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Agenda Item 4a

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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**GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR
NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NON-COMMUNICABLE
DISEASES FOR GENERAL POPULATION (NRVs-NCD)**

(Comments at Step 3)

Comments from:

CANADA

KOREA, Republic of

NORWAY

PHILIPPINES

SOUTH AFRICA

UNITED STATES OF AMERICA

ICBA - International Council of Beverages Associations

CANADA

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II. GENERAL PRINCIPLES

IIA. PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NRVS-NCD FOR THE GENERAL POPULATION: BRACKETED TEXT IN FIRST BULLET OF SECTION 3.1

NRVs-NCD GP—Text Options for Strength of the Scientific Evidence

23. Based on the above comments, Section 3.1 has been revised in the proposed draft NRV-NCD general principles in Attachment B (and in the proposed draft consolidated Annex in Attachment C) to reflect option B1 wording. In addition to the acknowledgement in the Preamble that governments have flexibility to establish their own food label reference values, this proposed text explicitly acknowledges in a separate sentence in Section 3.1 that governments may also consider the suitability of “probable evidence” in conjunction with other bases in establishing their own reference values.

24. It may further be noted that if the Committee ultimately supports option B1 text, this does not preclude consideration of also adding the following option A2 text to the Preamble which would provide a more explicit reference to level of evidence:

“Governments are encouraged to use the NRVs-NCD, or alternatively, consider the suitability of the general principles below [including the level of evidence required] and additional factors specific to a country or region in establishing their own reference values.”

Accordingly, the Preamble in Attachment B (and Attachment C) has been revised to include the underlined text in brackets for the Committee’s further consideration.

The eWG members’ positions on options to address the strength of the evidence were split between three approaches (A, B and C), with A offering the least support for including probable evidence and C offering the most. Canada most preferred approach A and least preferred approach C. The current proposal, which adds a sentence to the first bullet text in Section 3.1 that explicitly acknowledges that governments may also consider the suitability of “probable evidence” in conjunction with other bases in establishing their own reference values, reflects approach B. Canada continues to prefer approach A over approach B; however, since approach B retains a requirement for “convincing evidence” in setting Codex NRVs-NCD, Canada could consider this option in the interest of reaching consensus and advancing the item.

To help ensure that governments understand that establishing NRVs-NCD based on other strengths of evidence is an option at the national level, Canada continues to support option A2, in which the Preamble refers more specifically to levels of evidence.

NRV-NCD General Principles (GP) – Proposal to Clarify Text in 3.1, 1st bullet

30. Given that the majority of comments supported consideration of the added text in paragraph 26, but with certain comments raising questions about its need or wording, the added text is included in brackets in Attachment B (and C) for the Committee’s further consideration

Canada supports the added text that explicitly states that the evidence for a nutrient-NCD risk relationship need only be “convincing/generally accepted” for a major segment of the general population, not necessarily the whole population.

NRV-NCD GP – Definition of “Convincing Evidence”

36. Given that the definition of “convincing evidence” could change in the future, it is proposed in Attachment B (and C) that a reference to only the source of the definition be provided in the general principles using the proposed wording in paragraph 32. The Committee may wish to further consider whether it would be sufficient to simply reference the TRS 916 report in this footnote. In addition, based on some eWG members’ preference to retain the full definition of “convincing evidence” in the Guidelines and one country’s proposal that it be placed in Section 3.4.4 to provide a link between specific NRV-NCD values and the actual definition used for these, the full definition (with source) is placed in brackets in proposed amendments to 3.4.4 in Attachment D for the Committee’s consideration.

To save space and because the definition could change, Canada supports the proposal that the general principles reference only the source of the definition for “convincing evidence”. Canada continues to support the proposal to include the full definition (and source) in Section 3.4.4 of the *Guidelines on Nutrition Labelling*. To support transparency, Canada prefers this approach over referencing only the source of the definition in both places.

Canada notes that in Attachment D, the NRV-NCD for saturated fatty acids (SFA) references the definition but the NRV-NCD for sodium does not. While this is in all likelihood a typo, Canada notes that it is important to link each NRV-NCD to the definition that was considered during its selection for consideration. If, in the future, a different definition is considered during the selection of a future NRV-NCD, an additional footnote will be needed. Therefore, Canada proposes that footnote ^{“42”} apply to both SFA and sodium, and footnote ^{“43”} only to SFA.

NRV-NCD GP – Definition of “Probable Evidence”

40. Based on the above considerations, it is proposed in Attachment B (and C) to reference only the source of the definition for “probable evidence” in the Annex on general principles. As with the definition of “convincing” evidence, the Committee may wish to consider whether it would be sufficient to simply reference the TRS 916 report in this footnote.

To save space and to be consistent with the footnote for the term “convincing evidence”, Canada supports the proposal to reference only source of the definition for “probable evidence” if it is included in the first bullet of Section 3.1.

IIB. PROPOSED DRAFT CONSOLIDATION OF THE TWO ANNEXES ON GENERAL PRINCIPLES FOR ESTABLISHING NRVS FOR THE GENERAL POPULATION

Consolidated GP – Support

48. The terms of reference for this eWG included preparing separate documents for: 1) revised proposed draft general principles for establishing NRVs-NCD (Attachment B), and 2) a proposed draft consolidation of the two Annexes (Attachment C). It is suggested that at the start of discussion of this agenda item at the next CCNFSDU session, the Committee decide whether it supports finalizing Attachment B or D. Given that most eWG comments supported consolidation, the recommendation from this report is that the Committee proceed in finalizing the draft consolidated Annex in Attachment D at its next session.

