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Agenda Item 4a **CX/NFSDU 11/33/5**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NONCOMMUNICABLE DISEASES FOR THE GENERAL POPULATION

(Comments at Step 3 at the procedure)

Comments from:

- ARGENTINA
- AUSTRALIA
- COSTA RICA
- EUROPEAN UNION
- MALAYSIA
- MEXICO
- UNITED STATES OF AMERICA

ARGENTINA

Argentina appreciates the opportunity to make the following comments below:

2 DEFINITION(S)

2.1 Nutrient Reference Values – Noncommunicable Diseases (NRVs-NCD) refer to Codex nutrient reference values for food labelling purposes for nutrients that are associated with risk of diet-related ~~**chronic**~~ noncommunicable diseases not including nutrient deficiency diseases or disorders.

We consider that the term "chronic"should be eliminated from the definition, taking into account the terms used in the WHO Global Strategy on Diet, Physical Activity and Health.

[2.3 Upper Level of Intake (UL) is the maximum level of ~~**habitual**~~ intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.]

Con respecto a este punto Argentina opina que el término "habitual" es confuse, hay que ser cuidadoso con esta definición y tener en cuenta que no es la ingesta habitual sino la ingesta; que esta comprobada; que produce efectos adversos.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 Criteria for Selection of Nutrients

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

- Convincing/ Generally ***Accepted [or Probable]*** and relevant scientific evidence for the nutrient non communicable disease risk relationship.

Argentina considers that the criteria to be taken into account for the selection of nutrients for establishing NRV-NCDs should be relevant, available and with evidence which has been scientifically evaluated. On the other hand, the term "probable" has a different meaning from "acceptable", they are not synonyms, as the criteria do not demonstrate the relevant, available and acceptable character of the data. According to the Cambridge Dictionary:

Probable: likely to be true or likely to happen

Accepted: generally agreed to be satisfactory or right

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.2 Selection of Suitable Data Sources to Establish NRVs-NCD

3.3 Selection of Appropriate Basis for Determining and Expressing NRVs-NCD

We observe a typing error in paragraphs 3.3.2 and 3.3.3, in the English version the final figures of 2 and 3 respectively are omitted from the paragraphs in reference.

3.3.5

Governments may use a Codex NRV-NCD based on the reference energy intake of 2000 kilocalories/ 8370 kilojoules, or may derive their own reference values for nutrition labelling based on another reference energy intake that considers factors specific to their country or region.

Argentina is of the opinion that the paragraph before point 3.3.5 should be deleted as its is implicit in what is mentioned in the preamble of the document.

AUSTRALIA

Australia wishes to provide the following comments with regard to the Proposed Draft Annex to the Codex Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Noncommunicable Diseases for the General Population.

Specific Comments

1 Preamble

Australia notes that the Committee previously considered amending the wording of the third sentence to be consistent with the companion version, Principles for Establishing NRVs for Vitamins and Minerals. However, we support the current text for the time being i.e. "A government **may choose** to use the NRVs-NCD..." while we await the outcome of discussions on section 3.1 and the list of agreed NRVs-NCD.

2 Definitions

2.1 We suggest the word **chronic** be deleted as it was always an alternative to **noncommunicable***;* and not an additional descriptor. The inclusion of **chronic** also implies differentiation from diet-related **non-chronic** noncommunicable diseases that are not deficiency diseases, if there is such a classification.

The text should therefore read:

> ....risk of diet-related ~~chronic~~ noncommunicable diseases not including nutrient deficiency diseases or disorders.

3 General Principles

3.1 Criteria for selection of nutrients

a) As a principle, Australia considers that nutrition labelling should support nutrition policy. Where reference values for nutrients of public health importance (i.e. included in nutrition policy) are established on less than convincing evidence, labelling should also adopt those values since they are based on the best available evidence. We consider that Codex should provide international guidance to members on as many NRVs-NCD of public health importance as can meet an acceptable level of evidence. Given that the last session of the CCNFSDU was informed that not all nutrient-disease relationships for the nutrients under consideration would meet a Convincing/Generally Accepted level of evidence, Australia supports deletion of the square brackets around **or Probable** so as to include this alternative.

We agree with WHO recorded in paragraph 100 of REP11/NFSDU that the difference between *Convincing* and *Probable* still provides a basis for label declarations that would not mislead consumers.

We also suggest the dot point in Section 3.1 be slightly reworded to:

- delete the text **and relevant** as it is redundant in the context
- include 'strength of' which is the term used in WHO (2003) *Diet, nutrition and the prevention of chronic disease* TRS 916,
- allow for more than one disease risk relationship to contribute to the evidence base
- insert **that underpin the NRV-NCD** to add clarification.

