CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 4a - 4b **CX/NFSDU 11/33/6**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

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14 – 18 November 2011

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

Governments and interested international organizations are invited to submit comments on the above document at Step 3 in writing preferably by email to the Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, Fax +39-06-5705-4593, e-mail codex@fao.org with copy to Mr Georg Müller, Federal Ministry of Food, Agriculture and Consumer Protection, Rochusstraße 1, 53123 Bonn, Germany, Fax: +49 (228) 99 529 49 65, e-mail: ccnfsdu@bmelv.bund.de by **15 October 2011**.

(Prepared by the United States with the assistance of Thailand and Chile and members of the electronic work group including Argentina, Australia, Brazil, Canada, China, Costa Rica, European Union, Japan, New Zealand, Norway, Republic of Korea, Uruguay, European Committee of Sugar Manufacturers, International Daily Federation, and the World Sugar Research Organization)

I. BACKGROUND

Main Aspects of Work and Scientific Advice

1. In July 2010, the Codex Alimentarius Commission approved new work for the CCNFSDU to:
   1) Develop Codex principles and criteria for the establishment of Nutrient Reference Values for labelling purposes (NRVs) for nutrients associated with risk of diet-related diseases for the general population in an Annex to the Guidelines for Nutrition Labelling (hereafter referred to as the "Guidelines"); and
   2) Propose amendments to the listing of NRVs in Section 3.4.4 of the Guidelines based on these principles.

2. This work was deemed relevant and timely as a contribution to implementing the Global Strategy on Diet, Physical Activity and Health (WHA Resolution 57.17) in addressing the global burden of diet-related noncommunicable diseases (ALINORM 10/33/26, Appendix VII).

3. In identifying nutrients to review for these potential NRVs, the Committee indicated that the first priority is nutrients that are referred to the CCNFSDU by the Codex Committee on Food Labelling (CCFL).[1] The second priority is other nutrients that meet the criteria defined in the principles.

4. The project document noted that expert scientific advice on diet-related noncommunicable diseases is available through recent and comprehensive reviews by FAO/WHO and other recognized authoritative scientific bodies.

Status and Related Work

5. At the last session, the Committee made significant progress on the proposed draft general principles. Amendments are reflected in Appendix IV of the Committee report (REP11/NFSDU).
In developing these principles, an objective has been to retain, 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 nutrient reference values for nutrients associated with risk of diet-related noncommunicable diseases (NRVs-NCD). At the last session, the Committee agreed to advance the draft Annex on vitamin and mineral NRV general principles for adoption at Step 8 by the Commission[2] after the Codex Secretariat clarified that it would be possible, if the Committee agreed, to merge the two Annexes later and propose other consequential changes to the text of the Guidelines as required (paras 35-36, REP11/NFSDU). In addition, certain comments made by this electronic working group (EWG) referred to the consolidation of the principles, with one suggesting that this be addressed soon. Although specific proposals for consolidating text in these Annexes were not within the charge of this EWG, the Committee will want to keep potential consolidation of the two sets of principles in mind as they review the preliminary recommendations in this report.

For additional background on the discussion at the 32nd CCNFSDU Session, please refer to REP11/NFSDU, paras 91-114.

Conduct of Electronic Working Group

6. At the last session, the Committee agreed to establish an EWG chaired by the United States of America (U.S.) and co-chaired by Thailand and Chile to prepare a revised document for consideration at the next session (REP11/NFSDU, paras 111-113 and Appendix IV). The charge for this EWG was two-fold:

1) To revise the proposed draft general principles for establishing NRVs-NCD at Step 3 on the basis of comments received to a Codex Circular Letter (i.e., CL 2010/53-NFSDU), with a focus on issues that have not been addressed in sections 3.1 and 3.4; and

2) To make proposals on NRVs-NCD for saturated fatty acids (SFA) and sodium.

It was agreed that the EWG would work in both English and Spanish[3].

7. In February 2011, an invitation to participate in this EWG was extended to Codex members and observer organizations. Expressions of interest in participating were received from Australia, Argentina, Belgium, Brazil, Canada, Chile, China, Costa Rica, Ecuador, European Union, Finland, France, India, Ireland, Japan, Malaysia, New Zealand, Norway, Poland, Republic of Korea, Thailand, United States, Uruguay, European Committee of Sugar Manufacturers, European Salt Producers' Association, International Grocery Manufacturers Association, International Dairy Federation, Institute of Food Technologists, International Special Dietary Foods Industries, and the World Sugar Research Organization. In May 2011, the Chair and Co-Chairs circulated a consultation document to EWG members with the CL comments. (In addition to this report, please refer to CX/NFSDU

[1] Thus far, two nutrients have been referred to the CCNFSDU for consideration---sodium and saturated fat.
[2] The Commission adopted the Annex at Step 8 at its 34th (2011) session.
[3]The EWG greatly appreciates Chile's facilitating broader participation in this working group by translating documents and comments.

11/33/5 for the Comments at Step 3). The consultation document summarized CL comments and posed questions based on these about further amendments to the principles and criteria and proposals for SFA and sodium NRVs-NCD.

8. Eighteen responses were received from the EWG.[4] **This report presents a brief summary of the EWG responses with boxed text to highlight preliminary proposals and issues for the Committee's consideration at its next session.** The report is organized as follows:

- Background
- Proposed Draft Principles for Establishing NRVs-NCD
- Proposals for SFA and Sodium NRVs-NCD Based on the Draft Principles
- Additional Issues for Consideration at the Next Session

II. PROPOSED DRAFT PRINCIPLES FOR ESTABLISHING NRVS-NCD

Below is a summary of comments on the proposed draft principles in Appendix IV of Rep11/NFSDU that form the basis for revised text in Annex 1 for consideration by the Committee.

TITLE

9. The EWG was asked if the title in Appendix IV should be revised to refer to "...diet-related noncommunicable diseases..." to be consistent with the title in the project document, and the reference to "...diet-related noncommunicable diseases" in the preamble and definition.

Most comments supported this addition. Reasons included:

- To clarify that these principles are targeted to diet-related NCD.
- To be consistent with the objectives of the Global Strategy on Diet, Physical Activity and Health.
- To be consistent with the wording in the preamble and definition and maintain coherence throughout the document.
- To be consistent with the inclusion of this term in the definition of NRV proposed by CCFL.

One member country commented that the title was clear without it and stated that the definition of NRV-NCDs in Section 2.1 already referred to it. One observer organization was of the view that the use of the term "diet-related noncommunicable diseases" misleads the reader that the diseases in question are solely or largely influenced by the diet.

Title

10. Given most comments supported the proposed edit, the title in Annex 1 is revised to refer to "diet-related noncommunicable diseases."