Canada supports the proposal to finalize the consolidated Annex in Attachment D.

Consolidated GP – Proposed Organization

60. Based on consideration of the above comments, the proposed draft consolidation of the Annexes in Attachment C retains the organization proposed in the eWG consultation paper, with the exception of Section 3.2. For this section, the headings and numbering were revised in accordance with the above suggestions by an eWG member for the Committee’s consideration.

Canada supports the organization of the consolidated Annexes in Attachment C.

Consolidated GP—New term: Nutrient Reference Values- Requirements (NRVs-R)

65. Based on the above comments and the need to distinguish between the two types of NRVs in proposed amendments to Section 3.4.4 of the Guidelines (as discussed later in this report), it appears necessary to have terminology, abbreviations and definitions to distinguish between the two NRV subtypes. One option is to define these NRV subtypes in the consolidated Annex. In addition, given that a few comments noted the need to take into consideration the definition of NRVs in Section 2 of the Guidelines, another option is to remove the definitions of the two NRV subtypes from the Annex on general principles and instead propose to CCFL that the definition of NRVs be revised to incorporate the complete definitions and abbreviations for NRVs-R and NRVs-NCD.

The two options are presented in Attachment C for the Committee's consideration. In addition, these options are presented in Attachment B, since this issue is also applicable to the NRV-NCD general principles.

Canada continues to support terminology, abbreviations and definitions to help distinguish between the two NRV subtypes. To help reduce potential confusion caused by including related definitions in different documents (i.e., definitions for NRVs and NRVs-R in Section 2 of the *Guidelines* and the definition for NRVs-NCD in the *General Principles*), Canada supports option 2 in Attachments B and C, which proposes moving the NRVs-NCD definition from the *General Principles* and proposing to CCFL that it be added to Section 2 of the *Guidelines*. Canada has no objections to the proposed edits identified in option 2.

Canada continues to believe that the phrase “to help consumers achieve overall healthful dietary intake” in the second introductory paragraph could be reworded to be more consistent with the following statement in the *Guidelines on Nutrition Labelling*: “The information should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product”. Canada suggests revising the proposed phrase to, “to help consumers make choices that contribute to an overall healthful dietary intake”.

Consolidated GP—Edits to Preamble

68. In the Attachment C Preamble, the term “nutrient” is proposed to be deleted in two places. In the last sentence of the Preamble, the phrase “such as pregnant and lactating women” is left in brackets for the Committee to discuss whether it is necessary to retain this example.

Canada supports the proposal to delete the term “nutrient” in two places in the Preamble of the consolidated *General Principles*, since it is not needed and removing it may help distinguish between food label values established by Codex and by national governments.

Canada agrees that the phrase “such as pregnant and lactating women” is not necessary in the consolidated *General Principles*. An example is not necessary.

III. NEED FOR ADDITIONAL NRVS-NCD

Assessment of Evidence – FAO and/or WHO Data Sources

76. The two FAO/WHO reports, FNP 91 and TRS 916, are considered appropriate as an initial starting point for identifying nutrients with a convincing level of evidence.

77. The Committee may wish to request updates from the WHO and FAO at its next session on new procedures for obtaining joint FAO/WHO scientific advice on nutrition.

78. The Committee may wish to consider whether, and if so, how, the Committee could use information and/or recommendations from the WHO guidelines process. For example, it could be helpful to clarify whether it is possible with this process for the Committee to easily access scientific risk assessment results and recommendations based on systematic reviews of the scientific literature independent of WHO risk management advice which considers additional information, and to clarify how this process relates to Codex risk analysis principles.

Canada would support the points made in paragraph 78 to clarify whether it is possible to access risk assessment information based on systematic reviews of the scientific literature from the WHO guidelines process.

Canada would like again to note the concern that there is currently no common methodology or conceptual underpinning in place for applying nutrient risk assessment to situations where the increased risk of NCD in relation to increased intake of a nutrient has been identified as an adverse health effect with no apparent threshold of intake for NCD risk. There is a lack of a guiding framework to evaluate and draw conclusions from the available evidence in a way that permits consistent establishment of dietary intake reference values for upper levels related to this type of risk relationship. Canada believes that, before setting further NRVs-NCD for nutrients to be limited in the diet, the Committee should consider asking FAO/WHO to provide scientific advice on the appropriate method of derivation of dietary intake reference values for upper levels related to NCD risk in situations where there is no apparent threshold level of intake for NCD risk.

Assessment of Evidence – Recognized Authoritative Scientific Bodies

82. There was considerable eWG agreement that the IOM and EFSA are relevant to assessing whether nutrients have convincing evidence for NCD risk. However, the suitability of all proposed data sources and references as they relate to General Principle 3.2.2 was difficult to assess without defining “Recognized Authoritative Scientific Body”. Consequently, as with the Committee’s work on vitamin and mineral NRVs, it appears appropriate for the Committee to consider developing a working definition for RASB to assist in applying General Principle 3.2.2.

Canada supports work to develop a working definition for RASB to assist in applying General Principle 3.2.2. Canada notes that there is a definition for RASB being developed by the eWG for additional or revised NRVs and that it is important that the same definition apply wherever the term is used.

Global Public Health Importance of Additional Nutrients and their Prioritization

89. The eWG had mixed views on the global public health importance of additional nutrients assessed to have convincing evidence for NCD risk, and on whether consideration of additional NRVs-NCD should be limited to the nutrients in 3.2.1.2 of the Guidelines. The comments appear to support, however, the use of the 3.2.1.2 list and the WHO Global Strategy-DPAH as a means to prioritize additional nutrients for consideration of one or more additional NRVs-NCD.

