CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 7 **CX/NFSDU 10/32/7-Add.1**
October 2010

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Santiago, Chile
1 – 5 November 2010

PROPOSED DRAFT NUTRIENT REFERENCE VALUES (NRVS) FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NONCOMMUNICABLE DISEASES FOR GENERAL POPULATION AT STEP 4

- *Comments at Step 3 of the Procedure* -

Comments from:

ARGENTINA
CANADA
CHILE
EUROPEAN UNION
JAPAN
MALAYSIA
NORWAY
UNITED STATES OF AMERICA
IFT - Institute of Food Technologists

ARGENTINA

Referencias

Comentarios de Argentina en cursiva

Sugerencias de cambios de texto en cursiva y negrita

Argentina agradece la posibilidad de realizar los siguientes comentarios:

PREAMBLE

These principles apply to the establishment of Codex Nutrient Reference Values for labelling purposes for nutrients associated with risk of diet-related noncommunicable diseases (NRVs-NCD) for the general population identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products. 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, **for these nutrients and for other nutrients**. Governments may also consider whether to establish separate food label reference values for specific segments of the general population.

1) Se propone eliminar la ultima frase "Habrá gobiernos que decidan utilizar los (VRN-ENT) …..hasta …..con fines de etiquetado".

La razón de esta sugerencia se debe a que cada país como autoridad sanitaria, de acuerdo a su reglamentación y práctica jurídica decidirá la adopción o no plena de la Norma de Codex, sin necesidad de tener que reiterar esta potestad nacional en el preámbulo.

2) *Por otro lado se considera apropiado unificar la redacción de los puntos 1 y 2, unificándolos sin establecer un orden de importancia en ellos. Resultando lo siguiente:*

Estos principios se aplican al establecimiento de valores de referencia de nutrientes del Codex con fines de etiquetado en relación con los nutrientes asociados al riesgo de (enfermedades no transmisibles, VRN-ENT) para la población general, identificada como individuos sanos mayores de 36 meses. Estos valores pueden utilizarse para ayudar a los consumidores ~~1)~~ a la hora de calcular la contribución relativa de los diferentes productos a la ~~ingesta dietética total~~ ingesta diaria saludable ~~sana~~ y ~~2)~~ como ~~(~~ un medio ~~/una de las formas)~~ de comparar el contenido de nutrientes entre los productos. ~~Habrá Gobiernos que decidan utilizar los (VRN-ENT) y habrá otros que tengan en cuenta la idoneidad de los principios generales expuestos a Continuación, así como otros factores específicos del país o la región a la hora de establecer sus propios valores de referencia con fines de etiquetado. Los gobiernos podrán considerar si establecerán valores de referencia de ingesta de nutrientes a los fines de etiquetado nutricional para grupos etarios específicos de la población.~~

2. DEFINICIÓN /*DEFINITION(S)*

Nutrient Reference Values - Noncommunicable Disease (NRVs-NCD) refer to Codex nutrient referent values for food labelling purposes for nutrients that are associated with risk of diet-related ~~**chronic**~~ noncommunicable diseases **not including nutrient deficiency diseases**. **[The NRV-NCD represents the nutrient recommendations for the general population.]**

Se debería eliminar el termino ***"chronic"*** *de la definición, teniendo en cuenta los términos utilizados en la estrategia Mundial de la OMS sobre Régimen Alimentario, Actividad Física y Salud.*

[Daily Intake Reference Values as used in these principles refer to reference intake values provided by FAO/WHO or other recognized authoritative scientific bodies that may be considered in establishing an NRV-NCD based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g., as a single value or a range), and are applicable to the total population or to a segment of the population (e.g., commendations for a specified age range). For macronutrients, they are generally expressed as a percentage of energy intake).]

ESTOS DOS PÁRRAFOS EN NEGRITA SON PARTE DEL TEXTO, O SE LES HIZO ALGUNA MODIFICACIÓN NO EXPLICADA?

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

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:

Argentina considera conveniente eliminar de los párrafos lo tachado atento a que los criterios que deberían ser considerados para la selección de los nutrientes para el establecimiento de los NRVs-NCD deben ser relevantes, disponibles y con evidencia científicamente revisada, resultando de la siguiente manera:

• **~~[Convincing] [Convincing or Probable] [Generally accepted]~~** and relevant **[available] [peer-reviewed]** scientific evidence for the nutrient-noncommunicable disease risk relationship

- ***Relevant, available, peer-reviewed scientific evidence for the nutrient-noncommunicable disease risk relationship***
- ***Public health importance of the nutrient-noncommunicable disease risk relationship among Codex member countries***

• [**~~Convincing] [Convincing or Probable] [Probable~~**] and relevant **[peer-reviewed]** scientific evidence for a quantitative reference value for daily intake that is applicable to the general population older than 36 months ~~of Codex member countries~~

Con respecto a esta última oración se considera que es confusa, razón por la cual antes de adoptar una decisión, sería necesario contar con aclaraciones respecto a la intención del mismo.

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 **as primary sources** in establishing NRVs-NCD. Relevant and recent values **that reflect independent review of the science,** from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration. **These values should reflect intake recommendations for healthy populations.**

3.2.2 Higher priority should be given, as appropriate, to values from recognized authoritative scientific bodies **in which the evidence** has been evaluated through a systematic review.

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

3.3.1 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 energy intake.

3.3.2 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.

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

Argentina considera que el texto que sigue que se encuentra entre corchetes no es necesario, teniendo en cuenta sus observaciones respecto del preámbulo de este documento. Por lo tanto, se sugiere su eliminación.

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

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

[3.4 Consideration of Daily Intake Values for Upper Levels

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

CANADA

Canada would like to thank the US, Thailand and Chile for preparing the report of the electronic working group on Principles and Criteria on the Development of NRVs for labelling purposes for nutrients associated with diet-related noncommunicable diseases. We are pleased to offer the following comments on the report and proposed revised text.

