codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

**Agenda Item 8** **CX/NFSDU 09/31/8-Add. 1**
**September 2009**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**
**Thirty first Session**

**Robert Schumann Hall, Museum Kunst Palast, Düsseldorf, Germany**
**2 – 6 November 2009**

# DISCUSSION PAPER ON THE NUTRIENT REFERENCE VALUES (NRVS) FOR NUTRIENTS ASSOCIATED WITH RISK OF NONCOMMUNICABLE DISEASES

**Comments from:**

**ARGENTINA**
**AUSTRALIA**
**BRAZIL**
**COSTA RICA**
**IRAN**
**NEW ZEALAND**
**NORWAY**
**UNITED STATES OF AMERICA**

**CEFS - Comité Européen des Fabricants de Sucre**
**CRN - Council for Responsible Nutrition**
**NHF - National Health Federation**
**WSRO - World Sugar Research Organisation -**

# ARGENTINA

**References**

***Text in italics*: *Argentina's Comments***

3. GENERAL PRINCIPLES

**Question A1** For establishing principles and criteria for NRVs-NCD, do you support a similar organization as for the vitamin and mineral NRVs with separate sections for a Preamble, Definition(s), and General Principles at a minimum?

**Question A2**. Do you support the above topics under general principles or have other suggestions?

*A1 y A2 We support the proposals.*

**B. Description of Population(s) for Which NRVs-NCD Would be Applicable**

**Question B1.** How would you describe the population(s) for which NRVs-NCD would be applicable? For example, do you support their applicability to the "general population"?

B1 – *Yes, we support their applicability to the general population, taking account of the objective to set reference values for labelling purposes for nutrients associated with noncommunicable diseases.*

**Question B2.** If the answer to the second question above is "yes", is there a need to further define an age range for the "general population"? If so, what criteria should be used for defining this age range?

B2 *It should be circumscribed to children older than 36 months, given their particular nutritional requirements.*
*It is also worth mentioning that Argentina has mandatory nutrition labelling, as set out in the Mercosur Technical Regulation for Packaged Food Servings for Nutrition labelling Purposes* (REGLAMENTO TÉCNICO MERCOSUR DE PORCIONES DE ALIMENTOS ENVASADOS A LOS FINES DEL ROTULADO NUTRICIONAL*):*
*DEFINITIONS (Argentine Food Code, Chapter V. Standards for Nutrition Labelling,* CAA Capitulo V. Normas para el rotulado Nutricional*)*
*"…is defined as: 2.1. Serving: the average amount that should be consumed by healthy people older than 36 months on one occasion, with the purpose of promoting a healthy diet. That is, it applies to general population* ***older than 36 months***.

**C. Purpose and Use of NRVs-NCD**
**Question C1.** Do you agree that the purpose and use of NRVs-NCD should be addressed in a preamble in the development of general principles for these NRVs?

C1. *We agree.*

**Question C2.** If so, do you have comments on the above possible adaptation of text in the vitamin and mineral NRV preamble or other suggestions for text to describe the purpose and use of NRVs-NCD?

*C2 We propose to delete the last sentence: "A government may select to use the (NRVs-NCD), or alternatively, consider the suitability of the general principles below and additional factors specific to a country or region in establishing their own reference values for labelling purposes", because each country, as health authority, will decide, in accordance with its regulation, whether or not to adhere to the Codex Standard, without the need to express this explicitly in this preamble.*

*Further, it is advisable to merge items 1 and 2, without giving more importance to one of them.*
*We propose to replace the phrase "**ingesta dietética total**" with "**ingesta diaria saludable**" in the Spanish translation in the understanding that this is the correct translation in this context.*
*We also propose to establish the "older than 36 months" age range.*

**D. Definitions**

**Question D1.** Is there a need for a definition section in the general principles, and if so what term(s) should be defined?

D1. *Yes, there is a need for definition section, also including nutrients associated with noncommunicable diseases.*

**Question D2.** In the Annex to this paper, do you support option 1 or 2 or another option?

D2. *We support option 1, taking account of the terms used in the WHO Global Strategy on Diet, Physical Activity and Health.*

**E. Scope of nutrients to be considered**

**Question E1.** Do you agree that the Committee should consider CCFL proposals for expanding the list in section 3.2 but also consider additional factors and criteria in proposing nutrients for NRVs-NCD?

E1. *We agree*.

**Question E2.** Do you support including sodium and saturated fat in the scope of nutrients to be considered for NRVs-NCD?

E2. *We agree.*

**F. Criteria for Selection of Nutrients, Suitable Data Sources, and Prioritization**

**Question F1.** What are your views about the use of the above criteria for the development of NRVs-NCD?

F1. *We agree with the first two criteria selected and make this comment on item 3:*
*This item is nuclear, so further clarification is desirable.*

**Question F3.** What are your views about the use of the above principles and criteria for selection of suitable data sources in the development of NRVs-NCD?

*F3. We agree with the selected sources.*

**Question F6.** Based on your responses to F1 through 5 above and consideration of any other relevant information, are there particular nutrients that should receive the highest priority for the development of NRVs-NCD?

*F6 Sodium and trans-fatty acids.*
*In accordance with the WHO Strategy, the elimination of trans-fatty acids and sodium reduction from the diet is a key element in governments' actions to support the strategy.*
*In Argentina, in the context of the WHO and the PAHO Trans Fat Free Americas initiative, the Ministry of Health has created a program on research and assessment of actions focused on , the elimination of trans-fatty acids and sodium reduction from Argentina's diet (*Investigación y evaluación de intervenciones de eliminación de grasas trans y reducción del sodio en la dieta, en Argentina*).*

*If other nutrients are to be taken into account, scientific evidence regarding their health effects should be available.*

**Selection of Appropriate Basis for Expressing NRVs-NCD**

**Question G1.** With regard to daily intake reference values from recognized authoritative scientific bodies that are expressed as a percentage of caloric intake, do you support establishing a Codex NRV-NCD based on a reference diet of 2000 calories or another calorie level?

*G1. We agree.*

*It is worth pointing out that in its Mercosur Technical Regulation, Argentina establishes a reference diet of 2000 Kcal for the Labelling of Packaged Foods (Argentine Food Code) Chapter V Standards for Nutrition Labelling.*

**Question G2.** Do you agree that any single daily reference caloric intake selected for the Codex NRVs-NCD may not be applicable to all countries? If so, do you support: 1) indicating this in the general principles, and 2) including in any proposed table on NRVs-NCD not only the NRVs-NCD based on the single reference caloric intake (in milligrams or grams), but also daily intake reference values for the selected nutrients (as a percentage of calories) for governments to derive their own values based on another reference caloric intake?

*G2 We agree with 1 and 2.*

**PROPOSED DRAFT PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR NUTRIENTS ASSOCIATED WITH RISK OF *(NONCOMMUNICABLE DISEASES) (FOR THE GENERAL POPULATION)*1**

**1. PREAMBLE**

***In accordance with the above comments, the paragraph would read:***

These principles apply to the establishment of Codex Nutrient Reference Values for labelling purposes for nutrients associated with risk of *(noncommunicable diseases NRVs-NCD) (for the general population identified as healthy individuals older than 36 months)* ~~*SPECIFY LOWER AGE RANGE and older*~~).
These values may be used for helping consumers ~~1)~~ estimate the relative contribution of individual products to overall healthful dietary intake, and ~~2)~~ as ~~*(a means/one way)*~~ to compare the nutrient content between products. ~~A government may select to use the *(NRVs-NCD)*, or alternatively, consider the suitability of the general principles below and additional factors specific to a country or region in establishing their own reference values for labelling purposes.~~

***2. DEFINITION***
*(Option 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 noncommunicable diseases.*
*or*
~~*Option 2:*~~

~~***Nutrient Reference Values - Diet-Related Chronic Disease (NRVs-DRCD)*** *refer to Codex nutrient reference values for food labelling purposes for nutrients that are associated with risk of diet-related chronic diseases.*~~
*and*

*Any other terms identified in comments that may be needed to describe the type of science based values from suitable data sources that may be used as a basis for NRVs associated with risk of noncommunicable disease).*

**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):*

• *(Strong and relevant scientific evidence for the nutrient-disease relationship*

• *Public health importance of the nutrient-disease relationship among Codex member countries*

• *Strong and relevant scientific evidence for a quantitative reference value for daily intake that is applicable to the general population of Codex member countries.)*

**3.2 Selection of Suitable Data Sources to Establish *(NRVs-NCD)***

3.2.1 Relevant and recent daily intake reference values provided by FAO/WHO should be taken into consideration in establishing *(NRVs-NCD).* If such values are not available, then relevant and recent values from recognized authoritative scientific bodies other than FAO/WHO could be used.

3.2.2 The following criteria should be used to select suitable sources for these values:

• The sources should reflect independent review of the science by recognized authoritative scientific bodies;

• Higher priority may be given, as appropriate, to more recent values from recognized authoritative scientific bodies.

**3.3. Selection of Appropriate Basis for Expressing *(NRVs-NCD)***

3.3.1 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.

3.3.2 Daily intake reference values from recognized authoritative scientific bodies that may be considered for *(NRVs-NCD)* include values expressed in absolute amounts or as a percentage of caloric intake.

3.3.3 For daily intake reference values expressed as a percentage of caloric intake, the single *(NRV-NCD*) should be based on a reference caloric intake for the general population, and expressed in grams or milligrams. Governments may use a Codex *(NRV-NCD)* based on the reference caloric intake of *(2000)* calories, or may derive their own reference values for nutrition labelling based on another reference caloric intake that considers factors specific to their country or region.

1 This Annex summarizes some of the draft proposals and options presented in this paper, and identifies certain text in italics and round brackets that in particular may be the focus of discussion at the *ad hoc* physical working group meeting. We propose that the physical working group consider revisions to this Annex based on Codex member and observer comments to questions raised in this paper and discussion during the physical working group meeting.

# AUSTRALIA

**RESPONSE TO THE QUESTIONS**

A1. Australia supports separate sections for the Preamble, Definitions and General Principles at a minimum; similar to the format used in the vitamin and mineral NRVs (the April 27th draft).

A2. Australia supports the inclusion of Criteria for Selection of Nutrients and agrees with the deletion of the second last general principle heading. However, the determination of a reference value (i.e. a single number) for each selected nutrient may need to consider other features of specific values or in rare circumstances, the Upper Level of Intake such as for sodium. Australia is aware, for example, that many of the mean 'population nutrient intake goals' related to the 'prevention of diet-related chronic diseases' in *Diet, nutrition and the prevention of chronic disease* (WHO, 2003) are expressed in ranges. We also note that the most recent

recommendation from FAO/WHO in relation to trans fatty acids from partially hydrogenated oils and fats, has set a population goal of <1% encompassing the majority of the population (Uauy and Nishida (2009)[1]). In other words, it is couched more like an $INL_{98}$ than an ANR/EAR. On this basis, there is likely to be a need to agree on the basis for the selected single number as well as a method for its selection.