Canada agrees that the list of nutrients in 3.2.1.2 of the *Guidelines* and the WHO Global Strategy – DPAH are appropriate means to prioritize additional nutrients. Canada notes that the WHO Global Strategy- DPAH includes a list of major NCDs that contribute to the global burden of disease; however, specific nutrients other than sodium, total fats, SFA, USFA, TFA, and total sugars are not identified. Globally relevant NCDs listed in the WHO Global Strategy-DPAH include CVD, type 2 diabetes, certain types of cancer, dental caries, and osteoporosis.

Canada continues to believe in principle that nutrients considered for NRVs-NCD should not necessarily be limited to those listed in Section 3.2.1.2 of the *Guidelines on Nutrition Labelling*. The nutrients listed in Section 3.2.1.2 do not necessarily include all of the convincing nutrient-NCD risk relationships that are of global public health importance. Canada notes that not being a nutrient that must always be declared has not restricted the establishment of NRVs for vitamins and minerals. Also, there are nutrients in the list that are not associated with NCDs.

Additional Considerations with Macronutrients

93. The eWG comments emphasize the need to consider the nature of the scientific evidence for specific macronutrients, and their prioritization for NRVs-NCD. Comments further raised the question of the appropriate balance between nutrient-based and food-based recommendations, and whether more NRVs-NCD for certain macronutrients could introduce redundancy and dilute key messages that focus on SFA. Some comments pointed to the need to consider whether a substitution needed for a beneficial effect would be highly likely.

Canada continues to support consideration of additional NRVs-NCD for macronutrients in which the main effect is based on substitution. Canada believes that the risks of redundancy, dilution and potential confusion

do not outweigh the importance of accurately reflecting the true nature of the nutrient-disease relationship. Labelling of an NRV-NCD for a macronutrient in which the main effect is based on substitution could help consumers choose foods that contribute to the desired effect.

Need for One or More Additional NRVs-NCD

100. Although some eWG members expressed interest in establishing an NRV-NCD for one or more additional nutrients, there was no widespread support to establish an additional NRV-NCD for any specific nutrient at this time.

While Canada continues to believe that there are compelling reasons for the Committee to consider establishing NRVs-NCD for linoleic acid, EPA and DHA, TFA, and potassium, we are comfortable waiting until there is wider support to do so.

IVA. POTENTIAL FOR MORE THAN ONE NRV FOR CERTAIN NUTRIENTS

Consideration of More than One Basis for an NRV for Certain Nutrients

109. At this time, there is no general agreement or apparent compelling reason to establish both an NRV based on requirements and an NRV based on NCD risk for any specific nutrient, including sodium. Although the need for two types of Codex NRVs for the same nutrient could be evaluated in the future on a case by case basis, governments also have the flexibility to establish their own food label reference values.

Consideration of Separate NRVs for Population Segments for Certain Nutrients

110. With regard to comments that suggested that separate NRVs be considered for certain nutrients to target different groups, this is outside the scope of this current work to establish NRVs-NCD for the general population. It is noted that the project document for new work to establish additional and revised vitamin and mineral NRVs for the general population anticipated the development of vitamin and mineral NRVs for individuals 6 to 36 months of age following completion of that work (ALINORM 03/31/26, Appendix VII). It may further be noted that a key consideration in establishing NRVs for labelling purposes for any population segment is the extent to which a population segment consumes the same or different products from the general population.

Canada is comfortable with the proposal to establish one NRV, based either on requirements or NRV risk for any specific nutrient.

IVB. AMENDMENTS TO SECTION 3.4.4 OF THE GUIDELINES ON NUTRITION LABELLING (CAC/GL 2-1985)

Listing of NRVs in 3.4.4 for Reference by Governments

125. Proposed amendments for the listing of NRVs in new 3.4.4.1 and new 3.4.4.2 are identified in Attachment D based on eWG comments.

Since the Committee has not proposed any NRVs-NCD for nutrients to increase, Canada can support the proposed amendments for the listing of NRVs in Attachment D, in which there is no indication of whether the NRV-NCD is for a nutrient intake that should be increased or one that should be decreased to impact NCD-risk. Canada notes that, to support clarity, such indication may need to be considered if nutrients that should be increased are selected for an NRV-NCD.

Presentation of NRVs in Nutrition Labelling for Reference by Consumers

127. Based on the above comment and the new type of NRV for nutrients associated with NCD risk, the Committee could consider asking the CCFL whether additional guidance is needed in 3.4.4 (or elsewhere in the Guidelines) to enhance consumer understanding of NRVs in nutrition labelling.

Canada supports asking CCFL whether additional guidance should be developed to help governments at the national enhance consumer understanding of NRVs in nutrition labelling.

IVC. INTEREST IN PROPOSING NEW WORK RELATED TO NRVS FOR PROTEIN, TOTAL FAT AND/OR AVAILABLE CARBOHYDRATE*eWG Support for New Work to Review the Protein NRV*

135. Given: 1) the protein NRV is based on recommendations at least 25 years old, 2) suitable scientific updates are available, and 3) current CCNFSDU work to review NRVs for other nutrients, it is recommended that the Committee consider undertaking new work to review the protein NRV to decide whether to revise the 50 g value. Accordingly, a draft project document for new work is provided in Attachment F for the Committee's consideration.