The paragraph numbers refer to the paragraphs in the report.

Section 1. Preamble

Paragraphs 32-33: The report makes reference to one comment that did not agree with the proposal to allow governments to establish their own additional reference values as stated in the preamble because this would not be in the interest of international standardization and harmonization of labelling. While there may not be text in 3.4.4 of the Guidelines on Nutrition Labelling making reference to this not being in the interest of international standardization and harmonization of labelling, the food standards adopted by Codex Alimentarius are for the purposes of protecting consumers' health and ensuring fair practices in the food trade. The publication of the Codex Alimentarius is "intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so facilitate international trade." (Codex Procedural Manual, 19th edition, pg 17.) Thus the commenter is correct in bringing to the electronic working group's attention the fact that the current preamble does little to support the latter purpose of Codex standards. At the same time, there are legitimate health reasons for countries to adopt different NRVs than those set out by Codex. In order to bring the proposed draft General Principles into better alignment with the fundamental principles underlying Codex texts, Canada proposes the following change to the third sentence of the preamble paragraph, for consideration:

"A government may select to use the NRVs-NCD, or alternatively, *where these do not adequately protect the health of consumers in a given country or region, consider the suitability..."*

Paragraph 37: Canada agrees that there should be no examples of nutrients in the preamble given that there are none as yet in the Guidelines on Nutrition Labelling and inserting any here presupposes which nutrients will meet the criteria.

This concern suggests the need to specify in the Guidelines on Nutrition Labelling which NRVs are set on which basis once they are added there, as also discussed below. If examples are needed in the meantime to assist people in making deliberations, these could be noted during the physical working group meeting being held on October 29, 2010 and noted in the report of that meeting to the Committee for the record.

Paragraph 38: Canada agrees that it would be important for the Committee to consider the potential for having 2 NRVs for the same nutrient and the implications of this. For example, if two are identified, consideration will need to be given to establishing standards as to how these are to be positioned on the food label and their appropriate use conveyed to the consumer.

Paragraph 39: Overall, a distinction does appear to be needed both in the Guidelines on Nutrition Labelling and on food labels between NRVs set for different purposes, including in the potential case of setting two NRVs for the same nutrient. For example, currently there is discussion in Canada about changing the basis for the Daily Value (a type of NRV) for sodium from a number very close to the UL of 2300 mg down to the Adequate Intake (AI) of 1500 mg. This raises the question of how the consumer should use a given value depending on their understanding of the concerns about the nutrient: is it set at a level below which intakes should stay or one to which intakes should rise? Labels may need to provide information to guide the consumer about how to use the % Daily Value. Canada supports having a discussion, either in plenary or at a subsequent eWG, about distinguishing the types of NRVs in the GNL and about the type of format and presentation on labels that might be needed to distinguish nutrients set for different purposes.

Section 2. Definitions

Paragraph 44: Canada agrees with retaining the term "chronic" along with the additional clarification that the diet-related chronic non-communicable diseases exclude nutrient deficiency diseases.

Paragraph 47: Canada agrees that there is no need to include a definition of nutrient reference value (NRV) in the General Principles for NRVs-NCD if one will be included in the Guidelines on Nutrition Labelling. However, as noted above, Canada agrees that the question of whether the GNL and the label should distinguish different types of NRVs deserves further consideration. This would mean then that the definitions for the two types would also need to appear in the GNL. Even in this case, however, it would be acceptable to retain the definition of NRV-NCD in the General Principles for NRVs-NCD.

Paragraph 54: Canada previously indicated that it was not necessary to include a definition of UL here if there was one that can be used in another document, e.g. the Codex Procedural Manual (CPM). On further reflection and consideration of other comments made, there may be a need for a definition for Upper Level of Intake that is more pertinent to the type of values used to establish NRVs-NCD in these Principles although the definition of UL in the CPM may still be pertinent for some nutrients. How these values are to be used, however, is not clear (see also Paragraph 97, below).

Para 57-58: Canada would propose a small modification to the draft definition for "Daily Intake Reference Values" for greater clarity: add the word "nutrient" before "intake" in the definition.

Section 3. General Principles for establishing NRVs-NCD

3.1 Criteria for selection of nutrients

Paragraph 70: Canada agrees with using the FAO/WHO terminology. Also, Canada considers that evidence should be "convincing" for a nutrient-noncommunicable disease risk relationship to select nutrients for the establishment of NRVs-NCD.

Paragraph 71: Canada would support the inclusion of the term "peer-reviewed" in the first bullet of 3.1. We are not convinced of the need for the term "available".

Paragraph 72: Canada would be happy to keep the order of the three bullets the way it is but we don't have a strong view.

Paragraph 76: For the evidence for the value (third bullet), "probable" would be acceptable. If there is strong evidence of a relationship between a nutrient and the disease-risk but the data for a level of the nutrient is not unequivocal, the precautionary principle would suggest putting something reasonable in place to guide the public about this important information regarding the nutrient disease risk relationship until better information becomes available. This may perhaps be more the case for nutrients that are associated with increased risk than for those associated with increased benefit.

Canada suggests changing "reference value for daily intake" in 3.1 to "daily intake reference value" for consistency with the term proposed above.

Consideration of substitution effects

Paragraph 81: It would seem that, for an energy-contributing macronutrient, a substitution effect is a good enough reason to encourage intake if there is a net benefit. You have to move from one energy source to another and if there is a good substitute that does not increase risk or is of lower risk than other alternatives, then that seems like useful information and a reasonable basis for encouraging its use and therefore providing the information to the public to inform choices. The problem might be in conveying which other energy source should be substituted for.

3.2 Selection of suitable data sources to establish NRVs-NCD

Paragraph 85 and 86: As the text in 3.2.2 is written in the Annex 2, it appears that the higher priority is being given to values derived from a systematic review, whether from FAO or other recognized authoritative bodies. Canada is comfortable with this intention. This also would appear to serve potentially as the beginning of a set of criteria for deciding when a value set by an authoritative body should be used rather than one set by FAO/WHO. We are comfortable with the new wording for 3.2 overall but are interested in discussing further the issue of determining criteria for when values other than FAO/WHO should be used.