The text would then read:

> - A Convincing/Generally Accepted or Probable ~~and relevant~~ **strength of** scientific evidence for the nutrient–noncommunicable disease risk relationship**(s) that underpin the NRV-NCD**.

b) We also wish to raise the order of the two dot points in Section 3.1 and suggest that the order be reversed such that the more conceptual should precede the more technical i.e. public health importance should precede the strength of evidence.

3.3 Selection of Appropriate basis for determining and expressing NRVs-NDC

3.3.4 Australia considers that the population-group basis of the daily intake reference value for NRVs-NCD should follow as closely as possible those in support of NRVs for vitamins and minerals. We therefore suggest that the second mention of **general population** in Paragraph 3.3.4 could be misinterpreted to mean population-weighted values as mentioned in Paragraph 2 of the Preamble for only national consideration. We acknowledge that some NRVs-NCD such as the Australian Acceptable Macronutrient Distribution

Ranges are established from teenage years onwards, and that 'adult' is not strictly correct in this context. We suggest the following revision of Paragraph 3.3.4, noting the replacement of 'gender' by 'sex' to be consistent with paragraph 2 of the Preamble:

> 3.3.4 An NRV-NCD for the general population should be determined from the daily intake reference value for the ~~general~~ **adult or broader** population ~~or adults,~~ or if given by ~~gender~~ **sex**, the mean of adult males and adult females.

3.4 Upper level of intake. Australia queries the reference to a UL in the context of NRVs-NCD? Unlike vitamins and minerals, many macronutrient daily intake reference values in national references are not given according to fine age-sex groupings across the lifespan to allow for a comparison of a mean adult (or broader population grouping) NRV-NCD with a UL (or upper bound of a percentage energy range) for a young age group such as 4-8 years; sodium is the exception in Australia. More consideration of what is intended by inclusion of UL in the Principles is needed.

General Comments

Australia considers that the Principles need to allow for the NRV for protein to be established on the basis of its INL_{98} rather than percentage dietary energy.

A decision on the basis for a protein NRV should precede any consideration of the percentages of energy from fat and carbohydrate given that protein also contributes to dietary energy and that the sum of energy from protein, carbohydrate and fat, should total 100%.

COSTA RICA

Costa Rica appreciates the opportunity of sending preliminary comments on the referenced document. and thanks the United States, Thailand and Chile for drafting the document that was analised in the 32nd meeting of CCNFSDU.

(1) General comments

1. In definition 2.1, the word "chronic" was added; however the change is not reflected in the title or in the rest of the document. We consider that it is necessary to add "chronic" every time that "non communicable diseases" are mentioned in order to ensure consistency throughout the document.

2. In section 3.1 Criteria for selection of nutrients, we would agree to retain "probable" evidence, placing the corresponding definition in section 2, according to the concepts put forward by WHO in the 32nd Session of the Committee (CRD 26). Similarly we consider it is necessary to add the concept of "convincing" in the section on definitions. Introducing both concepts without their respective definitions may lead to wrong interpretations and errors in the application of principles and criteria to establish NRVs.

(II) Specific comments

1. In the Preamble it is suggested to apply the amendments that were made to the second paragraph of the Preamble of the draft Annex to the Codex Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population (at Step 8) and therefore the last sentence of the first paragraph of the Preamble would read: "Governments are encouraged to use the NRVs-NCD although alternatively, they may consider the suitability of the general principles below."

2. In section 3.3, we suggest adding to the last paragraph of point 3.3.5 a sentence recommending to specify in the labelling the reference energy intake that is used in the corresponding country or region so that the consumer should have a clear reference and would be able to make an informed choice and therefore the second paragraph would read:

3.3.5 Governments may use a Codex NRV-NCD based on the reference energy intake of 2000 kilocalories/8370 kilojoules, or may derive their own reference values for nutrition labelling based on another reference energy intake that considers factors specific to their country or region. **In this latter case, the energy intake used should be specified in the labelling**."

EUROPEAN UNION

The EU has the following comments on REP11/NFSDU Appendix IV.

SECTION 2. DEFINITION(S)

2.3 Upper Level of Intake (UL) - The EU is not convinced that there is a need to include a definition of upper level of intake in the document. The EU does not support the inclusion of section 3.4 in the document and considers that the inclusion of the definition is not necessary.

SECTION 3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 Criteria for Selection of Nutrients

First point - the EU believes that the evidence should be "Convincing/generally accepted". The EU does not agree to the inclusion of "or probable" as this would create a different basis of the strength of the scientific evidence as compared to the approach for health claims and could potentially undermine the strength of evidence required within the Guidelines for the Use of Nutrition and Health Claims (CAC/GL 23-1997).