SECTION 1. PREAMBLE

11. Because of mixed views at the last session and in CL responses, the EWG was asked to comment on whether to: 1) retain the current text that "A government may choose to use the NRVs-NCD"; or 2) place this text and another option (i.e., "Governments are encouraged to use the NRVs-NCD"…) in brackets for further discussion at the next session based on the EWG's progress.

Most comments supported placing both options for text in brackets to permit further consideration of the second option at the next session. Reasons for suggesting that the text be changed to "Governments are encouraged to use the NRVs-NCD…" included:

[4] Certain comments responded to only a subset of the questions.

- For consistency with the vitamin and mineral NRV general principles.
- To stimulate governments to respond to the World Health Assembly request that Codex take action in preventing NCDs.
- "Encourage" offers governments opportunities to adopt Codex NRVs-NCD more actively than passively.
- To convey the message that the common values should be used world-wide as much as possible.
- Sufficient flexibility is acknowledged in the Preamble to allow governments to consider their own particular circumstances in establishing reference values for labelling purposes.

Two member countries and two observer organizations suggested retaining the current text. Reasons included:

- This would allow governments to take into account factors specific to their countries.
- Governments should have flexibility in the adoption of NRVs-NCD in light of uncertainty in the choice of values.
- The decision on the appropriate text should be deferred until the two annexes are merged to ensure that the text selected is the most appropriate for all NRVs.

Section 1- Preamble:

12. Given most comments supported further consideration of the second option, both options are placed in brackets in Annex 1. With regard to the reasons identified in the first two bullets in comments that supported retaining the current text, another comment above noted that the second option would still allow governments flexibility to establish their own label reference values considering factors specific to their countries. With regard to the third bullet that proposed that the decision on appropriate text be deferred, this raises the question of whether the Committee supports consolidation of the two Annexes, and if so, the best timing to pursue this.

SECTION 2. DEFINITIONS

Background

13. In the vitamin and mineral general principles, definitions are provided for two types of daily intake reference values that are relevant to establishing vitamin and mineral NRVs: 1) Individual Nutrient Level 98 (INL_{98}) and 2) Upper Level of Intake (UL). At the last session, three definitions were discussed for inclusion in the Annex on NRV-NCD general principles: "Nutrient Reference Values – Noncommunicable Diseases (NRVs-NCD)", "Daily Intake Reference Values" and "Upper Level of Intake". The definition of Upper Level of Intake is from the Codex nutritional risk analysis principles (Codex procedural manual, 20th ed. p. 149). It is the same definition used in the vitamin and mineral NRV principles. This last term was kept in brackets because the Committee could not come to a conclusion about a related draft principle on consideration of daily intake values for upper levels in 3.4.

14. In a related matter, at its 2011 session the Commission adopted at Step 5 a draft definition on Nutrient Reference Values to include in the definitions section of the Guidelines (REP 11/FL Appendix IV). The CCFL report noted that at a later stage the definition could refer to the annexes on principles for establishing NRVs. The CCFL asked the CCNFSDU for comments before finalizing the definition.

Definition of Upper Level of Intake and Other Types of Daily Intake Reference Values

15. The EWG was asked about the desirability of including definitions of specific types of daily intake values which may be referred to in these principles (e.g., "Upper Level of Intake", "Upper Level of Acceptable macronutrient Distribution Range"). The consultation document noted that one option is to retain the definition of "Upper Level of Intake" in square brackets, and discuss the need for this and other definitions for specific daily intake values after further progress is made on the bracketed text in section 3.4 and NRV-NCD proposals.

16. The majority of EWG comments supported the Committee's further consideration of including the Codex definition of "Upper Level of Intake (UL)." Reasons included:

- The UL is applicable to considering NRVs-NCD for certain nutrients such as sodium.
- Relevant and recent UL values are available from a recognized authoritative scientific body. That is, the U.S. Institute of Medicine of the National Academies (IOM) published Tolerable Upper Intake Levels for sodium in 2004 using a similar definition to the Codex UL based on an independent review of the scientific evidence.
- The UL is applicable globally.
- Definitions of specific types of daily intake values should be included when used in the general principles to improve understanding and help clarify the principles.
- The UL definition is included in the Annex on vitamin and mineral NRV general principles, and thus would be included if the two Annexes are consolidated.

A few comments did not support including the definition of UL because they did not support the principle on upper levels in Section 3.4. (Please refer to reasons in Section 3.4 discussion).

Section 2 - Need for UL Definition

17. Given the majority of comments supported further consideration of including the Codex definition of UL, it is retained in brackets in Annex 1. It may be preferable to review its inclusion after the Committee's discussion of other principles, NRV-NCD proposals, and potential consolidation of the Annexes.

Footnote to UL Definition

18. One member country recommended that the UL definition include the related footnote in the vitamin and mineral NRV general principles on alternative terms that countries may use for this concept (e.g., "Tolerable Upper Nutrient Intake Level"). Two others suggested revising the definition of "Upper Level of Intake". One was of the view that including the term "habitual" is confusing and that proven consumption (not usual consumption) causes adverse effects. Another commented that the phrase "…*judged to be unlikely* to lead to adverse effects in humans" is open to wrong interpretation.

Section 2- Footnote to UL Definition

19. With regard to the first comment in paragraph 18, for consistency it appears appropriate to include the footnote with the UL definition in the vitamin and mineral NRV principles if the UL definition is retained in the NRV-NCD Annex. Consequently, this footnote is included in brackets in Annex 1. With regard to suggestions for revising the Codex UL definition, this appears outside the scope of this work given the current definition reflects agreement reached by the Committee and its adoption by the Commission in 2008, and reflects the definition used in the report of a 2005 joint FAO/WHO workshop on nutrient risk assessment..[5]

<u>Definition of Acceptable Macronutrient Distribution Range</u>

[5] World Health Organization, Food and Agriculture Organization. *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment.* Geneva, Switzerland. World health Organization. 2005.

20. At the last session, the Committee discussed but could not reach consensus on the need to include definitions of additional types of daily intake values that may be relevant to establishing NRVs-NCD and the draft principle in 3.4 (e.g., "Acceptable Macronutrient Distribution Range (AMDR)" and "Upper (Value of) Acceptable Macronutrient Distribution Range (U-AMDR)" (REP11/NFSDU, para 108-110)).