3.3 Selection of Appropriate basis for expressing NRVs-NCD

Paragraph 88: We would support placing the current 3.3.3 as a subsection under current 3.3.2 since 3.3.2 only seems to be stating a fact, i.e. that daily intake reference values are expressed in one of two ways. The next section (currently 3.3.3) states what to do with that, i.e. convert those that are expressed as a % energy

to grams or milligrams on the basis of a 2000 kcal diet.

Paragraph 91: Canada does not object to removing the statement "based on another reference energy intake that considers factors specific to their country or region", as proposed. If there is a need to ensure that this concept is understood, this phrase could be integrated into the preamble. For example, a sentence could be added after the second to last sentence of the preamble paragraph, such as, "This may include the reference energy intake that forms the basis on which % energy is stated."

Paragraph 92: Canada would suggest adding the word "adult" before "males and females" in the proposed text for 3.3.4 and agrees with the addition of this text.

Need for additional principle(s) related to upper levels

Paragraph 97: Canada considers that if there is a principle included, such as the proposed Sec. 3.4, regarding the need to "take into account" the upper level of intake, the General Principles should include guidance on how to use a UL or a U-AMDR in establishing NRVs-NCD. Although it does alert those implementing the General Principles in setting NRVs-NCD to consider the potential issues that may arise, it is not clear what to do about it. The same point applies to the General Principles for setting NRVs for vitamins and minerals as well. Canada would welcome discussion on this point.

CHILE

Relevance and topicality. Assess whether the text proposed contributes with health measures aimed at having an effect on the problem. The problem is presented as a risk profile in the introduction.	This document is relevant to ministerial policies in terms of covering nutritional labelling for certain vital nutrients, because of their association with non-transmissible diseases associated with diet. Information, directions or guidelines are then required to provide the consumer with better information, together with options for products that are actually healthier. When we consider the national survey of food consumption we will be able to know more about the situation in our country, and therefore apply these principles properly, especially as regards finding out how to limit certain nutritional content.
Another point of view would be to estimate whether the standard will improve or worsen the international exchange of this kind of foodstuff, in the medium and long term.	The document will contribute to the regulation of vital nutrients, as well as indicating their presence by means of labelling. The document provides common ground which would assist national decisions in every way, and will help to improve understanding between countries in order to respect differences, as well as providing common scientific factors in this area.
Consider whether the measures suggested in the preliminary study are feasible for application by developing countries. The review might consider technical complexity, available laboratory capacity and economic cost among other things.	It is feasible to implement, and should be adopted by the various governments according to their local situation, considering above all the studies and information available on the population. The population needs to be educated on the information delivered through the labelling, uniting criteria with the various sectors on how nutritional information will be delivered. On the other hand, Chile is presently measuring these nutrients and collaborating with the food industry to obtain information about final content values.

There should not be any duplication of existing regulations.	General principles are also being developed, in terms of adding essential nutrients, and once both these tasks are complete, a single document may be produced, perhaps with two sections.
If there are deficiencies, such as aspects that are lacking, or exist but are insufficiently considered, suggest how this could be improved or complemented with national and regional contributions.	A replacement concept is being discussed, relating to fats for instance: polyunsaturates instead of saturated or trans-fats. We also consider that VR should be covered for sodium and potassium, not just for physiological needs, but also in terms of preventing chronic diseases relating to diet. Points: 3.3.3. to correct the value shown of 2000 kilocalories and kilojoules. 3.d, keep the heading 3.2.3: it is not a decision 3.e, we recommend including it, as well as section 3.3.2 3.f, yes, using the vitamins and minerals model 3.g, agree, with percentage energy.
Introduction / Scope of application and objective	As regards the title, we agree with the concept that it should be binding with non-transmissible diseases *associated with diet*, and with the "General principles" document in terms of following the same line of work, that is, for labelling purposes. Thus, agree, with brackets removed. As regards the FOREWORD: Question 1b. What term would you agree should be used in this foreword and why? Keep "an average", also would you support making this change in the foreword to the NRVs for vitamins and minerals? For both, staying with "an average" since it is a broader concept. Question 1c: Should a phrase be added in the Foreword to clarify that it could be appropriate for governments to set additional reference values on food labels? If so, what are the aspects relating to adding the following after the third sentence? Allowing the broader concept (that is, governments can add any additional nutrient). "assessing how appropriate these principles and criteria are, it is recognised that governments can set up additional reference values as appropriate for purposes of labelling". Yes, with this sentence left in place.
Definitions	Question 2a: Please provide your comments on whether the term "chronic" should be added to the definitions. We do not agree with leaving the term "chronic",

	presently the concept is of non-transmissible diseases. We agree about the remaining content of the definitions. Question 2b: Please comment on whether these draft principles should be included, and define with reasons any of the above terms relating to higher levels of ingestion. YES, considered necessary. Discussed with respect to the need to include UL in the definitions; and in the criteria for choosing nutrients insist that scientific evidence must be “convincing”, a term already defined by the WHO and not use “generally accepted” which is ambiguous
Proposal for national position	Chile relies on this document, its promotion is of value to the Region because it provides reference values for nutrients associated with chronic diseases related to diet.

EUROPEAN UNION

European Union Competence

European Union Vote

The European Union (EU) would like to thank the United States, along with Thailand and Chile for preparing the paper. The EU has the following comments on the revised principles and criteria.

TITLE

The EU can agree to the proposed changes to the title of the document.

SECTION 1. PREAMBLE

The EU can agree to the proposed changes to the preamble of the document.