General Principles for Establishing a Protein NRV

137. There was general agreement that the general principles in the proposed consolidation of the two Annexes could apply to protein, with its draft wording that refers to NRVs that are based on levels of nutrients associated with nutrient requirements. If the Committee were to decide to retain two separate Annexes, the adopted Annex on general principles for establishing vitamin and mineral NRVs for the general population may need to be amended to encompass protein.

Suitable Data to Consider in Reviewing the Protein NRV

140. Relevant scientific updates on INL98 values for protein are available from WHO/FAO and other recognized authoritative scientific bodies that could be considered in potential new work.

Canada supports consideration of work to review the NRV for protein at this time.

eWG Support for New Work to Establish a Total Fat NRV

146. Some eWG members had an interest in establishing a Codex NRV for total fat. At this time, however, there does not appear to be sufficient evidence from a global public health perspective, nor a clear basis (and applicable general principles) upon which to derive a total fat NRV. Thus, the Committee may wish to consider if the establishment of total fat food label reference values at the national level may be more appropriate at this time.

eWG Support for New Work to Establish an NRV for Available Carbohydrate

Some eWG members had an interest in establishing a Codex NRV for available carbohydrate. At this time, however, there does not appear to be sufficient evidence from a global public health perspective, nor a clear basis (and applicable general principles) upon which to derive an NRV for available carbohydrate. Thus, the Committee may wish to consider if the establishment of food label reference values at the national level may be more appropriate at this time.

Canada agrees that there is not sufficient basis to establish a Codex NRV for total fat and available carbohydrate at this time.

KOREA, Republic of**Attachment B**

Note to CCNFSDU: Attachment B incorporates recommendations based on eWG comments for finalizing remaining bracketed text in the first bullet of Section 3.1, Appendix V in REP12/NFSDU. This bracketed text concerns the strength of the evidence for establishing Codex and government food label reference values, and related descriptors and definitions. In addition, two options are proposed for the placement of the NRVNCD definition (and related minor edits) based on eWG comments.

In this attachment, proposed new text is underlined text. Proposed deletions are identified by ~~strikeout~~.

1. PREAMBLE

These principles apply to the establishment of Codex Nutrient Reference Values for labelling purposes for nutrients associated with risk of diet-related noncommunicable diseases (NRVs-NCD) for the general population excluding pregnant and lactating women identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products. Governments are encouraged to use the NRVs-NCD, or alternatively, consider the suitability of the general principles below [including the level of evidence required,] and additional factors specific to a country or region in establishing their own reference values for labelling purposes, for nutrients associated with diet-related noncommunicable diseases.

For example, at the national level, population-weighted values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group. Governments may also consider whether to establish separate food label reference values for specific segments of the general population

2. DEFINITION(S)

[Option 1: Define NRV-NCD in Section 2 of the Annex on general principles as identified below:

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

Or

Option 2: Remove the NRVs-NCD definition from this Annex. Instead, propose to CCFL that the new definition of NRVs adopted by the Commission in 2012 for inclusion in Section 2 of the Guidelines be revised to incorporate the terminology, abbreviations, and complete definitions for Nutrient Reference Values-Noncommunicable Disease (NRVs-NCD) and Nutrient Reference Values-Requirements (NRVs-R). The proposed edits are identified below.

(new 2.4 in the Guidelines) Nutrient Reference Values (NRVs) are a set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims. They include the following two types of NRVs: ~~NRVs are based on levels of nutrients associated with nutrient requirements, or with the reduction in the risk of diet-related noncommunicable diseases.~~*

Nutrient Reference Values- Requirements (NRVs-R) refer to NRVs that are based on levels of nutrients associated with nutrient requirements.

Nutrient Reference Values - Noncommunicable Disease (NRVs-NCD) refer to NRVs that are based on levels of nutrients associated with the reduction in the risk of diet-related noncommunicable diseases not including nutrient deficiency diseases or disorders.

** See also the [Annex] [Annexes] for the General Principles for the Establishment of Nutrient Reference Values.*

2.# Daily Intake Reference Values as used in these principles refer to reference nutrient intake values provided by FAO/WHO or **other recognized authoritative scientific bodies (comment: It would be needed to concretely define “Recognized Authoritative Scientific Body” as a footnote. (e.g., for example, IOM, EFSA...)**

that may be considered in establishing an NRV-NCD based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g., as a single value or a range), and are applicable to the total population or to a segment of the population (e.g., recommendations for a specified age range).

2.# Upper Level of Intake (UL)³¹ 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.

2.# Acceptable Macronutrient Distribution Range (AMDR) is a range of intakes for a particular energy source that is associated with reduced risk of diet-related noncommunicable diseases while providing adequate intakes of essential nutrients. For macronutrients, they are generally expressed as a percentage of energy intake.

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:

Relevant convincing³²/ generally accepted³³ scientific evidence for the relationship between a nutrient and noncommunicable disease risk, including validated biomarkers for relevant disease risk

[, for at least one major segment of the population (e.g., adults).] In addition, governments may consider the suitability of probable evidence³⁴ in conjunction with other bases in establishing their own food label reference value(s).

Public health importance of the nutrient-noncommunicable disease risk relationship(s) among Codex member countries.

3.2 Selection of Suitable Data Sources to Establish NRVs-NCD

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

3.2.2 Relevant daily intake reference values that reflect recent independent review of the science, from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration. Higher priority should be given to values in which the evidence has been evaluated through a systematic review.

3.2.3 The daily intake reference values should reflect intake recommendations for the general population.

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

3.3.1 Relevant and peer-reviewed scientific evidence for quantitative reference values for daily intake should be available in order to determine an NRV-NCD that is applicable to the general population.