Protein has not been included in the work to review the vitamin and mineral NRVs, and therefore a review of its NRV should occur within this process. A decision will need to be made on whether the basis of the protein NRV is according to its requirement (See WHO Technical Report Series 935, 2007), or its population goal for reduction of chronic disease (See WHO Technical Report Series 916, 2003). This decision should be captured as a General Principle as it might also apply to other nutrients such as essential fatty acids.

B1. Australia supports the reference to the 'general population' in relation to NRVs-NCD.

B2. Australia considers that there is a need to define an age range for the 'general population'. As such, Australia supports reference to the general population as 'older than 36 months'. This is our position in relation to the vitamin and mineral NRVs.

C1. Australia agrees that the purpose and use of NRVs-NCD should be addressed in a Preamble as part of the development of general principles for these NRVs.

C2. Australia prefers 'a means' to compare content between products. The alternative option of 'one way' implies that consumers should be aware of 'other' ways, which is not the intention of the statement. We support the revision to the text but note that the last sentence i.e. "Governments may also consider….." does not appear in the draft Annex 1.

D1. Australia notes that there is already a Definitions section in the proposed outline, and that this should remain separate from the General Principles section. The term 'UNL' is taken from the companion draft Annex to the Codex Guidelines on Nutrition Labelling: *General Principles for Establishing Nutrient Reference Values of Vitamins And Minerals for the General Population*. While applauding this consistency, Australia suggests that relevant terms and their definitions should always be reproduced from the now adopted *Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses*. The corresponding term for UNL is Upper Level of Intake. We therefore expect that a Definitions section including reference to this term and its definition would be necessary.

D2. Australia supports Option 1: 'Nutrient Reference Values – Noncommunicable Disease (NRVs-NCD)' to maintain the link with the terminology and the impetus for this work from the Global Strategy and Draft Action Plan. Australia acknowledges however that 'diet-related chronic disease' is more accurate because it draws the link between diet and chronic disease whereas some noncommunicable diseases (e.g. many cancers) do not have a dietary/nutrient component in their causal pathway. We can see no practical implications, such as the selection of nutrients, that would be affected by the choice of either term.

E1. Australia supports the CCFL proposals for expanding the list of nutrients in section 3.2 of the Codex *Guideline on Nutrition Labelling*, however notes that the CCFL decision making is in its early stages at Step 3 (see Appendix II, ALINORM 09/32/22) and could be subject to change. We note, for example, that saturated fat and [salt/sodium] have been referred to CCNFSDU but not total sugars.

Our preference is for the list of nutrients that are always declared, whatever they may be, as well as conditionally declared (e.g. fatty acid classes) to all be assigned a NRVs-NCD. We suggest

[1] Uauy R et al (2009). WHO Scientific Update On Trans Fatty Acids: Summary And Conclusions. Eur J Clin Nutr 63,S68-75.

that as a first priority, the NRV work should consider nutrients in these categories that are already secure in the *Guidelines on Nutrition Labelling*. We also support the establishment of NRVs-NCDs for nutrients that are the subject of content claims and for which criteria are contained in the Codex *Guidelines for Use of Nutrition and Health Claims*.

E2. Australia supports including sodium and saturated fat in the list of nutrients to be considered for NRVs-NCD because criteria for content claims already exist for these nutrients. While we note that the expression for the declaration of sodium/salt is still under consideration by CCFL, our support is based on the content claim for sodium.

F1. Australia supports the proposed three criteria for the selection of nutrients for the development of NRVs-NCD. Australia notes that these criteria differ from the proposed criteria for selection of nutrients for mandatory labelling by CCFL, but considers this divergence is appropriate given the different purposes for which the nutrients are being selected. In relation to criterion two (the public health importance of the nutrient-disease relationship) and criterion three (a quantitative reference value for daily intake), Australia notes that these may vary between Codex member countries. Australia considers that this should not preclude the use of these criteria, but that where agreement cannot be reached on the selection of nutrients and daily intake values that these are provided as an indicative list, for use wherever applicable.

F2. Australia suggests that a fourth criterion (positioned first) be considered to account for nutrients that CCFL decides should always be declared such as those described in response to Question E. This criterion ensures a link between the selection of nutrients considered for NRVs-NCD and those nutrients that should always be declared, whatever they may be.

F3. Australia supports the principles and criteria for selection of suitable data sources in the development of NRVs-NCD as these criteria align with those in the proposed draft vitamin and mineral NRVs.

F4. Australia has no further principles and criteria to add to those already suggested in A2 and F2.

F5. Australia has no further suggestions for specific references other than publicly available WHO/FAO reports including those published in the scientific literature, since reference values cited in these reports have been developed specifically for international application.

F6. Australia considers that the nutrients that should receive the highest priority fulfil our suggested new criterion (see E1, F2) which at this stage relates to energy, fat, available carbohydrate and protein. High priority should also be accorded to other conditionally declared nutrients (those mentioned in paragraphs 3.2.4 and 3.2.5 of the nutrition labelling guidelines as *should* be declared) but existing content claim criteria should be regarded as a second priority. This would include saturated fat, sodium and total sugars. Any other nutrients for which population goals are recommended in the WHO (2003) report or elsewhere could then be considered. The WHO report includes nutrients with convincing evidence of either an increase or a decrease in the risk of chronic disease.

G1. Australia supports the establishment of a Codex NRV-NCD based on a reference diet of 2000 calories (8,700 kJ). However we would prefer that the text be silent on whether it should apply to developed countries.

G2. Australia agrees that any single daily reference caloric intake selected for the NRVs-NCD may not be applicable to all countries. Hence, we support the proposed two options to address this issue.

### IV. Proposal for New Work

Australia notes the last sentence of this paragraph anticipates that part of a proposal for new work would consider amendments to relevant sections of Codex texts. We are not clear on what type of amendments are intended here but presume that you are referring to the listing of new NRVs in the nutrition labelling guidelines. It would be helpful if that text could be clarified.

## BRAZIL

**Question A1.** For establishing principles and criteria for NRVs-NCD, do you support a similar organization as for the vitamin and mineral NRVs with separate sections for a Preamble, Definition(s), and General Principles at a minimum?

**Question A2**. Do you support the above topics under general principles or have other suggestions?

Brazil supports a similar organization of the documents (NRVs-NCD and NRVs), with separate sections for the preamble, definition and general principles.

**Question B1.** How would you describe the population(s) for which NRVs-NCD would be applicable? For example, do you support their applicability to the "general population"?

**Question B2.** If the answer to the second question above is "yes", is there a need to further define an age range for the "general population"? If so, what criteria should be used for defining this age range?

Brazil agrees with the establishment of a single value of NRV-NCD for general population, which should be set as individuals above 36 months, considering that the document's goal is to establish NRV-NCD for labelling and is not a recommendation for intake.

**Question C1**: Do you agree that the purpose and use of NRVs-NCD should be addressed in a preamble in the development of general principles for these NRVs?

**Question C2:** If so, do you have comments on the above possible adaptation of text in the vitamin and mineral NRV preamble or other suggestions for text to describe the purpose and use of NRVs-NCD?

Brazil believes that the preamble is the appropriate location. As to the text suggested, we suggest the replacing of the expression "Noncommunicable Diseases" by "Chronic Diseases" and to establish the age range.

**Question D1:** Is there a need for a definition section in the general principles, and if so what term(s) should be defined?

**Question D2:** In the Annex to this paper, do you support option 1 or 2 or another option?

Brazil considers that is very important to include a section of definitions of terms used in VRNs-NCD. Moreover, we consider the term "Noncommunicable Diseases" (option 1) more appropriate in the view of the use of the Global Strategy on Diet, Physical Activity and Health as a reference.

**Question E1:** Do you agree that the Committee should consider CCFL proposals for expanding the list in section 3.2 but also consider additional factors and criteria in proposing nutrients for NRVs-NCD?

**Question E2:** Do you support including sodium and saturated fat in the scope of nutrients to be considered for NRVs-NCD?

Brazil agrees with the expansion of the list of nutrients that must be declared (section 3.2 of the Guidelines on Nutrition Labelling). We agree with the inclusion of saturated fat, sugar, sodium, *trans*-fatty acids and dietary fibre in the scope of nutrients being considered for establishment of NRVs-NCD

**Question F1:** What are your views about the use of the above criteria for the development of NRVs-NCD?

**Question F2:** Are there other criteria that are applicable?

Brazil considers that the proposed criteria are relevant. However, not always there is strong evidence to establish quantitative reference values, despite the existence of evidences that relate quantity consumption of a nutrient with probable occurrence of one or more Noncommunicable Diseases

**Question F3:** What are your views about the use of the above principles and criteria for selection of suitable data sources in the development of NRVs-NCD?

**Question F4:** Are there other principles and criteria that are applicable?

**Question F5:** Do you have suggestions for specific references that the Committee should consider based on the above criteria?

Brazil agrees with the proposal to first consider the references of the FAO/WHO and in the absence of these, to consider current sources and scientific authorities recognized as criteria listed in item 3.2.2. We think it is important that FAO/WHO updates the 2004 publication of nutrient recommendations related to Noncommunicable Diseases

**Question F6:** Based on your responses to F1 through 5 above and consideration of any other relevant information, are there particular nutrients that should receive the highest priority for the development of NRVs-NCD?

Brazil suggests that saturated fats, trans-fatty acids and sugars totals NRVs-NCD establishment should be prioritized.

**Question G1:** With regard to daily intake reference values from recognized authoritative scientific bodies that are expressed as a percentage of caloric intake, do you support establishing a Codex NRV-NCD based on a reference diet of 2000 calories or another calorie level?

**Question G2:** Do you agree that any single daily reference caloric intake selected for the Codex NRVs-NCD may not be applicable to all countries? If so, do you support: 1) indicating this in the general principles, and 2) including in any proposed table on NRVs-NCD not only the NRVs- NCD based on the single reference caloric intake (in milligrams or grams), but also daily intake reference values for the selected nutrients (as a percentage of calories) for governments to derive their own values based on another reference caloric intake?

Brazil agrees with the text proposed in the item 3.3 of the annex I because it does not require the use of 2000 kcal as reference, enabling countries to establish other values considering the nutritional profile of its population.

## COSTA RICA

A1 We are in agreement with consideration of a breakdown similar to that of the NRVs (nutrient reference values) for vitamins and minerals with various sections, namely: at least a preamble, definitions and general principles.
A2 All the topics proposed for the section on general principles are supported.

