EFSA, these values seem low. Further scrutiny in step 3 considering the RASBs values included and/or into the “underlying data quality” and “strength of evidence” under step 4 should be carried out. Therefore, the EWG should clarify these aspects for CCNFSDU 45.

- Vitamin B12

The EU considers that in the light of most recent RASBs assessment, including by EFSA, the values for approach 2 older infants 6 to 12 months and approach 1 and 2 young children 12 to 36 months seem low. Furthermore, setting a lower NRV-R for young children vs older infants in approach 1 is an anomaly that has no scientific basis. Further scrutiny in step 3 considering the RASBs values included and/or into the “underlying data quality” and “strength of evidence” under step 4 should be carried out. Therefore, the EWG should clarify these aspects for CCNFSDU 45.

- Vitamin C

Setting a lower NRV-R for young children vs older infants in approach 2 is an anomaly with no scientific basis. Further scrutiny in step 3 considering the RASBs values included and/or into the “underlying data quality” and “strength of evidence” under step 4 should be carried out. Therefore, the EWG should clarify these aspects for CCNFSDU 45.

- Vitamin K

Vitamin K is present in foods as phylloquinone and menaquinones. The Guidelines on Nutrition Labelling (CXG 2-1985) are not clear in relation to reference to phylloquinone and/or menaquinones and define a NRV-R for “vitamin K” without further specification . In 2017, EFSA concluded that data were insufficient to conclude on a reference value for menaquinones. The EFSA AI proposed refers to phylloquinone only. The EU would like

to receive clarification about the value proposed and if the value is not limited to phylloquinone only, the EU proposes to discuss and resolve this issue. Therefore, the EWG should clarify these aspects for CCNFSDU 45.

- Folate

The term "DFE" needs to be defined. The Guidelines on Nutrition Labelling (CXG 2-1985) provide the following conversion factors: 1 µg dietary folate equivalents (DFE)= 1 µg food folate = 0.6 µg folic acid added to food or as supplement consumed with food = 0.5 µg folic acid as supplement taken on an empty stomach. However, the EU considers that there is no indication that conversion might be different in infants/young children in the text, while the EU considers that the conversion might be different.

Furthermore, in the light of most recent RASBs assessment, including by EFSA, the value of approach 2 for young children 21 to 36 months seems high. Further scrutiny in step 3 considering the RASBs values included and/or into the "underlying data quality" and "strength of evidence" under step 4 should be carried out, also in view of potential safety concerns associated with high exposure to folate (although concerns are restricted to supplemental folate, i.e. added to food).

Also, the EU notes that the latest UL reports from EFSA for folate should be considered.

Therefore, the EWG should clarify these aspects for CCNFSDU 45.

- Manganese

Values derived by various RASBs using various scaling methods are substantially different, by a factor of 3. This wide range reflects the substantial uncertainty regarding an adequate intake for manganese. Considering particularly the value of approach 1 for young children 12 to 36 months, the value differs substantially. Further scrutiny in step 3 considering the RASBs values included and/or into the "underlying data quality" and "strength of evidence" under step 4 should be carried out.

Further scrutiny is need ed also in view of potential safety concerns associated with high exposure to manganese. The EU notes that the latest UL reports from EFSA for manganese should be considered.

Therefore, the EWG should clarify these aspects for CCNFSDU 45.

- Phosphorus

The EU notes that the value for approach 2 for young children, 12 to 36 months (460 mg), is in the range of the ADI(Health Based Guidance Value) set by the EFSA ANS Panel for phosphates expressed as phosphorus of 40 mg/kg body weight per day. This corresponds to 344 mg/d for a 8.6kg infant and 476 mg/d for a 11.9kg young child. The EU considers that further scrutiny is needed in view of potential safety concerns associated with high exposure to phosphorus. Further scrutiny in step 3 considering the RASBs values included and/or into the "underlying data quality" and "strength of evidence" under step 4 as well scrutiny in step 6 should be carried out.

Therefore, the EWG should clarify these aspects for CCNFSDU 45.

- Selenium

The EU notes that the latest reports from EFSA for selenium on a Health Based Guidance Value is relevant and should be considered.

Therefore, the EWG should clarify these aspects for CCNFSDU 45.

Recommendation 5
The tables in the 2021 FAO Report (updated with new NCM DIRVs) will be updated further with the new NIHN data. This requires further information from NIHN on the derivation of the new values.

The EU has no comments and awaits further information from NIHN.