3.3.2 Daily intake reference values from FAO/WHO or other recognized authoritative scientific bodies that may be considered for NRVs-NCD include values expressed in absolute amounts or as a percentage of energy intake.

3.3.3 For practical application in nutrition labelling, a single NRV-NCD for the general population should be established for each nutrient that meets the principles and criteria in this Annex.

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

3.3.5 Where a daily intake reference value is based on a percentage energy intake, the single NRVNCD should be expressed in grams or milligrams based on a reference intake for the general population of 8370 kilojoules/2000 kilocalories.

Governments may use a Codex NRV-NCD based on the reference energy intake of 8370 kilojoules/2000 kilocalories, 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.

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 FAO/WHO or other recognized scientific authoritative bodies where applicable (e.g., Upper Level of Intake, Acceptable Macronutrient Distribution Range).

NORWAY

Norway is pleased to provide comments to the proposed draft general principles for establishing nutrient reference values for nutrients associated with risk of diet-related noncommunicable diseases for the general population.

We would like to comment on section 3.1 GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD stating the strength of evidence required to set an NRV-NCD presented in attachment B of CX/NFSDU 12/34/5.

SECTION 3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 Criteria for Selection of Nutrients

With the intention to give consumers the possibility to estimate the relative contribution of individual products to overall healthful dietary intake, we regard the NRVs-NCD to be a tool in public health work. We are of the opinion that Codex should provide international guidance to members on NRVs-NCD of public health importance which meet an acceptable level of evidence.

Norway also considers that *convincing and probable evidence* are sufficiently strong to support a judgment in relation to a causal relationship and to provide a basis for label declarations that would not mislead. We believe that it is important to include “*probable evidence*” for possible future evidence, showing a causal relationship between nutrients and NCDs.

The text for discussion in section 3.1 in CX/NFSDU 12/34/5 refers to both terms; “*probable*” and “*convincing*”, reflected in option B1, Attachment A. When both terms are quoted in the document, we find it essential that members of the committee have a common understanding of the content and meaning of the terms “*probable*” and “*convincing*”. Hence, we find it essential to refer to the definitions of both terms in the Codex *Guidelines on Nutrition Labelling* (CAC/GL 2-1985). This is especially important to meet the concern expressed that the strength of evidence required to set an NRV-NCD can influence the requirement of scientific substantiation of health claims.

Therefore, we support the wording of the definition and the footnote of “*probable evidence*” in paragraph 38 in CX/NFSDU 12/34/5, where this is highlighted as following in the last sentence; “*This definition is not applicable to Codex recommendations on the scientific substantiation of health claims (Annex, CAC/GL 23-1997)*”.

PHILIPPINES

POSITION

The Philippines expresses its thanks to the electronic working group chaired by the United States of America and co-chaired by Thailand and Chile for the progress made in the proposed draft.

The Philippines supports the retention of the new underlined text in brackets in the statement “Governments are encouraged to use the NRVs-NCD, or alternatively, consider the suitability of the general principles below [including the level of evidence required,] and additional factors specific to a country or region in establishing their own reference values for labelling purposes, for nutrients associated with diet-related non-communicable diseases.” in the Preamble only.

We find the proposed separate definitions for Nutrient Reference Values-Requirements (NRV-R) and Nutrient Reference Values-Non Communicable Diseases (NRV-NCD) more acceptable.

In the General Principles 3.1 Criteria for Selection of Nutrients, we also support retention of the bracketed text “Relevant convincing generally accepted scientific evidence for the relationship between a nutrient and non-communicable disease risk, including validated biomarkers for relevant disease risk [for at least one major segment of the population (e.g., adults).]”

RATIONALE

The Philippines reiterates its previous position of supporting the use of convincing/generally accepted scientific evidence as the sole basis for establishing Codex nutrient reference values for nutrients associated with diet related non-communicable diseases. The use of scientific evidence as having sufficient strength to allow formulation of dietary recommendations was contained in 2008 FAO/WHO Expert Consultation of Fats and Fatty Acids and 2002 FAO/WHO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases. In retaining the bracketed text [including the level of evidence required] in the Preamble, we are of the opinion that this would give enough flexibility to national government to consider the level of evidence other than convincing/generally accepted evidence in establishing NRV-NCD. However, we believe that the bracketed text in the Preamble is sufficient without specifying consideration of probable evidence in *other* sections.

We are of the opinion that a separate definition for Nutrient Reference Values-Requirements (NRV-R) and Nutrient Reference Values for Non-Communicable Disease (NRV-NCD) is much clearer and will give

delineation of functions for each specific NRV. A combined definition of both NRVs could be confusing and would not give a clear distinction between these NRVs.

We support retention of the bracketed text [for at least one major segment of the general population (e.g.adults)] since this clarifies the fact that the level of evidences could be different according to the studied populations, but need to be, at least convincing for one major part of the population which is the adult population. Scientific evidence relating a nutrient to diet related NCD should be with the adult population. In addition this added text is consistent with the distinction made for saturated fatty acids in the 2008 joint FAO/WHO Expert Consultation on Fats and Fatty Acids. Adult population and their exposure to risk factors was also used as set of indicators for global monitoring of progress towards reducing the impact of NCD (2012 Revised WHO Discussion Paper).

SOUTH AFRICA

For attachment B

South Africa supports this work because it is an important contribution to implementing the WHO Global Strategy on Diet, Physical Activity and Health (Global Strategy-DPAH) (WHA Resolution 57.17) in addressing the global burden of diet-related NCDs.