B1 We are in agreement with application of the NRVs-NCDs (nutrient reference values for non-communicable diseases) to the "general population" as from 36 months in compliance with the definition established by the Codex Alimentarius Commission for small children.
B2 We believe that establishment of more than one age interval within said population will depend on the availability of data that enables determination of the NRVs-NCD.

C1 We agree that the purpose and use of NRVs-NCD should be addressed in a preamble in the development of general principles for these NRVs.
C2 We support the formulation contained in Paragraph 18, 2) "as one of the forms of comparing the contents of nutrients". We also support removal of the text that appears deleted in Paragraph 18.

D1 We consider it necessary to include a section for definitions in the general principles which, for example, includes: NRV, NRV-NCD, individual nutrient level, maximum nutrient level. Moreover, consideration of definitions of the provisions on nutritional labelling, and the directives for the use of declarations of nutritional and health properties of the Codex.
D2 We support option 1 of the document's annex for definitions.

E1 We agree that the Committee should consider CCFL proposals for expanding the list in section 3.2 but also consider additional factors and criteria in proposing nutrients for NRVs-NCD.
E2 We support inclusion of sodium and saturated fat in the group of nutrients that must be studied.

F1 and F2 We support use of the criteria proposed for the preparation of NRVs-NCD, as we believe they are specific enough. We do not propose any additional criterion.
As regards trans fatty acids, we believe that these certainly should be a nutrient to be considered for study because there is evidence of their link to health and the fact that only some countries have taken measures to reduce their consumption does not imply that the consumption of trans fatty acids does not entail a health risk. If they are included, they may be considered for generation of nutritional education strategies for the population.

F3 and F4 The principles and criteria for selection of data sources on NRVs-NCD appear to us to be adequate.
F5 Suggestions for specific references for review: Instituto de Medicina de la Academia Nacional de Ciencias (medical institute of the national academy of sciences).
F6 Suggested nutrients that ought to be given maximum priority: sodium, saturated fat, sugar and evaluation of trans fatty acids.

G1 Many labels of commercially available products refer to an NRV of 2000 kcal, and so we support use of this as the reference. For those countries that use the international system of units, the equivalent of this amount in kilojoules must be stated (8378 kJ).
G2 We understand that establishment of a 2000 kcal reference for labelling purposes will not be applicable to all countries, nor to all individuals. Nevertheless, we believe that this involves establishing a standard and that it is important to have references above all for macronutrients in

relation to total energy consumption and so they may be applicable in compliance with the caloric level in use. In any case, we feel it is important to include in all the tables proposed for NRVs-NCD not only the NRVs-NCD based on the sole daily intake for the chosen nutrients (as a percentage of the energy) so that the Governments can establish their own values on the basis of another reference caloric intake.

## IRAN

Question A1: Yes, The Iranian committee supports a similar organization as for the vitamin and mineral NRVs with separate sections for a Preamble, Definition(s), and General Principles.

Question A2: Yes, We support the above topics.

Question B1: Yes, We support their applicability to the general population.

Question B2: General population identified as individuals 36 months and older because of particular nutritional needs of this age group, and we suggest that NRV- NCD be defined for this age group specifically.

Question C1: We do agree.

Question C2: We suggest that this part of the text should not be removed:
3-Line8:"In addition, governments…".until the end of line 10. Paragraph

Question D1: Yes, There is a need for a definition section in the general principles and the terms include: NRVs, NCD, NRVs-NCD

Question D2: We support option 1.

Question E1: We agree that the committee should consider CCFL proposals for expanding the list in section 3.2

Question E2: We strongly support.

Question F1: No. Criteria seem to be OK.

Question F2: No.

Question F3: Yes , Data sources seem to be suitable in the development of NRVs-NCD.

Question F4: Not that we can think of.

Question F5: No more suggestions.

Question F6: Saturated fatty acids- Sodium- Trans fatty acid - Added sugar- Cholesterol- Dietary Fibers- Iron- Folic Acid- Zinc- calcium- Vitamin B2- Vitamin A- Vitamin D- Vitamin C, and any other nutritional hazards related to NCDs that may be specific to a region or country or particular product.

Question G1: The Iranian Committee supports establishing a single codex NRV-NCD based on a reference diet of 2500 calories. This suggestion is based on the average per capita daily energy requirement of 2400 calories for Iranian adult population .This energy requirement level has been calculated on the basis of WHO/FAO energy requirement, taking into consideration sex, age and weight equations.

# NEW ZEALAND

New Zealand is pleased to submit the following comments on questions A1-G2 as presented in the discussion paper.

| | |
|---|---|
| A1: | For establishing principles and criteria for NRVs-NCD, do you support a similar organization as for the vitamin and mineral NRVs with separate sections for a Preamble, Definition(s), and General Principles at a minimum? |
| | Yes, this seems a reasonable approach. The obvious difference is around the role of the WHO Global Strategy on Diet, Physical and Health (the Global Strategy) in identifying the nutrients of significance with respect to NRVs-NCD (World Health Organisation 2004). This link would probably be addressed in the preamble. |
| A2: | Do you support the above topics under general principles or have other suggestions? |
| | New Zealand supports the above topics but it is unclear why consideration of upper levels of intake has been deleted from consideration within the general principles? As the NRVs-NCD refer to both risk promoting and risk reducing nutrients it is conceivable that excessive intakes of risk reducing nutrients e.g. potassium, linoleic acid, could pose deleterious effects on an individuals health and that these effects should be considered in setting NRVs-NCD. By including the statement on upper levels of intake, some judgement then needs to be applied when there is no prescribed value e.g. is this due to insufficient data quality and/or quantity; or a risk is present but a threshold level cannot be identified (FAO/WHO 2006). |
| B1: | How would you describe the population(s) for which NRVs-NCD would be applicable? For example, do you support their applicability to the "general population"? |
| | This possibly needs further consideration at the physical working and/or at the plenary session of CCNFSDU. The scientific evidence upon which the key objectives within the Global Strategy are drawn probably reflects findings examining adult or older adult populations. Therefore their generalisability and hence the NCDs-NRV to the wider population is unclear. However, the WHO/FAO Technical Report 916 on Diet, Nutrition and Prevention of Chronic Diseases established "population" goals based on its appraisal and summary of evidence (World Health Organisation 2003). Further, while the absolute risk of some NCDs is low among younger populations compared to middle-aged and older populations, New Zealand believes there is benefit in younger populations becoming accustomed to dietary patterns consistent with NCD reduction and selecting foods accordingly. New Zealand would support in principle the application of the NRVs-NCD to a broad population group e.g. aged 36 months and older. |
| B2: | If the answer to the second question above is "yes", is there a need to further define an age range for the "general population"? If so, what criteria should be used for defining this age range? |
| | Consistency with other recognised authorative scientific bodies and consistency with the Codex Guidelines on Nutrition Labelling: "General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population." |
| C1: | Do you agree that the purpose and use of NRVs-NCD should be addressed in a preamble in the development of general principles for these NRVs? |
| | Yes, the purpose of the NRVs-NCD is to enable consumers to make healthy choices and to |

| | |
|---|---|
| | allow for product comparison. |
| C2: | If so, do you have comments on the above possible adaptation of text in the vitamin and mineral NRV preamble or other suggestions for text to describe the purpose and use of NRVs-NCD? |
| | New Zealand would generally support the adaptation to the preamble that the United States and Thailand have kindly drafted. However, we do not like the reference to 'healthful dietary intake' and think that this could be better worded. The Global Strategy makes reference to a 'healthy diet', perhaps this wording could be considered e.g. "…estimate the relative contribution of individual products to an overall [healthy diet] and…". |
| D1: | Is there a need for a definition section in the general principles, and if so what term(s) should be defined? |
| | There is a need for a definition section in the general principles and acknowledge that some of the terms in this section will have been previously defined by other Codex documents. New Zealand suggests as a starting point the following terms be considered for inclusion in this section:<br><br>'Risk', 'Noncommunicable disease', 'Nutrient Reference Value', 'Upper level of intake', 'Daily Intake Reference Value' |
| D2: | In the Annex to this paper, do you support option 1 or 2 or another option? |
| | New Zealand supports Option 1 as the language is consistent with terminology used in the Global Strategy. It also captures the mandate that the physical working group was provided, specifically as a first step "…develop principles and criteria for the development of NRVs for nutrients associated with risk of non-communicable disease…" (Codex Committee on Nutrition and Foods for Special Dietary Uses 2009). |
| E1: | Do you agree that the Committee should consider CCFL proposals for expanding the list in section 3.2 but also consider additional factors and criteria in proposing nutrients for NRVs-NCD? |
| | The criteria need to future proof the Principles to accommodate changes and additions to the list of NRVs-NCD, however, in the immediate term New Zealand thinks that CCNFSDU should start with the nutrients currently under consideration at CCFL. New Zealand notes that CCFL have specifically asked CCNFSDU to consider "Inclusion of saturated fat and sodium in relation to nutrient reference values for nutrients associated with risk of non-communicable diseases" (Codex Committee on Food Labelling 2009). |
| E2: | Do you support including sodium and saturated fat in the scope of nutrients to be considered for NRVs-NCD? |
| | Absolutely. See above. |
| F1: | What are your views about the use of the above criteria for the development of NRVs-NCD? |
| | The criteria are related to selection of the nutrients which is mostly acceptable to New Zealand. In the immediate term however the nutrients that CCNFSDU need to develop NRVs-NCD for have already been selected by CCFL i.e. saturated fat and sodium (see comments E1). In general, criteria need to be developed that address issues of practicality with respect to the nutrients in question e.g. meaningful values, reliable analytical techniques, understandable expressions - if these are to be used for labelling purposes. Further, in making specific comments on the draft criteria New Zealand would support a broader perspective beyond the nutrient and the disease. For example, a nutrient relationship to a relevant validated biomarker could be used to justify selection of that nutrient e.g. saturated fat and plasma cholesterol concentrations for cardiovascular disease. |