In its comments to the electronic working group (eWG) the EU had raised the issue of vitamins and minerals which might fall within the discussions on NRVs for vitamins and minerals and NRVs for diet-related non-communicable diseases. The EU notes and accepts the comments of the Chair of the eWG that it is not possible at this stage to identify the nutrients that might potentially be affected. The EU believes that the additional wording "not including nutrient deficiency diseases" should be extended to include "or disorders". This additional wording would help to address this issue.

SECTION 2. DEFINITION(S)

Nutrient Reference Values – Noncommunicable disease - The EU can agree to the additional wording in the first sentence of the definition and would propose that the reference to "nutrient deficiency diseases" should be extended to include "or disorders".

The EU notes that the preamble of the general principles indicate that the establishment of NRVs is for the general population. The EU is not convinced that there is a need to include the second sentence "*The NRV-NCD represents the nutrient recommendation for the general population."* in the definition.

Additional Terms

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

SECTION 3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 Criteria for Selection of Nutrients

First point - In the case of the first principle the EU believes that the evidence should be "generally accepted", this wording is in line with existing Codex texts such as the Guidelines on the Use of Nutrition and Health Claims. In addition, the Guidelines on the Use of Nutrition and Health Claims indicate that the totality of the evidence should be assessed. Therefore the reference to the "available" scientific evidence appears appropriate. This would mean the first principle would be worded as:

- Generally accepted and relevant available scientific evidence for the nutrient-noncommunicable disease risk relationship

Third point – this principle indicates that there should be evidence of a quantitative reference value. The EU believes that this would not necessarily be applicable or possible for all nutrients. For certain nutrients there might be evidence of a positive association between its intake and the risk of developing a disease or disorder but there is not necessarily a clearly identifiable threshold. Therefore, it is not clear that a quantitative threshold could be identified for all cases.

In addition, consideration should be given to the practicalities of being within a certain intake in terms of the overall diet. In the case of the macronutrients the national dietary recommendations may take into account the existing diet of the population as a whole, the feasibility of achieving the recommended intakes, and that the diet is still considered as acceptable to their population. Also, the macronutrients are an integral part of the ingredients in foods, it is difficult to treat them in isolation, so the overall balance of the diet would need to be considered.

The EU would ask the Committee whether NRVs-NCDs could be established in the absence of a quantitative reference value.

If this principle is kept, in line with its position on with the first principle the EU proposes that the reference should be to "**generally accepted** and relevant **available** scientific evidence".

3.2 Selection of Suitable Data Sources to Establish NRVs-NCD

The EU supports the alignment of wording of first two sentences of section 3.2.1 to the equivalent section in the general principles for establishing NRVs for vitamins and minerals. The EU could accept the addition of the sentence "*These values should reflect intake recommendations for healthy populations.*".

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

Title – the EU can accept the proposed change to the title of the section.

Paragraph 3.3.3 – the EU can accept the basis of the NRVs when related to energy being related to a daily energy requirement of 2000 kcal.

The EU notes that the preamble indicates that Governments can use the Codex NRVs-NCD values or can establish their own. Taking into account the preamble it is not strictly necessary to include the sentence below, however, the EU does not have any particular objection to its inclusion in the text.

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

Paragraph 3.3.4 – The proposed paragraph is rather general, the intention of the sentence and any potential interaction with paragraph 3.1 is not clear. The EU would like further clarification but as presented the EU is not convinced that it is necessary.

3.4. Consideration of Daily Intake Values for Upper Levels

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

JAPAN

TITLE

Japan supports the revision of the title.

1. PREAMBLE

Japan supports the removal of all brackets and the new text as proposed.

- Other Bracketed Text: response to para. 28

Japan agrees with the use of the term “one way” and the removal of the brackets.

- Additional Comment on Preamble: Response to para. 38

Japan agrees with the opinion that the Committee could consider whether it would be appropriate to consider two NRVs for a single nutrient if that nutrient met all criteria in both sets of principles but had substantially different recommended intake values established by recognized authoritative scientific bodies with one based primarily on requirements and the other value also taking into consideration chronic disease risk. It is important for this work to take into account the situation of each country having different public health needs for nutrients. In addition, when the Committee decides to list two NRV values for the same nutrient, reference intake values, such as daily intake reference values provided by FAO/WHO or other recognized authoritative scientific bodies as well as dietary reference values (DRIs) provided by a government may be considered.

- Additional Comment on Preamble: response to para. 39

Japan agrees with the opinion that one option for distinguishing between NRVs derived from the two sets of principles as a reference for governments is to consider separate subheadings for the listing of: 1) NRVs based on nutrient requirement levels and 2) NRVs based on risk reduction of diet-related noncommunicable diseases. Based on this opinion, the logic that reference values used for calculation of NRVs should be based on Individual Nutrient Level 98 (INL98) may not be appropriate. For example, in the calculation of “NRVs based on risk reduction of diet-related noncommunicable diseases,” it may be necessary to use other reference values, such as estimated average requirement (EAR) and/or dietary goal (DG), in addition to $INL_{98.}$

2. DEFINITION(S)

- NRVs-NCD: response to para. 44

While it is recognized that NRVs may be expanded to all the nutrients in the future, it is important to clarify the aim and scope of this work, Japan supports retaining the term “chronic” in the Definition.

- Nutrient Reference Values (NRVs) : response to para 47

With regard to the issue whether a definition of “NRVs” should be included in these general principles in addition to the definition of “NRVs-NCD,” Japan commented at the eWG to insert the definition of “NRVs” in addition to that of “NRVs-NCD” in order to address the issue regarding use of Estimated Average Requirement (EAR). However, this issue may be discussed as commented in the para. 39, Japan supports that a definition of “NRV” is not proposed to be included in Annex 2 in addition to the subsidiary definition of NRV-NCD.

- Need for Definition(s) for Types of Values to Be Used to Establish NRVs-NCD: response to para. 54

Japan supports the placement of the Codex definition of Upper Level of Intake in brackets in the definition section of Annex 2.