3.4. Consideration of Daily Intake Values for Upper Levels

The EU considers that the question of defining an upper level of intake can be complex for macronutrients and, in general, it is not possible to identify a quantitative value. The EU is not convinced that there is a need to add principles related to upper levels of intake in the case of NRVs-NCD.

MALAYSIA

In the third sentence of the Preamble, Malaysia suggests to replace the sentence “A government may select to use the NRVs-NCD….” with “Governments are encouraged to use the NRVs-NCD….”. This is to be in line with the proposed Draft Annex to the Codex Guideline on Nutrition Labelling; General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Populations.

Under the first bullet of item 3.1; Criteria for Selection of Nutrients, Malaysia supports the use of the term “convincing” and proposes to delete the term “probable”. We are of the view that public health action should only be given by convincing evidence that is fully substantiated. For this purpose, Malaysia would also like to propose that priority should be given to the nutrient that have scientific data and have serious impact on health.

Under item 3.4; Consideration of Daily Intake Values for Upper Levels, Malaysia would like to reiterate our previous comments that we do not support the proposal to include terms related to upper levels of intake. We are of the view that the scientific data to establish the upper levels for many of these “nutrients” associated with NCDs are not sufficient or inconclusive at this time, with the possible exception of trans-fatty acids. In addition, it can be noted that the “*Interim Summary of Conclusions and Dietary Recommendations on Total Fat and Fatty Acids”* reported that full agreement among the experts regarding the U-AMDR for %E was not achieved.

MEXICO

APPENDIX IV "Proposed Draft Annex to the Codex Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Noncommunicable Diseases for the General Population"(at Step 3)

GENERAL COMMENTS:

During the last meeting of the CCNFSDU held in Santiago de Chile.

Mexico makes the following comments and submits them to the Committee for consideration

SPECIFIC COMMENTS:

The document reads:	**Comments and amendments:**
2. DEFINITION(S) [2.3 Upper Level of Intake (UL) is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.]	***Mexico agrees to retain this definition, only for reference for the establishment of the reference values. It is suggested to delete the brackets.***
3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD **3.1 Criteria for Selection of Nutrients** The following criteria should be considered in the selection of nutrients for the establishment of NRVs- NCD: • Convincing/Generally Accepted[3] [or Probable] and relevant scientific evidence for the nutrient noncommunicable disease risk relationship. • Public health importance of the nutrient-noncommunicable disease risk relationship among Codex member countries [3] For these General Principles these terms are considered synonymous.	***Mexico considers that it is important to have convincing information to establish NRVs but unfortunately the information necessary to establish NRVs is not always available or does note exist and therefore we consider that the concept of "generally accepted" is better.*** .
[3.4 Consideration of Daily Intake Values for Upper Levels The establishment of general population NRVs-NCDs should take into account daily intake reference values for upper levels established by recognized authoritative scientific bodies where applicable (e.g., Upper Level of Intake).]	***Mexico agrees to use the ULs as reference for the establishment of NRVs.***

UNITED STATES OF AMERICA

I. GENERAL COMMENTS

The United States of America (U.S.) is pleased to submit preliminary comments in response to CL 2010/53-NFSDU, Part B, on the Proposed Draft Annex to the Codex Guidelines on Nutrition Labelling: General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Noncommunicable Diseases for the General Population (at Step 3) (REP11/NFSDU Appendix IV). We anticipate providing additional comments as a member of the electronic working group on this agenda item.

The U.S. commends the Committee on the substantial progress made on these draft general principles that will guide the Committee in proposing NRVs-NCD.

Our comments address the text left in brackets in Sections 2.3, 3.1 (bullet 1), and 3.4, and include a couple of additional comments for the Committee's consideration.

II. SPECIFIC COMMENTS

1. PREAMBLE

The U.S. proposes the following edits to the preamble for consistency with the language agreed on by the Committee at the last session for the vitamin and mineral NRV draft principles:

"~~A government may~~ **Governments are encouraged** ~~choose~~ to use the NRVs-NCD…."

2. DEFINITION(S)

[2.3 Upper Level of Intake (UL) is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.]