21. A few EWG members commented on the desirability of including definitions of AMDR and/or U-AMDR, with mixed views. Two member countries stated that the U-AMDR is applicable to establishing NRVs-NCD (e.g., the SFA intake recommendation by the 2008 FAO/WHO expert consultation on fats and fatty acids in human nutrition is expressed as a U-AMDR). One country identified the IOM definition of AMDR as "the upper value of a range of intakes from a particular energy source that is associated with reduced risk of chronic diseases while providing adequate intakes of essential nutrients." A member organization did not consider the inclusion of additional definitions for daily intake values necessary. Two observer organizations were in favor of including a definition of UL in the principles but not the U-AMDR. One stated that the UL definition more adequately reflects the meaning of what an upper level is; the other was of the view that there is more uncertainty in setting AMDRs. Another comment noted the distinction in their country between a UL value and a "Dietary Goal"—with the latter being a range that persons in that country should aim to consume primarily to prevent lifestyle-related diseases.

Section 2- AMDR and/or U-AMDR

22. Given that the SFA intake recommendation by the 2008 joint FAO/WHO expert consultation is expressed as a U-AMDR, the IOM definition of AMDR is included in brackets for the Committee's consideration. It may be preferable to review its inclusion after the Committee's discussion of other principles and NRV-NCD proposals.

Definition of Daily Intake Reference Value

23. One member country suggested the following edits to the definition in 2.2 with the view that they might help clarify the types of values that may be considered in establishing NRVs-NCD and offered related comments on 3.4.

> "2.2. Daily intake Reference Values as used in these principles refer to reference nutrient intake values provided by FAO/WHO or other recognized authoritative scientific bodies that may be considered in establishing an NRV-NCD based on the principles and criteria in Section 3 **and include values that are recommended intakes, and values that are upper levels of intake.** ….."

The Committee could discuss the above proposal but it may be helpful to first clarify from this country whether the intent is for "upper levels of intake" to be specific to the UL or additionally encompass the U-AMDR. An alternative approach might be to identify examples of specific types of daily intake values that may be considered in establishing NRVs-NCD as follows:

> "2.2. Daily Intake Reference Values as used in these principles refer to reference nutrient intake values provided by FAO/WHO or other recognized authoritative scientific bodies that may be considered in establishing an NRV-NCD based on the principles and criteria in Section 3 **(e.g., Acceptable Macronutrient Distribution Range or Upper Level of Intake, where applicable)**."

Section 2- Daily Intake Reference Value

24. The two options for edits to 2.2 have been added to Annex 1 for the Committee's consideration. It may be noted that the current definition of "daily intake reference values" is specific to NRVs-NCD as clarified by "…as used in these principles". In a potential consolidation of the two Annexes, however, it is anticipated that the definition of "daily intake

reference values" would be reviewed again as it may relate to potential edits to encompass vitamin and mineral NRVs. For example, if this definition was revised to encompass all NRVs, the addition of Individual Nutrient Level 98 (INL_{98}) as an example could also be considered.

Definitions for the Strength of the Scientific Evidence for an NRV-NCD

25. The inclusion of definitions for the strength of the scientific evidence is addressed with comments received on criteria for selection of nutrients (Section 3.1).

SECTION 3: GENERAL PRINCIPLES FOR ESTABISHING NRVS-NCD

3.1 Criteria for Selection of Nutrients

Bracketed Text on Strength of the Scientific Evidence

Background

26. At the last session, the Committee agreed to retain "convincing/generally accepted" in the criterion on strength of the evidence with a footnote that clarifies that these terms are considered synonymous in these principles, and to retain "or Probable" in brackets for further consideration.

Delegations had the following views on this bracketed text:

> "Several delegations supported the inclusion of "probable" evidence because if only "convincing" criteria were considered, it would not be possible to establish NRVs-NCD for several important nutrients such as dietary fibre and sugars. These delegations also drew the attention of the Committee to the consequences of admitting only convincing evidence in relation to regulations. Other delegations supported only the reference to "convincing" evidence for the following reasons: the criteria for "probable" was not strong enough; the highest level of evidence should be required in the framework of Codex, with the understanding that "probable" evidence could be used at the national level; the use of "probable" evidence was not sufficient for regulatory purposes and may also result in misleading claims. The Delegation of the United States clarified that the criteria used in the 2003 Technical Report on Diet, Nutrition and Prevention of Chronic Diseases (WHO TRS 916) for "convincing" and "probable" were provided in the report of the EWG, and that the 916 report criteria were also used by the 2008 Joint FAO/WHO Expert Consultation of Fats and Fatty Acids in Human Nutrition. Shortcomings of the criteria for "probable' for work of the CCNFSDU were identified by the U.S. Delegation. In addition, it was pointed out that many factors can be considered to determine what nutrients should be declared on the label." (REP11/NFSDU, para 101).

27. In the consultation document, additional background on this topic was provided in conjunction with CL responses. Based on the draft principles and available FAO/WHO reports for this work, the EWG Chair and Co-Chairs suggested that the report of the 2008 joint FAO/WHO expert consultation on fats and fatty acids in human nutrition (hereafter referred to as "FNP 91") [6] be considered as a primary data source for proposing an NRV-NCD for SFA, and that the report of the 2002 joint FAO/WHO expert consultation on diet, nutrition and the prevention of chronic diseases (hereafter referred to as "TRS 916")[7] be considered as a primary data source for proposing an NRV-NCD for sodium. **Both reports use the following criteria for "convincing" and "probable" evidence.**

[6] Food and Agriculture Organization of the United Nations. *Fats and Fatty Acids in Human Nutrition: Report of an Expert Consultation*. FAO Food and Nutrition Paper 91. Rome. FAO, 2010. Web reference (Accessed April 17, 2011): http://www.fao.org/docrep/013/i1953e/i1953e00.pdf

[7] *Diet, Nutrition and the Prevention of Chronic Diseases: Report of a Joint FAO/WHO Expert Consultation.* WHO Technical Report Series 916. WHO, 2003. Web reference (Accessed April 17 2011): http://www.who.int/dietphysicalactivity/publications/trs916/en/

The criterion for "convincing" evidence is:

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

The criterion for "probable" evidence is:

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

28. In addition, at the last session a WHO representative noted that the above criterion for "probable" evidence had been "further clarified" in a 2007 World Cancer Research Fund (WCRF) report[8] as follows:

> "These criteria are for evidence strong enough to support a judgement of probable causal relationship, which would generally justify goals and recommendations designed to reduce the incidence of cancer. All of the following are generally required:
>
> - Evidence from at least two independent cohort studies, or at least five case control studies.
> - No substantial unexplained heterogeneity between or within study types in the presence or absence of an association or direction of effect.
> - Good quality studies to exclude with confidence the possibility that the observed association results from random or systematic error, including confounding, measurement error and selection bias.
> - Evidence for biological plausibility."