With regard to the definition of Upper Level of Intake in this work (the need for definitions pertaining to the type of values used to establish NRVs-NCD), definition of “a maximum level of the habitual intake that is considered to be free of the risk of causing a disease due to excessive intake” may be appropriate. Upper Level of Intake may pertain to two concepts: one as a level that cause disease due to excessive intake (toxicity) and the other as a level related with disease risk reduction, the level estimated to achieve reduction of a disease risk and/or a value of the marker in a specific population. In Japan, these ideas have been clarified in the Dietary Reference Intakes: tolerable upper limit intake (UL) as an upper limit of the habitual intake that is considered to be free of the risk of causing a disease due to excessive intake, and dietary goal (DG) as an intake level (or range) that Japanese should currently aim to consume primarily to prevent lifestyle-related diseases. Although further refinement may be necessary, discussion may be needed regarding such issues.

- Need for Definition(s) for Types of Values to Be Used to Establish NRVs-NCD: response to para. 58

Japan supports the addition of the definition in square brackets to Annex 2. However, further discussion may be needed. More issues need to be clarified.

- Need to Define Additional Terms: response to para 62

Japan does not disagree with the position that they have not proposed to include definitions for "noncommunicable disease" or "general population" in Annex 2.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 CRITERIA FOR SELECTION OF NUTRIENTS

- *Sec. 3.1 (1st Bullet)*: response to para. 70

Japan recommends using the terms, "convincing or probable."

- *Sec. 3.1 (1st Bullet)*: response to para. 75

Japan supports the opinion that it is important to describe a desired level of evidence for a quantitative reference value for daily intake would still appear to be an appropriate criterion in selecting nutrients for NRVs-NCD although source documents may not assign strength of evidence to a specific numeric value.

- *Sec. 3.1 (1st Bullet)*: response to para. 77

Japan reserves the opinion on "relevant peer-reviewed scientific evidence." "Relevant peer-reviewed scientific evidence" is a prerequisite for the "convincing" or "strong" evidence, so that the inclusion may not appear to change the meaning. However, the need of the inclusion may depend on whether this issue relates with a case for evidence that does not reach such level.

- *Sec. 3.1 (1st Bullet)*: response to para. 81

With regard to the issue whether a main effect being based on substitution of another nutrient should be addressed in some way in these General Principles and/or Section 3.4.4 of the Guidelines, prudent discussion may be necessary. Discussion with several examples of nutrients, whose main effects being based on substitution of other nutrients, may be helpful. Further discussions at the Joint FAO/WHO Expert Consultation or other recognized authoritative scientific bodies may also be needed.

3.2 SELECTION OF SUITABLE DATA SOURCES TO ESTABLISH NRVS-NCD

- 3.3.1 & 3.3.2: response to para. 89

Japan agrees with the proposal to include the text as a subsection of 3.3.2. since it may be a more logical presentation

- 3.3.3: response to para. 90

With regard to proposal for edition, Japan does not disagree with this proposal.

- 3.3.3: response to para. 91

Japan considers that proposal to delete the text, "based on another reference energy intake that considers factors specific to their country or region," is not appropriate. Considering the additional factors specific to a country or region in establishing their own reference values for labelling purposes is very important, and this is also important in perspective of the nature of this work.

- 3.3.4: response to para. 93

Japan supports an inclusion of a modified version of the proposal in new 3.3.4 for the Committee to consider. With regard to the need to determine an NRV-NCD by gender, however, evidence-based logical reasoning is required, and prudent discussion may be needed.

- 3.3: response to para. 95

Japan supports to retain the heading of "Selection of Appropriate Basis for Expressing NRVs-NCD. With regard to the proposal to add a provision in 3.3 that is related to the determination of NRVs-NCD, however, the determination and expression of NRVs-NCD may be better to be presented separately depending on the scope of the General Principles.

OTHER SUGGESTED TEXT FOR THE ANNEX: response to para. 100:

Japan supports the position of Canada at the 32nd CCNFSDU. In evaluating dietary intake and developing nutritional plans for the general populations, use of EAR established based on Probability Theory is necessary. This view is derived from the idea that recommending the intake for nutrients (based on the EAR) which are not in deficit is a way to avoid risk of excessive intake in the general population since variance of intake and requirement is substantial.

MALAYSIA

1. PREAMBLE

These principles apply to the establishment of Codex Nutrient Reference Values for labelling purposes for nutrients associated with risk of diet-related noncommunicable diseases (NRVs-NCD) for the general population identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products. 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, **for these nutrients and for other nutrients**. Governments may also consider whether to establish separate food label reference values for specific segments of the general population.

Comment:

Malaysia would like to reiterate our position as provided in the electronic working group that we do not agree with the provision to allow governments to establish their own reference values for labelling purposes. We are of the view that this provision would be contradictory to CODEX's intention of promoting uniform use of NRVs in the interest of international standardization and harmonization of nutrition labelling. This has been clearly stated in clause 3.4.4 of the *Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985).*

We noticed that in response to our previous comments, the Secretariat did mention in para 32 of CX/NFSDU 10/32/27 that the revised introductory text to 3.4.4 in the report of the 31st CCNFSDU Session (ALINORM 10/33/26) does not contain any text that refers to international standardization and harmonization.

However, we could not recall when this clause was removed. We noticed that in the proposed revised draft (Appendix IV, ALINORM 10/32/26), the clause on international standardization and harmonization has been deleted, but the deletion of this clause was not highlighted / not strikedout in the text. We strongly propose that the clause should be inserted back.

2. DEFINITION(S)

Nutrient Reference Values - Noncommunicable Disease (NRVs-NCD) refer to Codex nutrient reference values for food labelling purposes for nutrients that are associated with risk of diet-related **chronic** noncommunicable diseases **not including nutrient deficiency diseases. [The NRV-NCD represents the nutrient recommendations for the general population.]**

[Daily Intake Reference Values as used in these principles refer to reference intake values provided by FAO/WHO or other recognized authoritative scientific bodies that may be considered in establishing an NRV-NCD based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g., as a single value or a range), and are applicable to the total population or to a segment of the population (e.g., recommendations for a specified age range). For macronutrients, they are generally expressed as a percentage of energy intake).]