| | |
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| F2: | Are there other criteria that are applicable? |
| | None to put forward at this time. |
| F3: | What are your views about the use of the above principles and criteria for selection of suitable data sources in the development of NRVs-NCD? |
| | No comments at this time. |
| F4: | Are there other principles and criteria that are applicable? |
| | As these are NRVs-NCD for labelling purposes New Zealand do think that there should be criteria related to the ability to analyse and identify appropriate and meaningful labelling values for the nutrient (hence the use of total sugars rather than added at CCFL). |
| F5: | Do you have suggestions for specific references that the Committee should consider based on the above criteria? |
| | None to put forward at this time. |
| F6: | Based on your responses to F1 through 5 above and consideration of any other relevant information, are there particular nutrients that should receive the highest priority for the development of NRVs-NCD? |
| | Those nutrients that have already been selected by CCFL i.e. saturated fat and sodium (see comments E1). |
| G1: | With regard to daily intake reference values from recognized authoritative scientific bodies that are expressed as a percentage of caloric intake, do you support establishing a Codex NRV-NCD based on a reference diet of 2000 calories or another calorie level? |
| | New Zealand would support further discussion of this point at the physical working group and/or plenary session at CCNFSDU. Reference to a single energy value for a population will be problematic. Acknowledgement of this could be made in the general principles. It is unclear to New Zealand whether the '2000' calorie figure is current and relevant as it seems to have been generated from deliberations by the Food and Drug Administration more than 10 years ago (FDA 1993). If a single energy value is chosen, New Zealand is aware that FAO/WHO/UNU published an authorative text on human energy requirements in 2004 that provides a range of energy requirements based on an assortment of variables including, age, gender, BMR and PAL (FAO/WHO/UNU 2004). This text might provide CCNFSDU with guidance on an appropriate energy value. |
| G2: | Do you agree that any single daily reference caloric intake selected for the Codex NRVs-NCD may not be applicable to all countries? If so, do you support: 1) indicating this in the general principles, and 2) including in any proposed table on NRVs-NCD not only the NRVs-NCD based on the single reference caloric intake (in milligrams or grams), but also daily intake reference values for the selected nutrients (as a percentage of calories) for governments to derive their own values based on another reference caloric intake? Indicating the inherit difficulties in selecting one energy value for deriving NRVs-NCD could be discussed in the general principles. |

**References**

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# NORWAY

We would like to thank the United States and Thailand for preparing the discussion paper on the nutrient reference values for nutrients associated with the risk of noncommunicable diseases (NRVs-NCD), and for the opportunity to forward our comments.

General comments

To consider a new work of establishing NRVs-NCD is a proposal from WHO and FAO, as an action towards implementing the Global Strategy into the relevant Codex standards. Norway supports the implementation of the Global strategy for labelling purposes. We are looking forward to further discussions in the physical working group regarding NRVs-NCD, as a framework before the Committee makes a proposal for new work.

Comments to question E1 and E2

We agree that the Committee should consider the CCFL proposals for expanding the list in section 3.2. The proposal from the last meeting in CCFL is to add saturated fat and total sugars and to retain sodium/salt, *trans* fatty acids, added sugars, and dietary fibre in square brackets for consideration. We support the inclusion of the abovementioned elements described in Alinorm 09/32/22 no.13- 43.

In relation to the term added sugars, there are different opinions including the term itself and whether there is a need for recommendations or reference values for labelling purposes. In a recent American publication[2] it is recommended to introduce an upper limit on the intake of added sugars of 100 and 150 calories per day for women and men respectively. On the contrary the European Food Safety Authority (EFSA) concluded in a recent review of labelling reference intake values[3] that there is no need for a labelling reference intake for added sugars in addition to total sugars.

We are aware that it is controversial to include the term added sugars in Section 3.2 *Listing of nutrients* of the *Guidelines on Nutrition Labelling*, but we believe that for labelling purposes this term will contribute to consumers' ability to make health-wise and informed choices. It is important to ensure that consumers be provided with easily understandable information, and in our opinion the term added sugars meet this criterion. How to define the term added sugar may still be a subject for

[2] Johnson, R.K *et al* (2009), Dietary Sugars Intake and Cardiovascular Health, *Journal of the American Heart Association.*

[3] Scientific opinion of the Panel on Dietetic products, nutrition and allergies on a request from European Commission on the review of labelling reference intake values for selected nutritional elements. *The EFSA journal* (2009) 1008, 1-14

consideration. The WHO- definition of the term “free sugars” could be an input to a discussion on how to define “added sugars”.

Comments to question F1

The first criterion proposed reads: “Strong and relevant scientific evidence for the nutrient-disease relationship.” We suggest that the word “strong” be substituted with “Generally accepted”. We also suggest deleting the word “relevant” because it seems redundant in the criterion.

The second criterion proposed reads:” Public health importance of the nutrient-disease relationship among Codex member countries.” We support this, but would like to emphasise the importance of taking into consideration that public health importance may vary among Codex member states, as drawn attention to in point 26 in the discussion paper.

Regarding the third criterion, we are not familiar with the use of the term: “quantitative reference value for daily intake” in this context, and would appreciate that this be illustrated in an example.

Comments to question G1 and G2

We recognise many disadvantages in using a reference diet of 2000 calories or referring to other calorie levels when establishing reference values. Such reference diet will not be representative for the entire population as it does not take into account the different energy intakes of children, men and women. This may be misleading to consumers; hence, Norway is uncertain whether introducing a single daily reference caloric intake would prove beneficial.

We agree that any single daily reference calorie intake selected for the Codex NRVs-NCD may not be applicable to all Codex member states.

# UNITED STATES OF AMERICA

## I. GENERAL COMMENTS

The United States supports the Committee’s recommendation at the last CCNFSDU session to not delay consideration of new work on the development of NRVs for nutrients that are associated with risk of noncommunicable diseases (ALINORM 09/32/26, para 152). In the following comments, we respond to the questions posed by the United States and Thailand relating to the terms of reference for the ad hoc physical working group on this topic. They are to:

- Develop principles and criteria for the development of NRVs for nutrients associated with risk of noncommunicable diseases; and
- Based on the agreed upon principles and criteria, to select and prioritize nutrients for development of NRVs (ALINORM 09/32/26, para 153).

The United States notes the interest in treating this potential work as a separate CCNFSDU agenda item to develop general principles for establishing vitamin and mineral NRVs, which would then require subsequent revision of the list of NRVs in Section 3.4.4 in the Codex Guidelines on Nutrition Labelling. We believe it is appropriate for work on these two agenda times to progress on separate tracks and with different time frames, but also recognize the need to closely coordinate these two agenda items. With this approach and pending approval of the new work on these additional NRVs, the Committee can decide at a later stage whether it would be appropriate to merge certain text relating to the general principles and how best to present the NRVs in Section 3.4.4.

In addition, the U.S. recommends that at the next session the physical working group and the Committee consider the development of a draft project document to propose new work to establish these NRVs.

## II. SPECIFIC COMMENTS

The United States is pleased to offer the following preliminary comments in response to the questions posed in the discussion paper and based on consideration of the April 27, 2009, draft principles for establishing vitamin and mineral NRVs that the Delegation of the Republic of Korea circulated to an electronic working group. The U.S. anticipates updating these preliminary comments at the physical working group meeting to take into consideration the final report of this electronic working group (i.e., CX/NFSDU 09/31/4).

In these comments, we use the abbreviation "NRVs-NCD" to refer to NRVs for nutrients associated with risk of "noncommunicable diseases," which is the terminology used in the Global Strategy on Diet, Physical Activity and Health, but also make note that it may be more appropriate to use other terminology. Because this agenda item is not yet in the Codex step process, we have used italics and parentheses in lieu of square brackets to indicate text that may be of particular focus for discussion at the physical working group meeting.

### A. Overview and Organization of Topics

Question A1. For establishing principles and criteria for NRVs-NCD do you support a similar organization as for the vitamin and mineral NRVs with separate sections for a Preamble, Definition(s), and General Principles at a minimum?
Question A2. Do you support the topics (identified in the discussion paper) under general principles or have other suggestions?

Comments:

In establishing principles and criteria for NRVs-NCD, the United States supports retaining, wherever applicable, the same or similar text and organization as the vitamin and mineral general principles, with appropriate modifications to reflect topics specific to the NRVs-NCD.
We also support consideration of the following title for the general principles:

> "Proposed Draft Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of (Noncommunicable Diseases) for the General Population"

Our preliminary recommendation based on the April 27th draft is to organize the topics to be addressed in draft principles and criteria as follows:

1. PREAMBLE
   - Description of population for which these NRVs are applicable
   - Purpose and use of NRVs by governments
2. DEFINITION(S)
3. GENERAL PRINCIPLES FOR ESTABLISHING (NRVs-NCD)
   - Criteria for Selection of Nutrients
   - Selection of Suitable Data Sources to Establish (NRVs-NCD)
   - Selection of the Appropriate Basis for Expressing (NRVs-NCD)

### B. Description of Population(s) for Which NRVs-NCD Would be Applicable

**Question B1**. How would you describe the population(s) for which NRVs-NCD would be applicable? For example, do you support their applicability to the "general population"?
**Question B2**. If the answer to the second question above is "yes", is there a need to further define an age range for the "general population"? If so, what criteria should be used for defining this age range?

Comments:
The United States believes it may be appropriate to describe the population for which the NRVs-NCD are applicable as the "general population." With regard to the need to further define an age range, the U.S. would like to consider other Codex member and observer organization comments and their rationales. The Committee may also consider if it would be more appropriate to revisit this question after it has selected specific nutrients for the development of these NRVs.

C**. Purpose and Use of NRVs-NCD**

**Question C1:** Do you agree that the purpose and use of NRVs-NCD should be addressed in a preamble in the development of general principles for these NRVs?
Comment: Yes.

**Question C2:** If so, do you have comments on the above possible adaptation of text in the vitamin and mineral NRV preamble or other suggestions for text to describe the purpose and use of NRVs-NCD?
Comment: The United States supports the proposed draft language in the preamble of Annex 1 of the discussion paper, with further discussion of the text in parentheses by the physical working group.

**D. Definitions**

**Question D1**: Is there a need for a definition section in the general principles, and if so what term(s) should be defined?
**Question D2**: In the Annex to this paper, do you support option 1 or 2 or another option?

Comment:
If new work is approved to establish these NRVs, it may be helpful for the Committee to define a new term to differentiate the two sets of NRVs because of their different bases. As noted in the discussion paper, the Global Strategy (WHA 57.17) referred to "noncommunicable diseases" but did not appear to define the term. On the other hand, (diet-related) "chronic disease" was the focus of a 2003 report of a Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases. The United States believes that both terms may be interpreted to encompass both diet- and non-diet related disease, but that one interpretation of "noncommunicable disease" is broader---e.g., encompassing both nutrient deficiency diseases and chronic diseases. Accordingly, the United States tentatively supports Option 2 in the Annex of the discussion paper which is to refer to "Codex nutrient reference values for food labeling purposes for nutrients that are associated with risk of diet-related chronic diseases" (abbreviated as "NRVs-DRCD"). However, the United States is also open to considering other perspectives on the need to define a new term to differentiate the two sets of NRVs. It may be appropriate for the Committee to revisit the need to define terms and consider whether additional terms are needed after proposing draft principles and prioritizing nutrients for the development of NRVs.