29. In the consultation document, it was pointed out that the WCRF updated definition of "probable" evidence differs from the definition used in the two FAO/WHO data sources available for this work. Thus, the two sets of criteria are not interchangeable.

Retention of Bracketed Text

30. The EWG was asked to comment on whether the bracketed text with "or probable" should be retained. Views were again mixed, with slightly more respondents supporting the deletion of "probable" in 3.1, and only basing NRVs-NCD on "convincing/generally accepted" scientific evidence. Reasons included:

- The highest level of scientific evidence should be required in the framework of Codex.
- Priority should be given to the nutrient(s) that have serious impact on health.
- "Probable" does not have the same significance and meaning as the term "acceptable".
- The criteria for "probable" evidence in the FAO/WHO reports available for this work are not strong enough, with its reference to "perceived shortcomings in the available evidence or some evidence to the contrary, precluding a more definite judgement" which may include any of the following: "insufficient duration of trials (or studies); insufficient trials (or studies) available; inadequate sample sizes; and incomplete follow-up."

[8] World Cancer Research Fund. *Food, Nutrition, Physical Activity and the Prevention of Cancer: A Global Perspective.* Washington, D.C., American Institute for Cancer Research, 1997.

- The use of "probable" evidence would contradict the standard of evidential strength required by Codex in other texts. For example, its inclusion would create a different basis for the strength of the scientific evidence compared to the approach for health claims in the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997), and could potentially undermine this principle for the strength of the evidence.
- The Annex preamble provides flexibility to governments to establish their own food label reference values based on probable evidence and/or an alternative basis(es).
- The criterion for "convincing" evidence is not overly restrictive; FAO/WHO and other recognized authoritative scientific bodies have concluded there is convincing evidence for several nutrients.

31. Several comments continued to support retaining "probable" evidence in addition to convincing evidence as a basis for Codex NRVs-NCD. Reasons included:

- Codex should provide international guidance to Member states on as many NRVs-NCD of public health significance as can meet at least acceptable levels of evidence.
- In certain countries, "probable" evidence for a food label reference value is considered strong enough.
- The criteria for "probable" evidence (as defined in the WRCF report) are sufficiently strong to support a judgment of a causal relationship, and to provide a basis for label declarations that would not mislead.
- If only "convincing" criteria were considered, it would not be possible to establish NRVs-NCD for important nutrients.

Prioritization of NRVs-NCD based on Strength of the Scientific Evidence

32. The EWG was further asked to consider whether an NRV-NCD should be considered for any nutrients that have only "probable" evidence for a nutrient-disease relationship from the two FAO/WHO expert consultation reports (i.e., FNP 91 and TRS 916). If so, they were asked which of these should have the highest priority and why.

In posing this question, it was noted that in addition to distinguishing between nutrients that have been identified as having convincing evidence for a nutrient-disease relationship(s) as opposed to only "probable" evidence, the Committee also needs to consider which of these nutrients would meet the second criterion for selection of nutrients for NRVs-NCD in 3.1 that addresses the public health importance of the nutrient-noncommunicable disease risk relationship among Codex member countries. In this regard, only two nutrients thus far have been referred by the CCFL to CCNFSDU for consideration of NRVs-NCD (i.e., saturated fat and sodium). In addition, the recently revised Section 3.2.1.2 of the Guidelines includes the following nutrients that should always be declared (on a voluntary or mandatory basis): amounts of protein, available carbohydrate (i.e, dietary carbohydrate excluding dietary fibre), fat, saturated fat, sodium[9] and total sugars. The rationale for listing these nutrients on the nutrition label varies, and encompasses additional bases besides reduction of risk of diet-related noncommunicable diseases.

33. It was further noted that the 2008 joint FAO/WHO expert consultation on fats and fatty acids concluded that a number of nutrients had "convincing" evidence for major health and disease outcomes, including SFA. In addition, the 2002 joint FAO/WHO expert consultation identified additional dietary factors associated with risk of chronic diseases (e.g., for cardiovascular disease, there was convincing evidence for high sodium intake and increased risk, and convincing evidence for potassium and decreased risk).

34. Only a few EWG members identified specific nutrients that have only "probable" evidence in the two reports of FAO/WHO expert consultations that are available to consider NRVs-NCD. One indicated that an NRV-NCD could be considered for cholesterol, but stated it may be appropriate for the CCNFSDU to give priority consideration to NRVs-NCD for several nutrients that have "convincing" evidence. Two comments indicated that an NRV-NCD could be established for sugars if "probable" evidence was retained; one of these further commented that an NRV-NCD for dietary fibre could be considered.

[9] National authorities may decide to express the total amount of sodium in salt equivalents as "salt".

35. The above comments do not indicate widespread support for establishing an NRV-NCD for any specific nutrient based on "probable" evidence from available reports of FAO/WHO expert consultations. In addition, with regard to dietary fibre it may be noted that: 1) there is no single Codex definition of dietary fibre given that two issues are left to national authorities—whether to include carbohydrates from 3 to 9 monomeric units, and which isolated or synthetic compounds have physiological benefit (CL 2- 1985); 2) dietary fibre is not among the list of nutrients that the CCFL has proposed to include in its revised expanded list of nutrients to declare on the nutrition label; and 3) the Global Strategy for Diet, Physical Activity and Health does not recommend increasing consumption of dietary fibre *per se*, but instead recommends increasing consumption of fruits, vegetables, legumes, and whole grains.

Alternative Bases for Food Label Reference Values

36. The EWG was further asked about alternative bases for establishing Codex or country specific food label reference values. One member country commented that the 2008 FAO/WHO expert consultation on fats and fatty acids did not find "probable" or "convincing" evidence for significant effects of total dietary fats on coronary heart diseases or cancers, but maintained their recommendation for an adult dietary intake of 20-35% energy from fat for reasons related to the overall nutritional quality of the diet. This country proposed that the committee expand Section 3.1 Criteria for Selection of Nutrients beyond the evidence base for noncommunicable disease to include considerations related to the nutritional quality of the diet. With regard to this comment, it is recognized that governments may establish food label reference values for certain nutrients such as total fat taking into consideration the nutritional quality of the diet. However, since the primary basis for considering a total fat NRV would not be reduction of risk of a diet-related noncommunicable disease based on this expert consultation's conclusions, the proposal is not applicable to the current scope of work approved by the Commission. In addition, the report of the 2008 expert consultation noted that "further studies and a systematic review of all available evidence are needed to provide better evidence on which to base a recommendation on AMDR for % E fat (i.e., percent energy from total fat) that is applicable globally."