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

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 Criteria for Selection of Nutrients

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

- **[Convincing]** ~~**[Convincing or Probable] [Generally accepted]**~~ and relevant **[available]** **[peer-reviewed]** scientific evidence for the nutrient-noncommunicable disease risk relationship

Comment:

Malaysia supports the use of the term "convincing" and therefore proposes that the square bracket for "convincing" and "peer-reviewed" be removed.

- Public health importance of the nutrient-noncommunicable disease risk relationship among Codex member countries
- **[Convincing]** ~~**[Convincing or Probable] [Probable]**~~ and relevant **[peer-reviewed]** scientific evidence for a quantitative reference value for daily intake that is applicable to the general population older than 36 months of Codex member countries.

Comment:

Malaysia supports the use of the term "convincing" and therefore proposes that the square bracket for "convincing" and "peer-reviewed" be removed.

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 **as primary sources** in establishing NRVs-NCD. Relevant and recent values **that reflect independent "systematic" review of the science**, from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration. **These values should reflect intake recommendations for healthy populations.**

Comment:

Malaysia proposes inserting the word "systematic" before "review of the science"

~~3.2.2 Higher priority should be given, as appropriate, to values from recognized authoritative scientific bodies **in which the evidence** has been evaluated through a systematic review.~~

Comment:

Malaysia proposes that clause 3.2.2 be deleted, as it is not necessary. The intention of 3.2.2 can be taken care of by adding the word "systematic" into clause 3.2.1..

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

3.3.1 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 energy intake.

Comment:

Malaysia suggests rephrasing clause 3.3.1 to make it clearer. We feel that current clause does not refer to data from FAO / WHO. The proposed wordings are:

3.3.1 Daily intake reference values ~~from recognized authoritative scientific bodies~~ **from sources, as identified in 3.2.1 which may be** ~~include values~~ **expressed in absolute amounts or as a percentage of energy intake,** ~~that~~ **may be considered for NRVs-NCD** ~~include values expressed in absolute amounts or as a percentage of energy intake~~.

3.3.2 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.

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

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

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

[3.4 Consideration of Daily Intake Values for Upper Levels

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

Comment:

Malaysia would like to reiterate our previous comments in the electronic working group that we do not support the proposal to include terms related to upper levels of intake. We are of the view that the scientific data to establish the upper levels for many of these "nutrients" associated with NCDs are not sufficient or inconclusive at this time, with the possible exception of trans-fatty acids.

In addition, it can be noted that the "*Interim Summary of Conclusions and Dietary Recommendations on Total Fat and Fatty Acids"* reported that full agreement among the experts regarding the U-AMDR for %E was not achieved.

NORWAY

Norway would like to thank the United States, Thailand and Chile for preparing the revised document on the principle and criteria for the development of NRVs for labelling purposes for nutrients associated with risk of diet-related noncommunicable diseases (NRVs-NCD). Our preliminary comments on the draft Codex-provisions in Annex 2 at step 3 address the following:

1) Definitions
2) Criteria for Selection of Nutrients under the General principles for establishing NRVs-NCD
3) Selection of appropriate basis for determining and expressing NRVs-NCD
4) Consideration of Daily Intake Values for Upper Levels
5) Consideration of substitution effects (paragraph 76-81, p 12 in CX/NFSDU 10/32/7)

1) Definitions (section 2)

In general we believe that all terms used in the text and which can be interpreted differently, should be defined in the Codex Guidelines. Accordingly, Norway supports to include the two definitions on *Daily Intake Reference Values (DRV)* and *Upper Level of Intake (UL)* under the section 2.Definition(s).

The proposed definition in the project document on NRVs- NCD reads:

"Nutrient Reference Values - Noncommunicable Disease (NRVs-NCD) refer to Codex nutrient reference values for food labelling purposes for nutrients that are associated with risk of diet-related **chronic** noncommunicable diseases **not including nutrient deficiency diseases. [The NRV-NCD represents the nutrient recommendations for the general population.]"**

We support to include the word *chronic* so that the term reads diet-related chronic non-communicable diseases. This term is a more specific term and is also used in the 2003 FAO/WHO technical report on Diet, nutrition and the prevention of chronic diseases. We also support the inclusion of the last sentence of the definition which is put in square brackets for further discussion. However, we believe that it is necessary to clarify the word *represents* in this sentence. This word can lead to misunderstandings as it can be interpreted as the NRVs- NCD are the nutrient recommendations for the general population. To avoid this misunderstanding Norway proposes to replace "*represents"* with "*constructed on the basis of"*. The proposal will read as following:

> "The NRVs-NCD are constructed on the basis of the nutrient recommendations for the general population."

2) Criteria for Selection of Nutrients (section 3.1)

The project document reads:

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

• **[Convincing] [Convincing or Probable] [Generally accepted] and relevant [available]**

[peer-reviewed] scientific evidence for the nutrient - noncommunicable disease risk relationship.

• Public health importance of the nutrient-noncommunicable disease risk relationship among

Codex member countries.

• **[Convincing] [Convincing or Probable] [Probable]** and relevant **[peer-reviewed]** scientific evidence for a quantitative reference value for daily intake that is applicable to the general population older than 36 months of Codex member countries."

Comments to 1st and 3rd bullet point: We believe that it is important to use a term that reflects the strength of the scientific evidence that is internationally well established, i.e. the terms "Convincing" and "Probable" established by FAO/WHO.