There are two options of the presentation of definitions section 2; South Africa is in support of option 2 that incorporates all the terminology, abbreviations and complete definitions for Nutrient Reference Values-Noncommunicable disease (NRVs-NCD) and Nutrient Reference Values-requirements (NRVs-R).

South Africa supports the option chosen by most delegations in the eWG of “convincing/generally accepted” scientific evidence as the preferred basis for establishing a Codex NRV-NCD. In addition, it acknowledges in a separate sentence in the first bullet of 3.2.2.1 that governments may consider the suitability of a lower level of evidence than “convincing/generally accepted” in establishing their own food label reference values. At the last session an unresolved matter was the issue of “convincing evidence” and “probable evidence”. This is, however, not applicable to either saturated fatty acids or sodium, because there is convincing evidence that high intakes of these nutrients are related to risk of NCDs. Further discussion is required for the new text in brackets.

South Africa is in favour of the proposal for consideration of additional nutrients in the categories of total and types of protein, fat and carbohydrate if and when sufficient evidence of relationships with diet-related NCDs becomes available.

UNITED STATES OF AMERICA

A. CX/NFSDU 12/34/5 (NRV PRINCIPLES AND OTHER RECOMMENDATIONS): AGENDA #4

4 (a) PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NRVS-NCD AT STEP 4

We thank Thailand and Chile for co-chairing the eWG on this agenda item, and for the assistance of eWG members in forming the basis of proposals in CX/NFSDU 12/34/5.

The remaining bracketed text in Appendix V of REP12/NFSDU addresses the importance of the scientific evidence for food label reference values established by Codex and governments. The U.S. comments on the proposed draft revision of Appendix V in Attachment B of CX/NFSDU 12/34/5 are found below.

1. PREAMBLE

3rd Sentence

“Governments are encouraged to use the NRVs-NCD, or alternatively, consider the suitability of the general principles below [including the level of evidence required], and additional factors specific to a country or region in establishing their own reference values”

U.S. Comment: We support the addition of the underlined text in brackets.

2. DEFINITIONS

Options for Placement of NRV-NCD Definition

The United States supports Option 2. We prefer that definitions of the two NRV subtypes be introduced with the definition of NRVs at the beginning of the Codex Guidelines on Nutrition Labelling (hereafter referred to as the “Guidelines”) rather than at the end in an Annex.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

1ST Bullet in 3.1 (Criteria for Selection of Nutrients)

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

- Relevant convincing[#]/ generally accepted[#] scientific evidence for the relationship between a nutrient and noncommunicable disease risk, including validated biomarkers for relevant disease risk [for at least one major segment of the population (e.g., adults).] In addition, governments may consider the suitability of probable evidence[#] in conjunction with other bases in establishing their own food label reference value(s).”

U.S. Comment:

1st sentence. We support adding the bracketed text. Whereas most eWG comments supported “convincing/generally accepted” evidence as the sole basis for an NRV-NCD (i.e., either Approach A or B), the underlined bracketed text specifies that convincing/generally accepted scientific relationship between a nutrient and NCD risk pertains only to a major segment of the general population, that being, adults.

2nd sentence. Given that the provisions in the Preamble acknowledge that governments may establish their own food label reference values, the second sentence in the first bullet of Section 3.1 is not necessary.

Footnotes to Section 3.1. We support the underlined revised footnotes to the first bullet of 3.1 in Attachment B which identify the sources of the definition for “probable evidence” and “convincing evidence”.

4 (B): CONSOLIDATION OF 1) THE GENERAL PRINCIPLES FOR ESTABLISHING NRV_s OF VITAMINS AND MINERALS AND 2) THE GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

Another charge of this year’s eWG was to propose in a separate document for consideration a draft Annex to the Guidelines that consolidates the Annexes on general principles for vitamin and mineral NRVs and NRVs-NCD.

The United States agrees with the most eWG members that the two Annexes should be consolidated to avoid repetition and streamline text and to allow comparison between the general principles for the two NRV subtypes. The United States supports the proposed draft consolidation in Attachment C, including proposed headings and subheadings. The United States proposes deleting the bracketed text in the preamble (i.e., “such as pregnant and lactating women,)” since this example neither applies to both types of NRVs nor appears to be necessary. In addition, we agree with most eWG members to include a separate term and definition for NRVs related to nutrient requirements to distinguish the two NRV subtypes and include the proposed term, “Nutrient Reference Values-Requirements” (abbreviated “NRVs-R”) and its definition in Attachment C.

If the Committee supports this proposed reorganization and consolidation of the Annexes, the Committee could feasibly reach agreement on a consolidated Annex at the 2012 34th CCNFSDU session and focus on one remaining issue, which is left in square brackets.

4: OTHER RECOMMENDATIONS

Need for Additional NRVs-NCD

Suitable Data Sources for Identifying Additional Nutrients with Convincing Evidence

The United States agrees with most eWG comments that the two FAO/WHO reports, FNP 91 and TRS 916, are appropriate starting points for identifying nutrients with a convincing level of evidence. The final reports for the two types of NRVs raised as a major concern that CCNFSDU currently does not have a mechanism for obtaining joint FAO/WHO scientific advice on review of NRVs and other nutrition topics. Given this, we support the reports’ recommendation that the WHO and FAO representatives provide details at the 34th Session on the progress, concrete plans and timeframe for re-establishing JEMNU. This recommendation is also consistent with the draft Codex Strategic Plan for 2014-2019 where JEMNU is mentioned and identified under Objective 2.2- Achieve sustainable access to scientific advice (REP12/EXEC 2, June 2012).