E. **Scope of Nutrients to be Considered**

**Question E1**: Do you agree that the Committee should consider CCFL proposals for expanding the list in section 3.2 but also consider additional factors and criteria in proposing nutrients for NRVs-NCD?

Comment:
Yes. The United States believes it is appropriate to consider CCFL proposals to expand the list of nutrients that should always be declared in Section 3.2 of the Guidelines on Nutrition Labelling, but does not see a basis for the Committee to limit the scope of consideration of NRVs-NCDs to this list.

Consistent with section 3.4.4 of the Guidelines on Nutrition Labelling (CAC/GL 2-1985), we assume that the expression of nutrient content as a percentage of the NRVs-NCD would be voluntary (as it is currently for vitamins, minerals, and protein), whether or not the declaration of the nutrient in nutrition labelling is mandatory. As addressed later, we also support the Committee's establishment of specific criteria upon which to base the selection of nutrients for NRVs-NCDs.

**Question E2:** Do you support including sodium and saturated fat in the scope of nutrients to be considered for NRVs-NCD?

Comments:
As noted in the discussion paper, the Codex Committee on Food Labelling requested that the Committee consider including saturated fat and sodium in relation to nutrient reference values for nutrients associated with risk of noncommunicable diseases (ALINORM 09/32/22 para 42). The U.S. agrees that saturated fat and sodium appear to be strong candidates for the development of NRVs-NCD based on the proposed criteria in para 25 of the discussion paper.

## E. Criteria for Selection of Nutrients, Suitable Data Sources, and Prioritization

Criteria for Selection of Nutrients

**Question F1**: What are your views about the use of the criteria (proposed in the discussion paper) for the development of NRVs-NCD?
**Question F2:** Are there other criteria that are applicable?

Comments:
The United States believes that the following criteria, which are proposed in Annex 1 of the discussion paper, are relevant to the selection of these nutrients:
1. Strong and relevant scientific evidence for the nutrient-disease relationship
2. Public health importance of the nutrient-disease relationship among Codex member countries
3. Strong and relevant scientific evidence for a quantitative reference value for daily intake that is applicable to the general population of Codex member countries.

The United States may have additional comments on criteria at the upcoming CCNFSDU session.

Criteria for Suitable Data Sources

**Question F3**: What are your views about the use of the principles and criteria (proposed in the discussion paper) for selection of suitable data sources in the development of NRVs-NCD?

Comments:
The United States generally supports the proposed principles and criteria in Annex 1 (Section 3.2) of the discussion paper.

**Question F4**: Are there other principles and criteria that are applicable?

Comments:
The United States may have additional comments at the upcoming CCNFSDU session.

**Question F5**: Do you have suggestions for specific references that the Committee should consider based on the above criteria?

Comments:

The United States looks forward to an update on the outcome of the FAO/WHO Expert Consultation on Fat and Fatty Acids in Human Nutrition as it may relate to this potential new work. The United States also notes the relevance of Dietary Reference Intakes established by the Institute of Medicine of the National Academy of Sciences to this potential work.

Prioritization

**Question F6**: Based on your responses to F1 through 5 above and consideration of any other relevant information, are there particular nutrients that should receive the highest priority for the development of NRVs-NCD?

Comments:
As stated earlier, the United States agrees that saturated fat and sodium appear to be strong candidates for the development of NRVs-NCD based on the proposed criteria in para 25 of the discussion paper. The U.S. anticipates it will have additional comments with regard to other nutrients that may be considered after further discussion of criteria for prioritization at the next session.

G**. Selection of the Appropriate Basis for Expressing NRVs-NCD**

**Question G1**: With regard to daily intake reference values from recognized authoritative scientific bodies that are expressed as a percentage of caloric intake, do you support establishing a Codex NRV-NCD based on a reference diet of 2000 calories or another calorie level?
**Question G2**: Do you agree that any single daily reference caloric intake selected for the Codex NRVs-NCD may not be applicable to all countries? If so, do you support: 1) indicating this in the general principles, and 2) including in any proposed table on NRVs-NCD not only the NRVs-NCD based on the single reference caloric intake (in milligrams or grams), but also daily intake reference values for the selected nutrients (as a percentage of calories) for governments to derive their own values based on another reference caloric intake?

Comments: In the United States, we have found it appropriate to establish daily intake reference values for nutrition labeling purposes for certain nutrients associated with risk of chronic disease (e.g., saturated fat) based on a reference diet of 2000 calories. On the other hand, the U.S. acknowledges that this reference caloric intake may not be applicable to all Codex member countries. Consequently, the U.S. finds merit in the proposal to acknowledge in general principles that governments may use a Codex NRV-NCD based on a single reference caloric intake (to be determined by this Committee), or alternatively may derive their own reference values for nutrition labeling based on another reference caloric intake specific to their country or region. In the latter case, the Committee may wish to consider including in any proposed table on NRVs-NCD the daily intake reference values for the selected nutrients (as a percentage of calories) for governments to derive their nutrition label reference values.

## CEFS - Comité Européen des Fabricants de Sucre

CEFS (Comité Européen des Fabricants de Sucre), on behalf of all European sugar producers, welcomes the opportunity to present comments on some of the questions put forward in the aforementioned discussion paper.

***Section F - Criteria for Selection of Nutrients, Suitable Data Sources, and Prioritization***

- Question F1: What are your views about the use of the above criteria for the development of NRVs-NCD?

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| CEFS' response: CEFS concurs with the discussion paper's analysis. |

The discussion paper suggests a number of criteria that may be relevant when selecting the nutrients for which NRVs should be developed. Strong and relevant scientific evidence is needed at all stages of the decision process resulting in the setting of a NRV-NCD for a given nutrient. The relationship between the nutrient and a disease has to be supported by sound scientific evidence, and so has to be the possibility to derive a quantitative reference value for daily intake of that nutrient that is applicable to the general population of Codex member countries. Furthermore, the public health importance of the nutrient-disease relationship among Codex member countries has to be taken into account. In particular, nutrient-disease relationships for which only a limited number of Codex member countries are concerned do not justify the setting of NRVs-NCD at Codex level. Addressing them at governmental level would be a more appropriate and resource-wise (from a Codex perspective) option.

- Question F3: What are your views about the use of the above principles and criteria for selection of suitable data sources in the development of NRVs-NCD?
  Question F4: Are there other principles and criteria that are applicable?
  Question F5: Do you have suggestions for specific references that the Committee should consider based on the above criteria?

CEFS' response: Where recent, relevant data from recognized scientific bodies other than FAO/WHO does exist, it should be considered by the Committee.

CCNFSDU's work on NRVs-NCD has to be based on the latest relevant scientific evidence. Thus, where more recent data from the one provided by FAO/WHO that comes from a recognized authoritative scientific body does exist, it should be taken into account by the Committee along with the data provided by FAO/WHO. CEFS would therefore invite the Committee to give careful consideration to two recent Draft Opinions on Dietary Reference Values (DRVs) for Fat and for Carbohydrates and Dietary Fibre that were released for consultation by the European Food Safety Authority (EFSA) on 5 August 2009[1,2].

- Question F6: Based on your responses to F1 through 5 above and consideration of any other relevant information, are there particular nutrients that should receive the highest priority for the development of NRVs-NCD?

CEFS' response: Total energy, protein, total fat and carbohydrate are the priority nutrients for which NRVs-NCD should be set. On the other hand and on the basis of the selection criteria proposed under question F1, the inclusion of sugars (total and added) in the list of nutrients for which NRVs-NCD should be set at Codex level is not justified.

- Total energy is of major relevance from a public health perspective in the context of obesity. There is convincing scientific evidence supporting a link between high intake of energy-dense foods and obesity[3]. Many authoritative scientific bodies have derived recommended intakes for energy from the average requirements of specific age and sex group[4]. CEFS therefore sees total energy as a priority nutrient for the development of NRVs-NCD.

- Total fat is an important source of energy and facilitates the absorption of fat-soluble dietary components such as vitamins. Fats and oils are also important sources of essential fatty acids[2]. On the other hand, diets high in fat generally have a high energy density, can contribute to excessive energy intake and energy imbalance and thus might promote weight gain[5]. High-fat diets may also decrease insulin-sensitivity and increase cardiovascular risk[2]. The WHO Technical Report 916 (2003)[3] sets a population nutrient intake goal to 15%-30%E for total fat. The EFSA recently concluded that there is insufficient data to define a lower threshold of intake (LTI) or an upper limit (UL) for total fat intake but suggested that a recommended intake range can be established for total fat (20-35 E%)[2]. Against this background, total fat appears as an important nutrient for CCNFSDU to consider for the setting of NRVs-NCD.

- Carbohydrate should be the primary source of energy for the human body and is therefore a nutrient of key relevance to public health. The WHO Technical Report 916 (2003)[3] sets a population nutrient intake goal for total carbohydrates (including dietary fibre) to 55-75 E% for preventing diet-related chronic diseases. The recent FAO/WHO Scientific Update on Carbohydrates in Human Nutrition[6] proposes to extend this range to 50-75 E%. The EFSA recently concluded that there is insufficient data to define an LTI or an UL for carbohydrates but suggested that a recommended intake range can be established for total carbohydrates (45 to 60 E%)[1]. In light of the above, CEFS would recommend that carbohydrates receive high priority for the setting of NRVs-NCD.

- In light of the selection criteria proposed under question F1, on the other hand, the inclusion of sugars in the scope of the nutrients for which NRVs-NCD should be developed by CCNFSDU is not justified. The scientific evidence for a link between sugars (either total or added) and any noncommunicable disease is inconclusive; thus, the public health relevance of sugars . The annex of the WHO Technical Report 916 (2003)[3] states that there is no "convincing", "probable" or even "possible" evidence for a link between "free" sugars (frequency of consumption or amount) and obesity. In addition, the FAO/WHO Expert Consultation on Carbohydrates in Human Nutrition (1997)[7] highlighted that "*there is no direct evidence to implicate either [sugars or starch] in the etiology of obesity*". Most recently, the EFSA[5] pointed out that "*the evidence relating high intake of sugars (mainly as added sugars), compared to high intakes of starch, to weight gain is inconsistent*". There is also a clear consensus that frequency of consumption and not the amount of fermentable carbohydrates (not only sugars) is relevant with regard to caries[1,8,9,10]

In addition, there is no strong scientific evidence for a quantitative reference value for the daily intake of sugars. The WHO Technical Report 916 (2003)[3] itself qualifies a population intake goal for "free" sugars to 10%E as "controversial". In its recent review of existing population reference intakes in the light of new scientific evidence and taking into account more recent national recommendations, the EFSA concluded, however, that no intake recommendations for sugars (either total or added) can be given due to the insufficient data available[1]. Any NRV-NCD that might be developed for sugars (whether total or added), even if possibly in line with some existing intake recommendations, would thus not be based on scientific evidence. CEFS would thus recommend that sugars (whether total or added) be not included in the list of priority nutrients for which NRVs-NCD should be developed.