In development of new national dietary recommendations in Norway, the strength of the evidence for the nutrient- noncommunicable disease risk relationship "convincing or probable" was considered to be strong enough. In public health work it is considered to be unethical not to inform about when the evidence of disease risk is probable. Dietary recommendations are an important part of the public health work and are established as guidelines to the general population. The NRVs –NCD can also be seen as a tool in public health work, as the purpose of the NRVs- NCD is to help consumers to estimate the relative contribution of individual products to overall healthful dietary intake and as a means to compare the nutrient content between products.

Therefore, we support the term "Convincing or Probable".

Regarding the terms "available" and "peer-reviewed" used in 1st bullet point we believe that the term "available" is superfluous, because if the scientific evidence is relevant it is implied that the evidence is available.

In the Codex guideline for vitamin and minerals food supplements (CAC /GL 55-2005) section 3.2.2 the criteria for setting maximum amounts for vitamins and minerals in food supplements are outlined. 3.2.2a) reads:

"upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups"

We note the use of the term "generally accepted" when describing the scientific documentation and are of the opinion that this term implies that a peer-reviewed process has taken place. To be consequent in the Codex guidelines we propose the following sentence for 1st bullet point in section 3.1:

"**Convincing/Probable** and relevant **generally accepted** scientific evidence for the nutrient-noncommunicable disease risk relationship."

We propose the following sentence for 3rd bullet pointing section 3.1:

"Convincing/Probable and relevant **generally accepted** scientific evidence for a quantitative reference value for daily intake that is applicable to the general population older than 36 months of Codex member countries."

3. Selection of appropriate basis for determining and expressing NRVs-NCD (section 3.3)

In both paragraphs in section 3.3.3 the reference energy intake is given in this order:

2000 kilocalories/ 8370 kilojoules. We propose that the reference energy intake is given in the reversed order which is the international standard. We are also of the opinion that it shall be referred to megajoules and not kilojoules. Hence we propose that the reference energy intake shall read as following:

8,4 megajoules /2000kilocalories

Further the following text is proposed by the electronic working group for section 3.3.4 in the project document:

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

We note that the word "and" in the sentence should be corrected to the word "or", so that the sentence reads:

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

4. Consideration of Daily Intake Values for Upper Levels

We support the inclusion of the proposed section 3.4;

"[3.4 Consideration of Daily Intake Values for Upper Levels

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

5. Consideration of substitution effects

We believe that it is important to consider the substitution effects of the nutrients and if such effect should be addressed in some way when establishing NRVs-NCD.

UNITED STATES OF AMERICA

I. GENERAL COMMENTS

The United States thanks Thailand and Chile for co-chairing the electronic working group (eWG) on this agenda item, and for the assistance of eWG members in submitting comments which formed the basis of proposals in CX/NFSDU 10/32/7. We are pleased to offer the following preliminary comments on Annex 2 of this document, and anticipate providing additional comments at the upcoming session.

The United States continues to support close coordination of this work with the separate agenda item on vitamin and mineral NRVs. For example, we support retaining wherever applicable, the same or similar text and organization as the vitamin and mineral NRV general principles, with appropriate modifications to reflect topics specific to the NRVs-NCD. In addition, we agree with the report recommendation that the committee begin thinking about how best to present these two sets of NRVs in Section 3.4.4 of the Guidelines. It may be helpful to note that the provisions in this section encompass both information on presentation of nutrition information to the consumer and additional information intended as a reference for governments. With regard to the latter purpose, one option is to distinguish between the NRVs derived from the two sets of principles with separate subheadings for the listing of: 1) NRVs based on nutrient requirements, and 2) NRVs based on reduction of risk of diet-related noncommunicable diseases.

In addition, the eWG was asked if the Committee should consider an NRV-NCD for a nutrient if its main effect is based on substituting for another nutrient in the diet, and if so, whether it would be appropriate to identify any substitution effects in final Codex provisions. As an example, it was noted that in the FAO/WHO interim summary on fats and fatty acids, the experts identified the level of evidence for monounsaturated fatty acids based on its effect when substituting for saturated fats. As this work proceeds, the United States supports identification of substitution effects, and further consideration of whether the substitution effects should be addressed in some way in these general principles and/or in Section 3.4.4 of the Guidelines.

II. SPECIFIC COMMENTS ON PROPOSED PRINCIPLES AND CRITERIA IN ANNEX II

TITLE (Revised Text)

The United States agrees with the revised title, including referring to "general principles" and identifying their placement in the Codex Guidelines on Nutrition Labelling.

1. PREAMBLE (Revised Text)

The United States agrees with the revised text in the second and third sentences.

2. DEFINITIONS

Revised Definition of NRV-NCD

The United States agrees with the proposed edits to the first sentence to further clarify the nature of diet-related noncommunicable diseases that are the subject of these NRVs. We also concur with adding the second new sentence to clarify that the NRV-NCD represents the nutrient recommendations for the general population.

New Proposed Definition of Daily Intake Reference Value

The United States agrees that it may be helpful to include a definition of "daily intake reference value" in these general principles, since it is referred to several times and may not be clear to all, and we support the proposed draft definition. Whereas it may not be appropriate at this stage to propose definitions for all the specific types of values that may be used to establish NRVs-NCD, it should be possible to define this "overarching" term to refer to different types of values that may be considered in establishing NRVs-NCD.

New Proposed Definition of "Upper Level of Intake"

The United States supports either: 1) including the proposed definition in these principles or 2) providing a reference to the definition in the Codex nutritional risk analysis principles and guidelines. We note that the Codex definition of "upper level of intake" is included in the draft general principles for vitamin and mineral NRVs and relates to its reference in the following principle: "The establishment of general population NRVs should also take into account *upper level of intake* established by recognized authoritative scientific bodies."