37. Another member country commented that a food label reference value could be considered for nutrient(s) that have only "probable' evidence for a nutrient-diseases relationship, as long as one or more additional rationales exist for establishing the reference value. It also commented that it may be preferable for this to remain a consideration for national authorities. Additional rationales cited include: 1) nutrients that are the subject of national nutrition guidelines, 2) the essentiality of a nutrient, 3) nutrient information for chronic disease management, 4) public interest in nutrient information, and 5) the need for a country to harmonize with trading partners.

Section 3.1- Bracketed Text on Strength of the Evidence

38. Based on EWG comments, it appears unlikely that the Committee could reach agreement to establish Codex NRVs-NCD based on "probable" evidence given the concerns identified, the lack of widespread support for establishing an NRV-NCD for any specific nutrient based on "probable" evidence, and the flexibility provided to governments in the Preamble to establish their own food label reference values. More support is apparent for this level of evidence to be considered at the national level, either alone or in conjunction with other bases for food label reference values. In addition, the alternative bases for label reference values identified in comments may be influenced by national or regional factors. On the other hand, the Committee could consider whether it would be appropriate to acknowledge in these principles that governments may consider the use of "probable" evidence in establishing their own label reference values. As discussed later, it could also consider the inclusion of the WCRF definition in this Annex for reference by governments. Accordingly, the following new text is proposed for consideration in Sec. 3.1 in Annex 1 to replace the bracketed text "or probable":

> ["In addition, governments may consider the suitability of the use of probable evidence as defined in Section 2 in conjunction with other relevant bases in establishing their own food label reference value(s).]

Consideration of Disease Risk Biomarkers

39. One member country that supported "probable" evidence commented that stronger evidence for a relationship between a nutrient and validated biomarker for disease risk often exists than for a direct relationship between a nutrient and disease morbidity and mortality. Consequently, the country was of the view that a validated biomarker/risk factor should also be considered an appropriate endpoint, and interpreted the first bullet point in 3.1 as accommodating a validated disease risk biomarker.

Provisions in the Annex on substantiation of health claims in the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) appear to support this view. Specifically, Section 3.3.1 in this Annex refers to the use of relevant validated biomarkers when a claimed health effect cannot be measured directly (e.g., plasma cholesterol concentrations for cardiovascular disease risk).

Section 3.1 - Validated Biomarkers

40. The Committee may wish to confirm that the first bullet point in 3.1 accommodates validated biomarkers for disease risk. If yes, it might further consider whether additional text should be added to 3.1 to make this point explicit (such as an option for new text in Annex 1 that is in brackets), or alternatively, whether the current reference to the "nutrient-noncommunicable disease ***risk*** relationship" in 3.1 is sufficient.

Identification of Criteria Associated with Descriptors for Strength of the Evidence for a Nutrient-Disease Relationship.

Inclusion of Definition(s)

41. The EWG was asked whether a definition or criteria for the descriptor(s) of the strength of the evidence associated with NRV-NCD values should be included in the Guidelines. If so, comments were invited on preferences for placement (e.g., in the definition section of the Annex or in conjunction with values in the Sec. 3.4.4), considering also implications for potential updates to values and associated descriptors in the future.

Most respondents supported including a definition of the strength of the evidence associated with NRVs-NCD. Reasons included:

- To promote transparency and a clear understanding of the scientific criteria for a descriptor.
- To prevent wrong interpretations and errors in applying the principles in the absence of a definition.
- To clarify how the selection criteria were used to establish NRVs-NCD and should be used in the future.

42. Most of these comments supported including the definition(s) for descriptors in the definitions section (Section 2 of the Annex). One comment proposed that the definition(s) be placed at the beginning of Section 3.1 in the Annex where the selection criteria is defined. Another proposed to include the definition(s) in a footnote in the Annex. Two others proposed identifying the definitions in Section 3.4.4, with one of these supporting their placement in conjunction with the (NRV) values in Section 3.4.4.

43. One member organization was not sure whether descriptor criteria need to be included in the principles. This organization requested clarification of whether the descriptors established in this text would be applicable to other Codex texts.

Section 2 – Inclusion of Definition(s)

44. Based on the above comments, it is proposed that the Committee consider at its next session: 1) the inclusion of definition(s)/criteria for descriptor(s) in Section 2; and 2) whether the descriptor(s) established in this text would be applicable to other Codex texts. With regard to applicability to Codex texts, please also refer to the related discussion under "Definition of

Probable Evidence".

Definition of Convincing Evidence

45. The majority of respondents appeared to support including the definition of convincing evidence from the reports of FAO/WHO scientific advice that are available to establish NRVs-NCD (i.e., FNP 91 and TRS 916). One comment indicated that if the definition changes at some point, it will be necessary to be clear as to which NRVs-NCD were established before and after such a change or it will be necessary to change the NRVs-NCD in accordance with the change in criteria.

Section 2- Definition of Convincing Evidence

46. Based on the above comments, the definition of convincing evidence from FNP 91 and TRS 916 has been placed in brackets in Annex 1 for the Committee's consideration. In addition, the Committee could consider if it would help to identify in a footnote that accompanies the definition of "convincing" the specific nutrients for which NRVs-NCD were established using these specific criteria. Accordingly, draft text has been added to a footnote for the definition of convincing evidence in the Annex to clarify that "This definition was used in the following FAO/WHO reports that were considered in establishing NRVs-NCD for these nutrients [*specify nutrients]….*" .

Definition of Probable Evidence

47. For comments that supported probable evidence there appeared more support for the WCRF description of "probable evidence" than for the description in the two FAO/WHO expert consultation reports. An additional concern with referring to probable evidence in this Annex was that it could create a different basis for the strength of the scientific evidence compared to the approach for health claims in the Codex *Guidelines for Use of Nutrition and Health Claims*.

Section 2 – Definition of Probable Evidence

48. Based on the above comments, the WCRF description of "probable evidence" is included in brackets in 2.1 of the Annex for consideration. The definition includes draft footnotes to clarify that: 1) the 2007 WCRF report is the source of this definition; 2) this definition and application of "probable evidence" is specific to consideration of an appropriate basis for food label reference values by governments; and 3) the definition may be used in *future* FAO/WHO reports.

49. With regard to the selection of the appropriate definition of "convincing" and "probable", one member country suggested that WHO/FAO be requested to provide the most appropriate definition of "convincing" and "probable" for use in these draft guidelines. With regard to this comment, it may be helpful for FAO/WHO to confirm that there are currently no available FAO/WHO reports that are applicable to this work that have used the 2007 WCRF definition, and to also provide an update on when any future FAO/WHO reports using the WCRF criteria are anticipated to become available. However, an alternative view is that it is the role of this Codex Committee to decide which definition(s) is most appropriate to include in this Codex text.