***Section G - Selection of Appropriate Basis for Expressing NRVs-NCD***

- Question G1: With regard to daily intake reference values from recognized authoritative scientific bodies that are expressed as a percentage of caloric intake, do you support establishing a Codex NRV-NCD based on a reference diet of 2000 calories or another calorie level?
  Question G2: Do you agree that any single daily reference caloric intake selected for the Codex NRVs-NCD may not be applicable to all countries? If so, do you support: 1) indicating this in the general principles, and 2) including in any proposed table on NRVs-NCD not only the NRVs-NCD based on the single reference caloric intake (in milligrams or grams), but also daily intake reference values for the selected nutrients (as a percentage of calories) for governments to derive their own values based on another reference caloric intake?

According to the EFSA, a daily reference caloric intake of 2000 kcal is about the middle of the range

CEFS' response: The choice of the daily reference caloric intake should be left for national government to decide, depending on their national situation and priorities in term of diet-related public health issues.

of the average energy intakes observed for women (1625-2400 kcal) and lower than the average intakes for men (2200-3200 kcal) in European countries; it corresponds to the recommended energy intake for a moderately active woman[4]. While the choice of such a rather restrictive value may be sensible in countries where overweight and obesity are the primary diet-related public health issue as it may encourage moderate energy intake, this may not be the case in those where undernutrition is also

of concern. CEFS would thus support it if the definition of the reference caloric intake would be left for national governments to decide, depending on their national situation.

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## CRN - Council for Responsible Nutrition

**General Comment:**

The Discussion Paper should be rearranged to provide at the beginning a clear explanation of the purpose and use of the concept. This explanation is imperative to ensure that the NRV-NCD are understood to be NRV, and not to as Dietary Reference Intakes (DRI, including $INL_{98}$, RDA, PRI, UL, UNL and similar). These specications will affect the meaning and the details to be provided in the various sections. An expanded Preamble is the best location for this explanation, but some reinforcement in the General Principles would be useful.

The current draft states the purpose only as an outcome in an abstract manner (e.g., "helping consumers" and "providing a means." The current draft does not make it clear how and where these actions are to be accomplished. The discussion is about a type of NRV, which seems to indicate that the NRV-NCD would be used on food labels. If this is the idea, is the NRV-NCD to be used instead of or in addition to the usual NRVs? Either way, how does the NRV-NCD accomplish anything that is not already done by the NRV and health claims? If the NRV-NCD is intended to advise specific groups of consumers about nutrient intakes that they need to reduce the risk of specific non-communicable diseases, how does this differ from the combination of Dietary Reference Intakes ($INL_{98}$, RDA, PRI, etc.) and health claims?

The current draft does not clearly address the issues described above. We believe this step to be necessary in order for the succeeding sections to make sense.

**Question A1:**
Yes, sections titled Preamble, Definitions(s) and General Principles are necessary and appropriate.

**Question A2:**
Yes, the topics listed under General Principles are appropriate, but may not be sufficient—depending upon the suitability and completeness of the Preamble and Definitions sections. Great care must be used to sufficiently explain the differences in definitions and uses between NRV-NCD and NRVs for

nutrient content labeling, and between NRV-NCD and DRI values. This could be accomplished in an expanded Preamble or later in the document, but it is essential

**Question B1**:

The identification of the population to which the NRV-NCD applied would have to be specific to each NCD. For example, the population for a NRV-NCD for folic acid and neural tube defects (NTDs) would be very different from the population of a NRV-NCD for omega-3 fatty acids and risk of coronary heart disease. A broad term such as "general population" should not be used unless justified by the evidence, e.g., iron and anemia.

**Question B2:**

The applicable age range needs to be identified from the same dataset that provides justification for the selection of the quantitative value for the NRV-NCD. For example, a NRV-NCD for folic acid and NTDs clearly would not apply to all adult women.

**Question C1:**

Yes, the purpose and use should be described in a Preamble, and perhaps repeated in General Principles.

**Question C2**:
If the NRV-NCD values are defined, identified and used, the Preamble should be edited for the second sentence to read, "These values may be used on food labels for helping…" The draft does not indicate how the difference between an NRV-NCD and an ordinary NRV would be communicated on the label, or elsewhere. It is not clear to CRN how this could be done without including a statement that would approximate a health claim.

**Question D1:**

There is a need for a definition section, or a detailed description of the purpose, character, and use of an NRV-NCD.

**Question D2:**

Option 2. Both options are acceptable but the language is simpler in Option 2.

Yes to both questions. There is no reason not to consider suggestions by CCFL.

**Question E2:**

Yes. Sodium and saturated fat have impacts on diet-related chronic diseases. Trans-fats should be added to this list.

**Question F1:**

In the criteria for selection of nutrients, sources, etc., the requirement for applicability to the "general population" will need to have exceptions for some nutrient-disease relationship. The criteria should state that the application is to the "general population" unless an exception is identified by Codex (example, folic acid-NTDs).

**Question F2:**

Not at this time.

**Question F3:**

These principles and criteria are acceptable.

**Question F4:**

Not at this time.

**Question F5:**

No.

**Question F6:**

Yes: Folic acid, calcium, vitamin D, omega-3 fatty acids, lutein, etc.

**Question G1:**
The 2000 calorie is probably a good compromise.

**Question G2**:

Codex could consider working out perhaps three levels, with each country obliged to select one for application in their country. Such action would facilitate achievement of both of the primary purposes of Codes: 1) help protect health of consumers, and 2) help assure fair practices in food trade.

## NHF - National Health Federation

GENERAL COMMENTS
Background

The draft should make clear that, although it has been decided to limit the present scope of work to vitamins and minerals (an approach that was contrary to the NHF's written recommendations made to the CCNFSDU in June 2004, March 2007, and June 2008), there are a wide range of other important micronutrients which are required by consumers, these including essential fiber, fatty acids, amino acids, nucleotides, phytonutrients, enzymes, probiotics, and prebiotics. Failure to make clear the importance of micronutrients other than vitamins and minerals – as well as recommendations for particular categories and sub-categories of macronutrients – would be both misleading and a disservice to consumers. It would also be contrary to the general principles laid out in the WHO's Global Strategy on Diet, Physical Activity, and Health.

The range of factors that contribute to a variation in micronutritional requirement between individuals should also be made clearer. Factors that should be expanded upon include, but are not limited to: variations in dietary intake; genetic make-up; ethnicity; gender; life stage; lifestyle; body weight; health status; physiological/immunological stress; and mobility/exercise regimen.

**COMMENTS ON SPECIFIC QUESTIONS**
**Question A1. For establishing principles and criteria for NRVs-NCD, do you support a similar organization as for the vitamin and mineral NRVs with separate sections for a Preamble, Definition(s), and General Principles at a minimum**?

**Response**: Yes, because this will track better the format and organization of other Codex documents.

**Question A2. Do you support the above topics under general principles or have other suggestions?**

**Response:** In the past, NRVs, usually expressed as RDAs, have been a vehicle for merely attempting to ensure the minimal necessary health to avoid death (such as in the case of preventing scurvy through small amounts of Vitamin C) or extreme ill-health (such as arguably in the case of the small amounts of Vitamin D). This is an outmoded and narrow-minded way of thought. A far better approach would be to take this opportunity to consider NRVs as a vehicle for optimizing health, particularly in strengthening the body so as to prevent noncommunicable diseases. Therefore, we propose that the topic "Consideration of values that would optimize human health" be added to the list of general principles.

**Question B1. How would you describe the population(s) for which NRVs-NCD would be applicable? For example, do you support their applicability to the "general population"?**

**Response:** NHF believes that there are population groups to which NRVs-NCD would be applicable. In that sense, the second question is vaguely worded since the NRVs-NCD would of course be applied to the "general population" but with further explanation. That is, various differences within the general population should be considered. An NRV-NCD that might be appropriate for an adult female may very well not be for an adult male, and vice versa. It would be inappropriate and remiss on our part to not take into account such important biological and physiological differences within the general population group.

**Question B2. If the answer to the second question above is "yes", is there a need to further define an age range for the "general population"? If so, what criteria should be used for defining this age range?**

**Response:** Yes, as mentioned above, there is most definitely a need for further definition. Given the above, the NHF does not think it is appropriate to issue a single value for each NRV for a given population group.

As stated by the NHF during the CCNFSDU's 29th Session (see page 21, paragraph 131 of Report), the NHF had proposed the idea of providing an NRV for the population group with the greatest requirement. Given that this was not accepted by the Committee, the NHF, having consulted with medical doctors working in the field of clinical and functional medicine, wishes to propose an alternative approach. This would involve the publication of a Nutrient Reference Range (NRR), in addition to an NRV. Ranges are already widely used in the medical profession for such markers as cholesterol, triglycerides, and hormones and are well understood by the consumer. An average value is scientifically weak compared with a range of values, given that the average represents nothing more than a mathematical approximation of a given range (each with variable statistical distributions) and does not necessarily indicate a requirement for an individual. The range could be comprised of the 10th centile requirement for the lowest value in the range and the 90th centile for the highest value.

The NHF proposes that a nutrient range is an extremely useful indicator, but for it to have scientific value, as well as value to the consumer, it must be based upon the most recent scientific evidence, that includes an assessment of all available, and the most recent, observational and clinical evidence, as well that derived from qualified experts with the greatest experience and knowledge of the effects of micronutritional intake and supplementation, namely medical doctors practicing clinical nutritional or functional medicine. The range should also take into account the requirement for optimum health, rather than provide the minimum value for the prevention of certain well-known vitamin or mineral deficiency-related diseases (e.g. scurvy, beri-beri, rickets, pellagra, anemia, etc.).

**Age-specific Reference Values**. Given that the Committee has agreed to develop NRVs for infants by 2012 (that is, by the 34th Session of the CCNFSDU), it is important that current NRVs, and any subsequent modifications to NRVs, are expressly indicated to exclude infants. To ensure that the risk of young persons being exposed to excess nutrients – a concern of some Codex delegations such that they are inclined to support an Average Requirement/Estimated Average Requirement (AR/EAR) approach rather than a highest-level approach – the NHF recommends that a clear indication is made that the values apply to adults only, with further indications of any additional exemptions (e.g.,

pregnant or lactating women). This could be by way of a footnote describing the meaning of the value or range of values.