The United States also supports including the following new proposed principle in 3.4 on "Consideration of daily intake values for upper levels":

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

We believe the above principle would be applicable to the two nutrients that the CCFL referred to the CCNFSDU for consideration of NRVs-NCD (i.e., saturated fat and sodium) as well as other nutrients that may be considered for NRVs-NCD. However, we also recognize that upper levels of intake that are established by recognized authoritative scientific bodies may be derived in different ways, and thus it is important for the

Committee to understand the bases for these values. Likewise, we agree that it is possible that definitions for certain other terms (e.g., Upper Level of Acceptable Macronutrient Distribution Range) may vary among recognized authoritative scientific bodies, and again emphasize the importance of understanding how such values were derived if proposed as a basis for an NRV-NCD.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 Revised text:

First bullet: The United States supports using FAO/WHO terminology to characterize the strength of the scientific evidence for a nutrient-noncommunicable disease risk relationship which has associated criteria for the following levels of evidence: 1) convincing, 2) probable, 3) possible, and 4) insufficient. Based on a review of the criteria for "convincing" and "probable" in CX/NFSDU 10/32/7, we propose "convincing" evidence for the nutrient-noncommunicable disease risk relationship. We are not opposed to the addition of "available" and/or "peer-reviewed", but welcome further discussion on whether these additions are necessary.

Third bullet:

The United States believes the third criterion is important to include and should be applicable to all nutrients considered for an NRV-NCD. Whereas source documents may not assign strength of evidence to a specific numeric value, a description of a desired level of evidence for a quantitative reference for daily intake would still appear appropriate to consider in selecting nutrients for NRVs-NCD. With regard to the options in bracketed text, we again support use of FAO/WHO terminology and further consideration of either "convincing" or "convincing or probable". Moreover, we believe the third criterion is needed for the CCNFSDU to function in its appropriate role as a risk manager rather than as a risk assessor. That is, it is important for the Committee to not only have convincing evidence that there is a causal relationship between a nutrient and risk of a noncommunicable

disease, but also for there to be strong evidence that a *specific quantitative daily intake* established by a recognized authoritative scientific body will reduce risk of the noncommunicable disease in the general population.

With regard to combining the first and third bullet, if the Committee agrees that the level of evidence should be the same for both of these, we believe the two bullets could be combined. Otherwise, we support retaining them as separate criterion.

With regard to the proposal to delete "of Codex member countries", we agree that this text is not necessary.

3.2 revised text:

The United States supports the new edits to Section 3.2 which, among other things, slightly revises and reformats the first two sentences in the previous 3.2.1 text to align with Section 3A in the draft principles for the vitamin-mineral NRVs at Step 5, and includes a new sentence to clarify that the values should reflect recommendations for healthy populations.

3.3 revised text:

The United States supports the new edits to Section 3.3 including the new proposed principle in 3.3.4.

3.4 new proposed text:

As noted in our comments that supported including a definition of "upper level of intake", the United States supports including the new proposed principle which we believe is applicable to the two nutrients that the CCFL referred to the CCNFSDU for consideration of NRVs-NCD (i.e., saturated fat and sodium). Please refer to earlier comments in Section 2.

Additional editorial comment: In the wording of the new principle, we suggest edits to refer to "recognized authoritative **scientific** bodies…".

The United States appreciates the opportunity to share these preliminary comments, and looks forward to providing additional comments at the upcoming session.

IFT - Institute of Food Technologists

The Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases held in 2002 articulated a new platform that included the concept of the human organism's subtle and complex relationship to its environment in relation to chronic diseases. Importantly, the evidence-based concepts included in the platform encompassed the notions that chronic disease risks begin in fetal life and continue into old age.

IFT believes that the current description of the target population as "the general population aged older than 36 months" to be inadequate for the purposes of Prevention of Chronic Diseases. As noted in our comments on *General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population* (ALINORM 10/33/26, Appendix III, at Step 5), IFT believes that allowance for separate NRVs for healthy subpopulations of the general population will help to prevent nutrient shortfalls in these groups as well as providing a means to become consistent with WHO/FAO platforms for Prevention of Chronic Diseases.

Thus, we believe that clarification is necessary regarding principles for establishing NRVs for healthy segments of the general adult population that exhibit increased nutritional needs due

to life stage or gender. For example, nutrient requirements change during pregnancy, and indeed provision of proper nutrition during pregnancy is emerging as crucial to reduce chronic

disease susceptibility in the resulting child. However, establishing NRVs for the general population based on the increased needs of particular subpopulations could result in needless overconsumption by others and, perhaps, increased risk. Failure to recognize the increased nutrient needs of healthy subpopulations through labelling NRVs limits the usefulness of food labels as a tool that allows consumers to recognize and select foods that meet their unique nutritional needs. IFT therefore respectively requests that guidance for the establishment of NRVs for the general population be clarified so as not to exclude future work on NRVs for additional segments of the general population. We believe that such a clarification will also facilitate the close coordination of the development of principles and criteria for separate but related agenda items, ALINORM 10/33/26 (Agenda item 3) and CX/NFSDU 10/32/5 (Agenda item 5)

Specifically, **Section** 1**. PREAMBLE** could be modified as follows, indicated by text in *underlined italics*:

These principles apply to the establishment of the Codex Nutrient Reference Values for labelling purposes for nutrients associated with risk of *non-deficiency* diet-related noncommunicable diseases (NRVs-NCD) for the general population identified as *healthy* individuals older than 36 months *and excluding pregnant and lactating women and adults over 50 years.*

Alternatively, the IFT would support removal of the phrase "identified as *healthy* individuals older than 36 months *and excluding pregnant and lactating women and adults over 50 years*." If in **SECTION 2 DEFINITIONS** were modified to include new definitions of "general population" and "general population subgroup" in order to unify NRVs-NCD when requirements are similar, while providing the means and flexibility to specify specific NRVs-NCD for subgroups with specific and different requirements.

2. DEFINITIONS

Nutrient Reference Values – no changes suggested

General Population*: refers to the healthy adult population (> 36 months).*

General Population Subgroup*: refers to any healthy subgroups of the general population with nutrient requirements that differ substantially from the General Population, such as pregnant and nursing women, or the elderly for which increased nutrient needs may require separate [NRVs] [NRVs-NCD].*