In addition, the United States recommends that the Committee develop a working definition for “Recognized Authoritative Scientific Body (RASB)” to assist in applying General Principle 3.1.2 in Attachment C when establishing and updating NRVs. In this regard, we offer comments on a proposed definition of an RASB in U.S. comments in CX/NFSDU 12/34/8.

Finally, the United States supports the report’s recommendation to consider whether to use information and/or recommendations from the WHO guidelines process. We agree that it would be helpful to explore whether the Committee can easily access scientific risk assessment results and recommendations based on systematic reviews of the scientific literature to evaluate their consistency with Codex risk analysis principles. It is our understanding that WHO risk management advice also considers additional information such as costs, feasibility and value preferences.

Assessment of Need for Additional NRVs-NCD

The United States does not believe that the Committee needs to establish an additional NRV-NCD for another nutrient at this time. The United States supports the establishment of NRVs-NCD for both SFA and sodium, which were referred by the CCFL because of their global public health importance. We agree with the ewg Member’s comment that there could be redundancy and dilution of key messages on the SFA if we were to consider NRVs-NCD for additional macronutrients in which the effect depends on replacing SFA in the diet. Establishing NRVs for macronutrients that do not have independent effects on NCD risk could be difficult; for example, whereas SFA intake independently increases risk of coronary heart disease¹, the effect on NCD risk of macronutrients such as polyunsaturated fatty acids and monounsaturated fatty acids is dependent on their substitution in the diet for SFA. Additionally, the majority of ewg members did not support establishing an NRV-NCD for any additional nutrient at this time, recognizing that the Preamble provides governments with flexibility to establish their own food label reference values for additional nutrients.

Potential for More than One NRV for Certain Nutrients

The United States does not see a compelling reason to establish both an NRV based on requirements and an NRV based on NCD risk for any specific nutrient, including sodium. For example, no recent daily intake reference values for requirements are available for sodium from FAO/WHO, and values from other recognized authoritative scientific bodies may not be globally relevant. The sodium Adequate Intake values from the Institute of Medicine of the National Academies of Science (IOM) in the United States were based on meeting sodium needs of apparently healthy individuals *and* on ensuring that an overall Western-type diet provides an adequate intake of other nutrients. In addition, we consider that sodium NRV based on reduced risk of diet-related NCDs (that would also meet requirements) would have more public health relevance than sodium NRV based on minimum requirements. The need for two types of Codex NRVs for the same nutrient could be evaluated in the future on a case by case basis. Additionally, the Preamble provides governments flexibility to determine the most appropriate basis for food label reference values that take into consideration country and region specific factors.

Amendments to Section 3.4.4 of the Guidelines on Nutrition Labelling (CAC/GL 2-1985)

Below are U.S. comments on the proposed amendments in Attachment D of CX/NFSDU 12/34/5.

Introductory Text

The United States supports the text in Option 2 and all other proposed amendments to the 3.4.4 introductory text in Attachment D. Whereas all previous NRVs were based on levels of nutrients associated with nutrient requirements, the United States agrees with the proposed amendments to distinguish between NRVs based on nutrient requirements and NRVs based on NCD risk to assist governments in their interpretation. In the last sentence for the introduction, we prefer Option 2 text based on our preference that the definitions of the two NRV subtypes be introduced at the beginning of the Guidelines on Nutrition Labelling in Section 2 on Definitions. We also support proposed amendments to clarify that these “general population” NRVs are for individuals older than 36 months (as previously agreed by the Committee), and that they are intended to help consumers achieve overall healthful dietary intake.

¹ Specifically, a 2002 IOM expert panel concluded that there is a positive linear trend between total SFA intake and total and LDL concentration and increased risk of coronary heart disease.

Listing of NRVs in 3.4.4 for Reference by Governments

The United States supports the proposed amendments in 3.4.4 that provide for a separate listing of values related to requirements (in new proposed 3.4.4.1) and for NRVs-NCD (in new proposed 3.4.4.2). Consistent with a recommendation from the eWG on vitamin and mineral NRVs, the United States agrees that it may be preferable to present conversion factors for vitamin equivalents in a table format rather than in footnotes (as is the current format).

With regard to proposed footnotes to the NRVs for SFA and sodium, the United States agrees with the footnote for SFA to clarify that this value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories. However, with regard to the bracketed footnote for SFA and sodium which provides a complete definition of convincing evidence, we consider it sufficient to only reference the source of the definition in 3.4.4 and suggest the following edits to footnote 42:

[⁴² The selection of these nutrients for the establishment of an NRV was based on “convincing evidence” for a relationship with NCD risk as defined in using the following definition:

“Convincing Evidence is evidence based on epidemiological studies showing consistent associations between exposure and disease, with little or no evidence to the contrary. The available evidence is based on a substantial number of studies including prospective observational studies and where relevant, randomized controlled trials of sufficient size, duration and quality showing consistent effects. The association should be biologically plausible.”

This definition of ‘convincing evidence’ was taken from the following FAO/WHO reports: 1) *Fats and Fatty Acids in Human Nutrition: Report of an Expert Consultation*. FAO Food and Nutrition Paper 91. Rome. FAO, 2010. and 2) *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003.]

Please note the following correction in Attachment D: The footnote number with the sodium NRV in proposed new 3.4.4.2 should be 42 instead of 43.