It is important to remember, though, that the Estimated Average Requirement is defined as the usual intake level that is required to meet the requirement of ***half*** the ***healthy*** individuals in a life stage and gender group. At this level of intake, the other half of the healthy individuals would not have their needs met. Therefore, the NHF in no way condones or suggests use of an AR/EAR approach or application.

A ***highest*** RDA/PRI approach, while more valid than any approach utilizing either weighted RDA/PRIs or highest ARs, is only scientifically valid if it takes into account the following factors:

a) dietary intake

b) genetic make-up

c) ethnicity

d) gender

e) life stage

f) lifestyle

g) body weight

h) health status

i) physiological/immunological stress

j) mobility/exercise regimen.

k) The most recent clinical and published evidence (from observational and clinical studies)

Based upon the above, NRV-NCD values could be established for multiple life stages, as previously suggested by the NHF. These would provide a more nuanced approach and would include the following:

Infants 0-6 months
Infants 7-12 months
Children 1-3 years
Children 4-8 years
Males 9-13 years
Males 14-18 years
Males 19-70 years
Males > 70 years
Females 9-13 years
Females 14-18 years
Females 19-70 years
Females > 70 years
Pregnancy
Lactation

An assessment of the existing proposed ***highest*** RDA/PRI values, though, demonstrates very clearly that the levels for adults are still well beneath those that would be typically considered, by medical doctors practicing clinical nutrition or functional medicine, both safe and beneficial (particularly in terms of reducing the risk of chronic, degenerative diseases) for the majority of individuals.

**Question C1: Do you agree that the purpose and use of the NRVs-NCD should be addressed in a preamble in the development of general principles for these NRVs?**
**Response:** Yes.

**Question C2: If so, do you have comments on the above possible adaptation of text in the vitamin and mineral NRV preamble or other suggestions for text to describe the purpose and use of NRVs-NCD?**

**Response:** The NHF suggests that the words "one way" be used in preference to "a means" since the wording "one way" is more vivid and absorbable by the human mind when reading the text. In addition, NHF supports the deletion of the first struck-through sentence ("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.") because it merely amplifies the problem NHF mentioned above whereby an average requirement leaves at least half of the population at a huge nutritional disadvantage.

NHF supports retention, however, of the second struck-through sentence because there could exist nutrient absorption or utilization factors specific to a country or region that could also impact these nutrient values. The Working Group and the Committee need to be careful to avoid adopting a "one size fits all" approach out of sheer convenience or even laziness. Consumer health is too important for that approach.

Most importantly, though, we propose the addition of the words "and optimize health" be added to the end of the first sentence reading, "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/a means) to compare the nutrient content between products."

**Question D1: Is there a need for a definition section in the general principles, and if so what term(s) should be defined?**

**Response**: We have generally found a need for definitions in Codex texts, with this document being no exception. All major terms of art used in this text should be defined, but especially NRVs-NCD and, if adopted, NRRs.

**Question D2: In the Annex to this paper, do you support option 1 or 2 or another option?**

**Response**: Of the two choices, Option 1 may be the better wording. However, NHF suggests that a blend of the two, or an Option 3, could be better overall. The suggested wording would be as follows: "Nutrient Reference Values – Noncommunicable Disease (NRVs-NCD) refer to Codex nutrient reference values for food labeling purposes for nutrients, the lack or less-than-optimal amounts of which are associated with risk of noncommunicable diseases, including diet-related chronic diseases."

**Question E1: Do you agree that the Committee should consider CCFL proposals for expanding the list in section 3.2 but also consider additional factors and criteria in proposing nutrients for NRVs-NCD?**

**Response**: Yes, sodium should be included. Additionally, it is inappropriate, and indeed even irresponsible, to publish revised values, if a range of other key essential nutrients are missing from these determinations. Very obvious omissions are currently: Vitamin E; Vitamin K; pantothenic acid; biotin; inositol; potassium; sulfur; chromium; and phosphorus. Omissions may give the consumer the impression that these nutrients are of lesser value than those for which values are published, or, worse still, are of no nutritional significance.

**Question E2: Do you support including sodium and saturated fat in the scope of nutrients to be considered for NRVs-NCD?**

**Response**: The NHF supports including sodium (as well as the other additional, above-named nutrients) for consideration for NRVs-NCD. The NHF has mixed opinions on the inclusion of saturated fats, but generally notes that given an adequately-nutritional-dense diet, saturated fats are not typically a health problem in that cholesterol is not a major cause of heart disease, rather it is

calcification of the arteries. Establishing an NRV-NCD for saturated fat would mislead the consumer away from the true cause of heart disease. Moreover, there are other sources of saturated fat than from meat; and consumers could be misled by high vegetable sources of saturated fats that are not necessarily harmful, given the above facts.

**Question F1: What are your views about the use of the above criteria for the development of NRVs-NCD?**
**Response**: These three criteria are a good start, but, as written, the criteria are not comprehensive enough.

**Question F2: Are there other criteria that are applicable?**

**Response:** Other criteria for the establishment of NRVs-NCD are that they should be based upon those amounts necessary to prevent disease, promote optimum health, and prolong lifespan in the majority of the general population.

**Question F3: What are your views about the use of the above principles and criteria for selection of suitable data sources in the development of NRVs-NCD?**

**Response:** The referenced principles and criteria for suitable data sources appears to be very limited in that they call only for consideration of sources outside of FAO/WHO in establishing NRVs only when FAO/WHO has not set such values! That is an incredible and unbelievable limitation, especially when many respected scientific bodies throughout the World would be ignored as possible sources of information. Does this Codex Committee really think that FAO/WHO holds a monopoly on such scientific thought? With all due respect to FAO/WHO, they do not. Why unnecessarily limit ourselves? The Committee can still select and choose amongst many other reputable sources in establishing NRVs-NCD.

Therefore, the introductory language should preferably read:

"Relevant and recent values provided by FAO/WHO and other recognized and authoritative scientific bodies should be taken into consideration in establishing NRVs." [delete the second, following sentence as unnecessary]

**Question F4: Are there other principles and criteria that are applicable?**

**Response:** Please see our response immediately above. In addition, the NHF holds that published data sources from nutritional surveys are presently insufficient to allow scientifically meaningful values for global application. Data relating to trace and ultra-trace elements, for example, are particularly inadequate. In the absence of adequate data, there can be no alternative but to gain interim input from a panel of experts, derived from leading medical doctors practicing in the fields of clinical nutrition and functional medicine.

It would be quite irresponsible to continue such work if the appropriateness and benefits of any values were not considered by a panel of experts with the greatest expertise in this field. A great concern is that most of the expertise presently being deployed in the development of NRVs is derived from experts in the field of risk assessment, who utilize primarily published data, based upon highly precautionary models. At no time has clinical expertise been sought, nor has there been adequate input from experts deeply familiar with the beneficial effects of nutrients and micronutrients, their ability to promote optimum health and minimize risk of disease. Again, we strongly recommend that an expert panel with relevant clinical expertise be established to allow a meaningful review of proposed values.

**Question F5: Do you have suggestions for specific references that the Committee should consider based on the above criteria?**

**Response:** Please see our response to Question F3 above.

**Question F6: Based on your responses to F1 through 5 above and consideration of any other relevant information, are there particular nutrients that should receive the highest priority for the development of NRVs-NCD?**

**Response**: Vitamin C, Vitamin D, Folic Acid, Magnesium, and Selenium.

**Question G1: With regard to daily intake reference values from recognized authoritative scientific bodies that are expressed as a percentage of caloric intake, do you support establishing a Codex NRV-NCD based on a reference diet of 2000 calories or another calorie level?**

**Response**: Yes, if any Codex NRV-NCD is to be established, then it should be based upon a 2000-calorie diet.

**Question G2: Do you agree that any single daily reference caloric intake selected for the Codex NRVs-NCD may not be applicable to all countries? If so, do you support: 1) indicating this in the general principles, and 2) including in any proposed table on NRVs-NCD not only the NRVs-NCD based on the single reference caloric intake (in milligrams or grams), but also daily intake reference values for the selected nutrients (as a percentage of calories) for governments to derive their own values based on another reference caloric intake?**

**Response:** Yes, the NHF agrees. This is exactly why the suggested Nutrient Reference Ranges (NRRs) would accommodate this variability. NRRs should be acceptable to all Codex members and INGOs as a viable compromise that makes sense given this variability.

***Summary of Specific Recommendations***
***1. A range of daily intakes (NRRs) is much preferable to a single value, as indicated above. These ranges should not only be based on experimental data, as these data are often too limited to be applicable to all key sub-population groups. It is critical that observational studies as well as clinical evidence are taken into account. An expert panel comprising leading medical experts in the field of clinical nutrition and functional medicine should be assigned to assist with this work. The Institute of Functional Medicine (www.functionalmedicine.org) is probably the World's largest repository of such international expertise and the IFM should be contacted to assist in gathering an international panel of experts for this purpose, for evaluation by the Committee.***
***2. A highest RDA/PRI approach is preferred over the weighted RDA/PRI or highest AR approach, but it is essential that all factors and the most recent scientific evidence is taken into account in determination of any values. These determinations should consider evidence from observational and clinical studies, as well as input from medical doctors practicing in the field of clinical nutrition and functional medicine. A panel of such experts should be consulted in the determination of these levels.***
***3. Data for "missing nutrients" should be included as a matter of priority, and revised values should not be published until such time as agreed upon.***
***4. The NHF considers that, in the absence of adequate international sources of data, it is of utmost importance to establish a panel of medical experts with extensive clinical experience in the fields of clinical nutrition and functional medicine. Input from this panel will be invaluable in dealing with deficiencies in the quality or applicability of existing sources of data from existing international and national authorities***
***5. We propose that the re-evaluation and development of NRVs cannot be continued without bringing to bear a new expert panel with extensive clinical experience in the fields of clinical nutrition and functional medicine.***

## World Sugar Research Organisation - WSRO

Before addressing the detailed questions posed in the Discussion Paper, a number of general observations are pertinent.

1. It is important to bear in mind that the scientific evidence currently available suggests an association between excessive consumption of certain nutrients and an increased risk of certain noncommunicable diseases. It is important that the consumer is not misled into believing that ***all*** the nutrients under consideration are each associated with an increased risk of ***all*** noncommunicable diseases. On the contrary, the evidence suggests only specific associations, such that a given nutrient may be associated with an increased risk of certain noncommunicable disease but not others. Consequently, it would be unhelpful to adopt any terminology, or form of words, that obscures this central issue. For this reason, WSRO is strongly opposed to the application of the terminology NRV-NCD to an isolated nutrient, since it implies that the nutrient is generally responsible for increasing the risk of all noncommunicable diseases. Equally, misleading and simplistic phrases should be avoided, such as " a diet high in fat, salt and sugars is (sic) associated with an increased risk of obesity, cardiovascular disease, cancer and tooth decay".