50. In addition, one member country suggested including a definition of "possible" to indicate the next level of evidence for comparison with "convincing" and "probable" evidence. The inclusion of additional descriptors can be raised at the next session.

Additional Comments on the 1st and 2nd bullets in Section 3.1

51. A CL comment proposed the additional edits below to the bullet on the level of scientific evidence in Appendix IV of the last session's report.

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

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

This country expressed the view that "and relevant" is redundant in this context and indicated that "strength of" is a term used in WHO TRS 916. It further proposed to add an "(s)" to "relationship" to allow for more than one relationship, and to add "that underpin the NRV-NCD" for clarification.

52. Most comments supported adding an "(s)" to relationship. Annex 1 has been revised accordingly. The majority of comments supported replacing "relevant" with "strength of". One respondent preferred to retain "relevant" for consistency with the *Guidelines for Use of Nutrition and Health Claims* which indicates that health claims must be based on current relevant scientific substantiation.". There was not widespread support to add the text, "that underpin the NRV-NCD". Comments noted that the introductory sentence in 3.1 refers to the establishment of NRVs-NCD which implies that the scientific evidence for the nutrient-noncommunicable disease risk relationship(s) underpin the NRVs-NCD.

Section 3.1 – Additional Edits

53. Based on these comments, Annex 1 has been revised to refer to "strength of the scientific evidence" and "relevant" has been placed in brackets for the Committee's further consideration.

54. One comment suggested deleting "generally accepted" to avoid semantic confusion. In this regard, it may be noted that the Committee agreed at its last session to refer to "convincing/generally accepted" evidence and to include a footnote that these terms are considered synonymous for these general principles (REP11/NFSDU, para 99).

Section 3.1 Reversal of the 1st and 2nd Bullets

55. A CL comment suggested reversing the order of the 1st and 2nd bullets in 3.1, so that the criterion for the public health importance of a nutrient-disease relationship to Codex member countries would precede the level of the evidence for the relationship.
The majority of comments supported retaining the order of the bullets. Reasons included:

- The bullets are already in a logical order.
- The first bullet point (related to strength of scientific evidence needed) is a prerequisite for considering the second bullet (related to public health importance to Codex member countries).
- The level of evidence should form the basis for public health importance.
- The strength of the scientific evidence should be identified first given the importance that NRVs-NCD have a strong scientific basis.
- Nutrition labeling should support nutrition policy from the view of public health importance.

Several comments supported changing the bullet order. Reasons included:

- It allows the more conceptual point to precede the more technical point.
- The public health importance is probably the first consideration.
- It seems logical that the first criteria should be that there is a public health importance across Codex member countries and that it is not just a national or regional issue.
- The main criteria to include a nutrient in the list are the epidemiologic profile of each country.
- It is highly likely that public health concerns would be the primary driver for selection of nutrients for NRV-NCDs.

Other comments noted that the order of the bullets is not important because both criteria would need to be met.

Section 3.1 - Reversal of the 1st and 2nd Bullets

56. Taking into consideration these comments including that both criteria would need to be met, the order of the bullets based on the outcome of the last session is retained in Annex 1.

3.2 Selection of Suitable Data Sources to Establish NRVs-NCD

3.2.1

57. A CL comment proposed the following edit to 3.2.1:

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

The comment noted that 3.2.2 refers to values that are based on "review of the science" from recognized authoritative scientific bodies other than FAO/WHO. The country was of the view that it is also important to clarify in 3.2.1 that the daily intake values provided by FAO/WHO should be based on relevant and recent *review of the science*. It further commented that this could be an independent review of all scientific evidence, or alternatively, a review of the scientific evidence from recent and relevant independent reviews conducted by other recognized authoritative scientific bodies.

58. The majority of comments supported adding the text while others did not consider it necessary or were opposed to its addition. One comment inquired about how this proposal would affect the language in the vitamin and mineral NRV principles (in 3.1), and if its language would need to be reviewed. Another proposed slightly different wording to qualify the type of review as follows:

> "Relevant ~~and recent~~ daily intake reference values provided by FAO/WHO **that are based on a <u>recent</u> review of the science…"**

59. With regard to the comment made about consistency with the vitamin and mineral NRVs, if the principles in the two annexes are consolidated, there should be an opportunity to consider consequential changes to both sets of principles, and improved wording. The above wording may be preferable with the assumption that the Committee would be most interested in when a scientific review was conducted, taking into consideration that the time between completion of a scientific review and its publication can vary.

3.2.1 and 3.2.2 – Proposed edits

60. Based on the above comments, new proposed wording is included in 3.2.1 in brackets with the current wording for the Committee's consideration. The above wording could also apply to 3.2.2. Accordingly, a new option for similar text in 3.2.2 has been added.

3.2.3

61**.** One respondent proposed that 3.2.3 be clarified as follows:

> "~~These values~~ **<u>The NRVs-NCD</u>** should be based on intake recommendations for healthy populations."

3.2.3 – Proposed Edit

62. The above proposed edit is placed in brackets in 3.2.3, Annex 1 for consideration.

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

3.3.4

63. With regard to 3.3.4, one country was of the view that the population-group basis of the daily intake reference value for NRVs-NCD should follow as closely as possible those in support of NRVs for vitamins and minerals. It suggested that the second mention of "general population" in Paragraph 3.3.4 could be misinterpreted to mean population-weighted values as mentioned in Paragraph 2 of the Preamble for only national consideration. The country further acknowledged that some potential data sources for NRVs-NCD are established from younger ages onwards, and that 'adult' is not strictly correct in this context. It suggested the following revision of Paragraph 3.3.4, noting the replacement of 'gender' by 'sex' to be consistent with paragraph 2 of the Preamble:

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

64. The comments generally agreed to replace "gender" with "sex"; Annex 1 is revised accordingly. The comments were not in agreement on whether edits to 3.3.4 were needed, and some countries offered alternative text for consideration. In addition, the country that proposed the above edits subsequently suggested a modification of their edits to refer to "the mean of ~~adult~~ males and ~~adult~~ females". Given the different views on whether and if so how this text should be revised, no revisions are proposed in Annex 1, but with the understanding that this text can be discussed at the next session.

3.3.5

65. A couple of comments suggested that the metric unit of kilojoule precede the unit of kilocalories, with one noting that this would be the same order as in 3.4.2 of the Guidelines. The reference would then be "8370 kilojoules/2000 kilocalories." For consistency with 3.4.2 of the Guidelines, the proposed reordering is reflected in 3.3.5 of Annex 1.