Comment:

The U.S. supports removing the square brackets and retaining the above Codex definition of Upper Level of Intake (UL) in these general principles. The U.S. notes that the Codex definition of "Upper Level of Intake" is included in the draft general principles for vitamin and mineral NRVs at Step 8, and relates to its reference in a principle about consideration of Upper Levels of Intake established by recognized authoritative scientific bodies. As with the vitamin and mineral NRVs, we believe the establishment of general population NRVs-NCD should take into account Upper Levels of Intake and other daily intake values for upper levels that are established by recognized authoritative scientific bodies, where applicable. Consequently, we support retaining the principle on "Consideration of Daily Intake Values for Upper Levels" in Section 3.4 and retaining the reference to Upper Level of Intake as an example. We believe the Codex definition of Upper Level of Intake is applicable to consideration of NRVs-NCD for certain nutrients such as sodium. For example, the Institute of Medicine of the National Academies of science has established recent (2004) and relevant Tolerable Upper Intake Levels (UL) for sodium using a comparable definition to the Codex UL which was based on an independent review of the scientific evidence (http://www.iom.edu/Activities/Nutrition/DRIElectrolytes.aspx).

In addition, the U.S. notes additional proposals at the last session to consider other intake reference values such as the Acceptable Macronutrient Distribution Range or Upper Level of Acceptable Macronutrient Distribution Range. We agree that there should be further discussion of their applicability to the general principles and establishment of NRVs-NCD.

3.1 Criteria for Selection of Nutrients

(First Bullet) Convincing/Generally Accepted[3] [or Probable] and relevant scientific evidence for the nutrient-noncommunicable disease risk relationship.

[3] For these General Principles these terms are considered synonymous.

Comment:

The U.S. believes that only convincing scientific evidence should be used as a basis for establishing Codex NRVs-NCD, and supports the removal of "probable" in brackets. We agree with the delegations that commented at the last session that the highest level of scientific evidence should be required in the framework of Codex and that the criteria for "probable" (that is used in the joint

FAO/WHO expert consultations that are available for reference in this work) are not strong enough (REP11/NFSDU, para 101). Specifically, the following criteria were used for "probable" evidence in: 1) the 2002 Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases (WHO TRS 916, Geneva 2003), and 2) the 2008 Joint WHO/FAO Expert Consultation on Fats and Fatty Acids in Human Nutrition:

> "Probable" evidence:
>
> "Evidence is based on epidemiological studies showing fairly consistent associations between exposure and disease, but where there are perceived shortcomings in the available evidence or some evidence to the contrary, precluding a more definite judgement. Shortcomings in the evidence may be any of the following: insufficient duration of trials (or studies) insufficient trials (or studies) available; inadequate sample sizes; and incomplete follow-up. Laboratory evidence is usually supportive. Again, the associations should be plausible."

The above highlighted text illustrates why the U.S. supports convincing scientific evidence for a Codex NRV-NCD. We do not support proposals for NRVs-NCD in which a more definite judgment is precluded because of shortcomings in the available evidence and some evidence to the contrary.

The U.S. further notes that if some Codex member governments have an interest in providing additional food label reference values for nutrients in which the strength of the scientific evidence is not "convincing" but "probable", that the preamble to the draft general principles for the NRVs-NCD provides flexibility to governments to establish their own food label reference values. In addition, although the work approved by the Commission to establish NRVs for nutrients associated with risk of diet-related noncommunicable diseases requires an assessment of the strength of the scientific evidence for a nutrient-disease relationship, there are alternative bases that governments can consider for establishing food label reference values for nutrients (e.g., nutrient requirements, macronutrient balance).

3.2 Selection of Suitable Data Sources to Establish NRVs-NCD

3.2.1 Relevant and recent daily intake values provided by FAO/WHO [**based on a review of the science]** should be taken into consideration as primary sources in establishing NRVs-NCD.

Comment:

The U.S. proposes the new bolded text in brackets for the Committee's consideration. We note that the first sentence in 3.2.2 states that "Relevant and recent values that reflect independent *review of the science*, from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration." The U.S. believes it is also important to clarify in 3.2.1 that the daily intake values provided by FAO/WHO should be based on a relevant and recent review of the science (which could be an independent review of all scientific evidence, or alternatively, a review of the scientific evidence from recent and relevant independent reviews conducted by other recognized authoritative scientific bodies).

[3.4 Consideration of Daily Intake Values for Upper Levels

The establishment of general population NRVs-NCDs should take into account daily intake reference values for upper levels established by recognized authoritative scientific bodies where applicable (e.g., Upper Level of Intake).]

Comment:

As previously noted, the U.S. supports including this principle (and removing the brackets). In addition, we noted the need to further consider the applicability of other daily intake values such as the Upper Level of Acceptable Macronutrient Distribution Range to these general principles and to the establishment of NRVs-NCD.

The U.S. appreciates the opportunity to provide these preliminary comments, and looks forward to progress on this agenda item this year.