2. At the same time, it must be kept in mind that in ***no case*** is any nutrient, or group of nutrients, the ***sole influence*** on risk of any of the noncommunicable diseases. Several forms of words currently in common usage among nutritionists have the potential to mislead non-specialists audiences into believing that nutrients, or dietary patterns, are the only modifiable influence on risk of noncommunicable diseases. These include "diet related chronic diseases" and might include " Nutrient Reference Values – Noncommunicable Diseases" or Nutrient Reference Values – Diet-Related Chronic Disease" were either of these terminologies to be adopted as a result of the current discussions.

3. It is also relevant that little, if any, direct evidence from intervention studies is available relating to the influence of specific nutrients on the risk of noncommunicable disease ***in a general population***. Such studies have generally been considered too expensive to conduct. In some cases (e.g. fat-modified diets and coronary heart disease risk indicators) intervention studies have been conducted in population groups not subject to clear evidence of pre-existing disease (primary prevention) but these studies have rarely assessed "hard" end points (such as confirmed myocardial infarction) focussing instead on surrogate risk indicators (such as circulating LDL cholesterol). If NRVs are to be derived in relation to the risk of noncommunicable disease in a general population, this weakness in the evidence base must be kept in mind and suitable caveats applied to any conclusions drawn.

4. A further limitation has also been highlighted by the recent FAO/WHO update group considering carbohydrates. This is that much of the evidence that has been used to derive associations between specific nutrients, or other food components, and the risk of the different noncommunicable diseases cannot distinguish between the influence of the nutrients in question, and that which relates to the food (or indeed the food matrix) in which the nutrient is embedded. Thus it is currently difficult to assert with any certainty that a given nutrient/disease association is, in fact, not a surrogate association for another component of those types of food that are important sources of the nutrient. Although the report of this group mentions this issue specifically in relation to dietary fibre, their comments are relevant *mutatis mutandis* to much of the evidence associating "nutrients" to the risk of noncommunicable disease.

5. In light of these considerations as to the difficulties likely to be encountered in the proposed work to establish credible values for the NRVs of macronutrients associated with noncommunicable diseases, it might be wise to limit the list of macronutrients to be considered in this work to those identified by CCFL as desirable for food labelling purposes. Indeed, it is not clear that work to derive NRVs for any nutrient that will not be used for food labelling purposes is within the operational mandate of CCNFSDU.

Specific Questions Posed in the Discussion Paper

**Question A1** The structure of any paper addressing principles and criteria for deriving NRVs in relation to noncommunicable diseases might sensibly be as described, i.e. Preamble followed by

Definitions and then General Principles (to include Criteria for selection of which nutrients to consider).

**Question A2** In addition to the three headings suggested (Criteria for selection of nutrients; selection of suitable data sources to establish NRVs; selection of appropriate basis for expressing NRVs) there must be consideration of age and sex specific values, if only to establish that these are unnecessary for each nutrient considered. The question of upper levels of intake is also extremely important, since without evidence that an UL can be identified with some degree of certainty, confidence in the necessity to define NRVs, and any values chosen, will be considerably weakened.

**Question B1** The population for which any macronutrient NRV applies must be a general population if it is to provide any practical help in food labelling. It therefore follows that it must be shown to be possible to identify a single set of NRVs, for any of the nutrients under consideration, that is applicable to the general population, without evidence of unintended consequences for sections of the population. If sections of the population would be disadvantaged by following the advice provided by the quotation of the NRVs on food labels, then they should not be so used.

**Question B2** It is certainly necessary to define a "general population" age range for which any NRV is applicable, if they are to be cited on food labels. To avoid confusion, the same age range should be applicable to all the NRVs cited on a given food label. The selection of this age range must be undertaken with great care in light of evidence that mothers of young children may disregard, or be unaware of, advice not to apply adult guidelines on fat intake to infants. The age range for which a "general population" NRV is applicable should ideally be very wide (including infants from weaning if possible). If the evidence available suggests that only a narrower age range is possible, then practicable and effective means of informing the public of this narrower range must be available and applied before the NRVs are introduced onto food labels.

**Question C1** The purpose and use of these NRVs should be made clear in the Preamble to the Principles for their development, together with relevant limitations on their interpretation and use. So, in addition to a range of other matters, the Preamble should mention the five issues raised at the beginning of this response paper.

**Question C2** The proposed deletions to the text are not necessary and may lead to important considerations being neglected. As one example, the NRV for saturated fat is likely to be significantly different for populations whose diets contain a high proportion of fish, compared with those that contain little.
WSRO would strongly suggest the preamble should address the issues raised in points 1-5 of this paper.

**Question D1** A definition section would be invaluable and should include unambiguous definitions of all terms used in the text that are unfamiliar to most members of the public or of a state legislature. Crucially, definitions should be given for any technical term used where there are other terms with similar meaning in common technical use, especially where there are significant differences in the meaning of two otherwise comparable terms.

**Question D2** Both option 1 and option 2 in the annex use terms that are likely to mislead (as outlined in paragraphs 1 and 2 of this paper). A simpler term, **plain NRV**, would be preferable, since the criteria used to set NRVs differ for each macro and micro nutrient. Provided the quality and reliability of evidence is available to justify the choice of NRV, it is unnecessary and unhelpful to try to specify the reasons for each figure chosen. Labelling a particular NRV as being relevant to the prevention of noncommunicable diseases could lead to confusion as to the purpose of other NRVs.

**Question E1** The list of nutrients to be considered in the present context of noncommunicable diseases should correspond to those that CCFL intends to recommend for nutrient labelling, whether CCFL recommend a mandatory or voluntary list. For the reasons given above, an overambitious

expansion of the list will lead to insurmountable difficulties in resolving all the issues of evidence that will arise.

**Question E2** The answer to this question is given above in E1. These nutrients should only be included in the current discussions if CCFL have decided to recommend they should always be labelled. In addition, particular problems arise with labelling for sodium that are to be considered by an e-working group. A decision whether to include sodium should logically await the outcome of the e-working group's deliberations.

**Question F1** The three criteria suggested for the development of these NRVs are ambiguous and vague.

In particular, in **Criterion 1**, the use of the term "strong" scientific evidence is subjective and lacks clear meaning. What is needed is consistent evidence of a quality that is generally accepted to be persuasive (i.e. carefully controlled intervention studies). Evidence that is circumstantial, however reproducible, should not be accepted (e.g. observational epidemiology). Evidence that is based on methods that are known to be unreliable (such as case control studies and dietary assessments using food frequency measurements) should also not be accepted. Expert opinion, unsupported by evidence as outlined above is unacceptable. The nutrient disease relationship must also be of sufficient affect size to merit attempts to modify consumption.

**Criterion 2**. A further relevant example of a "public health importance" hurdle that should be addressed is where more practicable and effective non-nutritional approaches to the prevention of the disease in question are available. The selection of a NRV in this case will mislead the public into focussing on nutritional approaches to disease prevention rather than better, non nutritional means.

**Criterion 3.** Provided the term "strong evidence" is defined as above, this criterion is acceptable.

**Question F2** In addition to these criteria, it is extremely important that there is evidence of safety. Populations conforming to the proposed desirable intake ranges must be identified and shown not to have any adverse long term affects from their nutrient intake, or unacceptable unintended consequences (for example, unacceptably altered intake of another nutrient). In the absence of such evidence of safety, the wisdom of making population-wide recommendations on intake should be questioned, especially if those recommendations differ substantially from current intake levels. "First do no harm" is a universal medical maxim that must be applied here. The issue of unintended consequences, either for vulnerable population groups, or for specific products, is highlighted in the Global Strategy (see **WHA 57.17 paragraph 2.8).**

**Question F3** The use of the term "data source" represents a significant weakening of the necessary evidence base. Data is only as valuable as it is reliable and interpreted objectively. Reviews are insufficient evidence unless these can be seen to be independent, comprehensive, objective and unbiased. WHO/FAO Technical Report 916 "Diet, nutrition and the prevention of chronic diseases" (referred to elsewhere in this Discussion Paper) failed to meet these exacting standards and should not be used further as a source of opinion. The WHO Global Strategy on Diet Physical Activity and Health made no reference to this controversial Technical Report.

The reliability of estimates of NRVs or of the evidence underpinning their assessment, is more dependent on the quality of the review process than its date of completion. Priority should be given first to the quality of the review of the data, and more recent reviews should only take precedence if they contain significant new evidence, that was not available to an earlier review, and which materially influences the conclusion that should reasonably be drawn. More recent reviews overturn the conclusions of an earlier review should be judged on their scientific merits, not merely on their date of publications.

**Question F4** Other principles and criteria that are crucial to the selection of a reliable evidence base are to select reviews that are systematic and comprehensive; that have involved independent groups of experts chosen by a transparent selection process; that have used appropriate statistical methods; have excluded unreliable evidence (see above); that have considered untoward consequences of intervention seriously and thoroughly; and that have been free ***not*** to draw conclusions when the evidence is considered insufficient.

**Question F5** Reviews have differed markedly in their conclusions with regard to any involvement of sugars in the aetiology of obesity or other chronic diseases. For the current discussions, a non-exclusive list of the reviews that should be consulted would include:

FAO/WHO (1998) Carbohydrates in Human Nutrition. Report of a Joint FAO/WHO Expert Consultation. FAO Food and Nutrition Paper No 66.FAO, Rome.

Health Council of the Netherlands (2001) Dietary Reference Intakes: energy, protein, fats and carbohydrates. Health Council of the Netherlands, The Hague

Food and Nutrition Board, Institute of Medicine, National Academy of Sciences (2002) Dietary reference intakes for energy, carbohydrates, fiber, fat, protein and amino acids. National Academic Press.USA.

World Health Organisation (2003) Diet, nutrition and the prevention of chronic diseases. Technical Report Series 916. WHO,

FAO/WHO (2007) Scientific update on carbohydrates in human nutrition. European Journal of Clinical Nutrition. 61 (Suppl. 1) S1-S137

World Cancer Research Fund / American Institute of Cancer Research. Food, Nutrition and the Prevention of Cancer: a Global Perspective. Washington DC: AICR, 2007.

**Question F6** The nutrients that should be given the highest priority are those that most closely meet the criteria outlined in this response paper. These are carbohydrates, proteins, fats. Only if it proves possible to derive acceptable NRVs for these major macronutrient groups, should NRVs for the ***recommendations*** contained in the Global Strategy be attempted ***(see WHA 57.17 paragraph 2(1) and Annex paragraph 22)***.