66. Another country suggested adding a second sentence to 3.3.5 that would specify in the labelling the reference energy intake that is used in a country or region so that the consumer has a clear reference and would be able to make informed choices. Section 3.3.5 would then read:

> "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 the factors specific to their country or region. **In this latter case, the energy intake used should be specified in the labelling.**"

67. The EWG was asked whether Codex text should be added to provide for the reference energy intake to be identified on the nutrition label, and if so, where this provision might most be appropriately placed in the Guidelines.

68. The majority of comments agreed that the reference caloric intake should be specified in nutrition labelling. However, the comments generally supported its declaration in all cases where applicable (including when a Codex NRV-NCD is used), not only "in the latter case" when governments use another reference energy intake. One comment indicated that national authorities should decide whether this information would be useful to consumers and required on the label. A few comments suggested that the proposed text be placed in 3.3.5. However, given the proposed text addresses presentation of nutrition information to consumers, other comments suggested that it may be more appropriate for the CCNFSDU to make recommendations to the CCFL concerning this text and for this information to be placed in Section 3.4.4 of the Guidelines, or placed after 3.4.4.

3.3.5 – Identification of Reference Energy Intake in Nutrition Labelling

69. Based on the above comments, the following slightly revised draft text is included in 3.3.5 in brackets, with the intent that the Committee discuss at its next session the most appropriate placement of this text and possible referral of a recommendation to the CCFL.

> "Governments may use a Codex NRV-NCD based on the reference energy intake.... [**In either case, the reference energy intake should be specified in nutrition labelling]**.**"**

3.4. Consideration of Daily Intake Values for Upper Levels

70. At the last session, the Committee could not reach a consensus on whether to include a draft principle on consideration of daily intake values for upper levels, and left it in brackets to consider further. Some delegations supported retaining the text, and were of the view that in some cases, such as sodium and saturated fat, consideration of ULs and other daily intake values for upper levels was essential in establishing NRVs-NCD.

71. The EWG was asked if they supported including the draft principles with the new text below that would add the U-AMDR as an example. The EWG was also asked to comment on "limits" as an alternative to "levels".

> [3.4 Consideration of Daily Intake Values for Upper [Levels/**Limits**]
>
> The establishment of NRVs-NCD should take into account daily intake reference values for upper [levels/**limits]** where applicable (e.g., Upper Level of Intake, **Upper Level of Acceptable Macronutrient Distribution Range**).

72. The majority of comments supported including a principle in this Annex on consideration of daily intake values for upper levels. Reasons included the applicability of the UL in considering NRVs-NCD for certain nutrients such as sodium (either alone or in combination with other daily intake values established by recognized authoritative scientific bodies) given its global relevance and scientific basis. Among those that supported including the draft principle, there was not consensus on whether the U-AMDR should be added as another example. Certain comments supported its inclusion given it is the basis for the FAO/WHO expert consultation SFA intake recommendation. One country considered the addition unnecessary. An observer organization commented that the upper level of the estimated AMDR is too uncertain.

73. A member country that supported including this principle and adding the U-AMDR as an example commented that in the case of sodium and saturated fat, which are associated with an *increased* risk of NCD, that upper levels could themselves be the basis for the NRV and not just taken into account. It further commented that in other cases where *increased* intake of a nutrient is associated with *reduced* risk of an NCD, the upper levels should be taken into account, in a manner more similar to those of vitamins and minerals. Thus, this country suggested that the Committee might want to consider if it is possible to amend 3.4 to include guidance about when to use the recommended intake and when to use an upper level.

74. Comments that supported including the principle did not support replacing the term "levels" with "limits". Accordingly, "levels" is retained in Annex 1.

75. A few comments did not support including the principle. One respondent was of the view that defining an upper level of intake is complex for macronutrients, and that in general it is not possible to identify a quantitative upper level of intake for macronutrients. Another stated that the scientific data to establish upper levels for many nutrients associated with NCDs are inconclusive at this time, with the possible exception of *trans*-fatty acids.

76. One country commented that the 3.4 principle is very general and does not add value. This country stated that the EWG consultation document suggested adoption of the adult SFA U-AMDR (10% E) although the children's (2-18 years) U-AMDR is 8% E, and asked, "If the principle (in 3.4) were to be applied, would this

mean that % E for saturated fat should be reduced to ensure that the U-AMDR for children was not exceeded?" With regard to this latter comment, it may be noted that the wording of the draft principle is that "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***…..". Thus, the wording provides flexibility to *take into account* upper levels (alone or in conjunction with other daily intake reference values). The draft principle does not prescribe how they should be applied or that they should be applied in all cases.

77. Another country was of the view that inclusion of a principle that considers upper limits might seem contrary to sections 3.2.3 and 3.3.4. With regard to this comment, the respondent may wish to further clarify their view at the next session. This country further commented that there might be a view that the current definition of 'daily intake reference values' in section 2.2 does not preclude the use of values based on upper levels of intake or "UMDRs" in deriving NRVs-NCD.

Section 3.4 - Consideration of Daily Intake Values for Upper Levels.

78. Given that the majority of comments supported further consideration of this principle, it is retained in brackets in Annex 1. In addition, given that certain comments supported identifying "Upper Level of Acceptable Macronutrient Range" as another example in this draft principle, it is included in 3.4 for the full committee's consideration.

III. PROPOSALS FOR NRVS-NCD FOR SFA AND SODIUM BASED ON THE DRAFT PRINCIPLES

79. At the last session, the Committee agreed that in conjunction with ongoing work on the general principles, the EWG would make proposals on NRVs-NCD for SFA and sodium for consideration at the next session. The NRVs-NCD to be established are for the general population identified as individuals older than 36 months. In the conduct of the EWG, relevant background was provided, some of which is summarized below, and questions posed to the EWG about the application of the draft principles to the two nutrients. The version of the draft principles in Appendix IV in REP11/NFSDU was used as the reference document. At the next session, the Committee will have a revised set of draft principles to further consider proposals for these NRVs-NCD.

80. As mentioned earlier, based on the draft principles two joint FAO/WHO expert consultation reports were proposed as primary data sources for the EWG to consider in proposing NRVs-NCD for these two nutrients: 1) for SFA—the report of the 2008 joint FAO/WHO expert consultation on fats and fatty acids in human nutrition (FNP 91), and 2) for sodium—the report of the 2002 joint FAO/WHO expert consultation on diet, nutrition and the prevention of chronic diseases (TRS 916).