Interest in Proposing New Work Related to NRVs for Protein, Total Fat and/or Available Carbohydrate

Protein

Given that the protein NRV is based on recommendations at least 25 years old, the availability of suitable scientific updates from FAO/WHO and other recognized authoritative scientific bodies and current CCNFSDU work to review NRVs for other nutrients, the United States concurs with the report recommendation to consider undertaking new work to review the protein NRV to decide whether to revise the 50 g value. Accordingly, we support the Committee’s consideration of the draft project document for new work that is provided in **Attachment F** of CX/NFSDU 12/34/5.

In addition, the consolidated principles in Attachment C could apply to protein if the INL₉₈ basis for the protein NRV is retained, and therefore, a new set of general principles would not need to be developed.

Total Fat

The United States is not persuaded that new work should be initiated to establish a Codex NRV for total fat, in the absence of a strong scientific basis and public health need for a global NRV. The types of fatty acids consumed are more important in influencing cardiovascular disease risk than total amount of fat in the diet.² In addition, even if a globally applicable recommendation for an acceptable macronutrient distribution range were identified, it may still be difficult to reach consensus on a globally relevant single value on this range as a basis for a Codex NRV. We further consider that the general principles for establishing NRVs based either on requirements or NCD risk are not applicable to establishing a total fat NRV.

This does not preclude governments from establishing their own food label reference values for total fat which is provided for in the Preamble of the general principles for establishing NRVs.

² U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for American, 2010. 7th Edition, Washington DC: Web reference (Accessed July 12, 2012): <http://www.health.gov/dietaryguidelines/2010.asp>

Available Carbohydrate

The United States is not persuaded that new work should be initiated to establish a Codex NRV for available carbohydrate, in the absence of a strong scientific basis and public health need for a global NRV. For example, it is unclear how a percentage NRV for “available carbohydrate” on the nutrition label would help consumers plan healthful diets. In addition, in a 2007 article on conclusions from a FAO/WHO Scientific Update on Carbohydrates in Human Nutrition, it was noted that “A wide range of intakes, as a proportion of total energy intake, is compatible with low risk of chronic diseases although excess intake of any macronutrient is likely to lead to obesity,” and that “the nature of dietary carbohydrate appears to be a more important determinant of health outcomes than the proportion of total energy derived from carbohydrate intake.”³ An additional consideration is whether it would be possible to establish a Codex NRV for available carbohydrate, given that the definition of dietary fibre may vary among countries, which in turn affects what would be measured by available carbohydrate. We further consider that the general principles for establishing NRVs based either on requirements or NCD risk are not applicable to establishing an NRV for available carbohydrate.

This does not preclude governments from establishing their own food label reference values for available carbohydrate, which is provided for in the Preamble of the general principles for establishing NRVs.

ICBA - International Council of Beverages Associations

With respect to Agenda Items 4(a) and 4(b), ICBA:

- Supports on-going work to establish principles for the development of NRVs for nutrients associated with risk of noncommunicable diseases (NRVs-NCDs). Such NRVs can help consumers estimate the relative contribution of individual foods and beverages to an overall healthful diet and serve as a means to compare, via labeling, the nutrient content among various foods and beverages. Furthermore, they can serve as a valuable reference that facilitates international harmonization of NRVs related to diet-related noncommunicable diseases.
- Supports the use of the highest level of scientific evidence for establishing NRVs-NCDs, i.e., convincing/generally agreed evidence. Within this context, ICBA does not support the use of “probable” evidence to set national NRVs-NCDs, as is proposed in the current draft. Any public health importance that is attached to a nutrient must be based on the demonstrated importance of the nutrient/NCD risk relationship.
- Supports consolidation of the Principles for Establishing NRVs for Vitamins and Minerals and the Principles for Establishing NRVs-NCD.

NRVs, whether for vitamins and minerals, or those set in relation to NCDs, should be positioned as a tool for building a healthful diet, and should not be used as a means to judge the nutritional value, either positive or negative, of an individual food or beverage. Consumer education about the consumption of an overall healthful diet, combined with regular physical activity, is important in this regard.

Based on the above, ICBA supports the draft consolidation that is presented in CX/NFSDU 12/34/5, amended as indicated.

<p>1. PREAMBLE <i>(Slight proposed revision of adopted text in VM NRV GP as a result of consolidation)</i> These principles apply to the establishment of Codex Nutrient Reference Values (NRVs) for the general population identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products. Governments are encouraged to use the NRVs, or</p>	<p>ICBA does not support allowances for governments to consider levels of evidence that are less than what is considered to be convincing/generally accepted.</p>
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³ *Joint FAO/WHO scientific update on carbohydrates in human nutrition.* European Journal of Clinical Nutrition, (2007) 61 (Supp 1), S132-S137.
http://www.who.int/nutrition/publications/nutrientrequirements/scientific_update_carbohydrates/en/index.html

<p>alternatively, consider the suitability of the general principles below [including the level of evidence required], and additional factors specific to a country or region in establishing their own nutrient reference values for labelling purposes.</p>	
<p>3.2.2.1 The following criteria should be considered in the selection of nutrients for the establishment of NRVs-NCD:</p> <ul style="list-style-type: none"> <input type="checkbox"/> <input type="checkbox"/> Relevant convincing^{37/} generally accepted³⁸ scientific evidence for the relationship between a nutrient and noncommunicable disease risk relationship, including validated biomarkers for relevant disease risk f, for at least one major segment of the population (e.g., adults).[†] In addition, governments may consider the suitability of probable evidence³⁹ in conjunction with other bases in establishing their own food label reference value(s). <input type="checkbox"/> <input type="checkbox"/> Public health importance of the nutrient-noncommunicable disease risk relationship(s) among Codex member countries. 	