A. Saturated Fatty Acids

Application of Section 3.1 Draft Criteria for Selection of Nutrients

81. With regard to the first 3.1 criterion on strength of the scientific evidence for the nutrient-disease risk relationship, the 2008 joint FAO/WHO expert consultation on fats and fatty acids in human nutrition concluded that there is convincing evidence: 1) that replacing SFA with polyunsaturated fatty acids (PUFA) decreases the risk of coronary heart disease (CHD), and 2) that replacing SFA (C12:0-C16:0) with PUFA and monounsaturated fatty acids (MUFA) decreases LDL cholesterol concentration and total/HDL cholesterol ratio (pp. 14-15, FNP 91). The expert consultation further recommended in the report's conclusions section that "the total intake of SFA not exceed 10% E" (p. 15). The report included separate recommendations expressed as a U-AMDR for adults 19 years and older (i.e., 10% E) and for children 2-18 years (i.e., 8% E) (pp. 11-12)

82. The EWG was asked whether they agreed that SFA meet the two criteria for selection of nutrients for NRVs-NCD in the draft principles. Most comments agreed that SFA met the two criteria in 3.1.

83. As additional comments on the first criterion on scientific evidence, one member organization noted that a 2010 EFSA Scientific Opinion conclusion that there was evidence of a relationship between SFA intake and blood lipid profile/disease risk.[10] Another member country cited a 2002 IOM expert panel conclusion that there is a positive linear trend between total SFA intake and total and LDL concentration and increased risk of CHD.[11] One country again commented that they interpret the first bullet to accommodate a relationship with a biomarker/risk factor. Another was of the view that SFA met the two criteria in 3.1 only if the term "probable" is retained in the first bullet. This country's rationale was because there is no randomized control study on replacement of SFA with PUFA to evaluate prevalence of CHD. With regard to the last comment, the FAO/WHO expert consultation did conclude that there is convincing evidence that replacing SFA with PUFA decreases the risk of CHD based on the criteria for convincing evidence that is identified in Annex 1. In addition, the Committee has been asked to confirm at its next session that the current 3.1 text accommodates validated biomarkers for disease risk, and to consider new text to make this point explicit. One observer organization was against continuing work on NRV-NCD proposals because the principles were not set. This organization opposed developing a SFA NRV-NCD, stating among other things, the importance of considering the complete nutritional contributions of foods to the diet rather than only nutrient level(s) related to disease risk, and that not all SFA individually have the same biological effects.

84. The second criterion in 3.1 for selection of nutrients is the public health importance of the nutrient-noncommunicable disease risk relationship among Codex member countries. With regard to this criterion, a member country commented that CHD is prevalent in many developed and developing countries and that cardiovascular disease—which includes CHD—is a leading cause of death globally (WHO Factsheet, 2011). It further considered that TRS916, FNP91 and the Global Strategy on Diet, Physical Activity and Health provide a sufficient case to take action to reduce SFA.

3.1 - Criteria for Selection of Nutrients

85. The EWG generally agreed that the criteria were met for SFA.

Application of Section 3.2 Draft Principles for Selection of Suitable Data Sources for NRVs-NCD

3.2.1 (Suitable Data Sources from FAO/WHO) and 3.2.3 (Recommendations for Healthy Populations)

86. The EWG was asked if they agreed that the daily intake recommendation for SFA provided in FNP 91 meets the first and third criteria in 3.2. They were also asked whether any other report with recent and relevant FAO/WHO scientific advice is available to consider in proposing a SFA NRV-NCD.

87. Most comments agreed that the SFA daily intake recommendation in FNP 91 met the first and third criteria in 3.2. No other report was identified with recent and relevant FAO/WHO scientific advice for proposing a SFA NRV-NCD. One member country was of the view that the 10% E value met the criteria in 3.2.1 but was unsure whether this value is the most appropriate value for a healthy population. This respondent suggested that Section 3.2.3 be amended as follows:

> " 3.2.3 These values should be based on **the most suitable** intake recommendations ~~for healthy populations.~~"

With regard to the above comment, the respondent may wish to propose this amendment in the plenary session with an expanded rationale. However, since no text in 3.2.3 was left in brackets at the last session and this suggestion was not raised in CL comments, this alternative text is not identified in Annex 1.

[10] EFSA Journal 2010;8(3):1461 (http://www.efsa.europa.eu/en/efsajournal/doc/1461.pdf). Language English.

[11] Institute of Medicine. Food and Nutrition Board. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids.*. Washington DC: National Academies Press, 2002, 2005. p. 422, summary section on dietary fats. http://www.nap.edu/openbook.php?record_id=10490&page=422

88. An observer organization was of the view that the SFA daily intake recommendation in FNP 91 does not meet the first criterion which refers to "relevant and recent".

3.2.1 and 3.2.3

89. The EWG generally agreed that the first and third criteria in 3.2 were met for SFA.

3.2.2 – Suitable Data Sources from Other Recognized Authoritative Scientific Bodies

90. With regard to draft principle 3.2.2, the EWG was asked if there is a compelling reason to also consider relevant and recent SFA values that reflect an independent review of the science from other recognized authoritative scientific bodies. If so, information was requested about the reason, how the full report and scientific review could be accessed, the specific daily intake value(s), and information needed to interpret the value(s), including how it was derived, the type of daily intake value(s), and associated definition.

91. Two respondents noted that neither the IOM nor the EFSA had identified quantitative daily intake values for SFA, but instead recommended that SFA intake be as low as possible while consuming a nutritionally adequate diet. One member country noted the availability of a recent systematic review of the scientific evidence on SFA that included studies published after 2008. Another commented that consideration of dietary guidelines issued by many countries that are intended to be specific to a country's population and diet should not be part of the general principles to establish Codex NRVs-NCD.

3.2.2 – Suitable Data Sources from Other Recognized Authoritative Scientific Bodies

92. The EWG generally agreed that daily intake reference values for SFA from other recognized authoritative scientific bodies were not available to consider in proposing a SFA NRV-NCD.

Application of Section 3.3 Draft Principles for Selection of Appropriate Basis for Determining and Expressing NRVs-NCD

Background

93. In the EWG consultation document, it was noted that the 2008 joint FAO/WHO expert consultation recommended that SFA should be replaced with PUFA (n-3 and n-6) in the diet and the total intake of SFA not exceed 10% E (p.15, FNP 91).

10 % Energy as a Basis for a Proposed NRV-NCD for SFA

94. The EWG was asked if they supported further consideration of 10% E from SFA as a basis for a proposed NRV-NCD (in addition to further consideration of any additional suitable data sources based on responses to the consultation document).

95. Most comments supported further consideration of 10% E as a basis for a proposed NRV-NCD for SFA. One member country commented that 10% E is probably a pragmatic choice but that lower % E values would also be acceptable, and was of the view that the CCNFSDU would need to first agree that upper limits of intake can form the basis of NRVs-NCD. In addition, a member organization requested further consideration of whether criterion 3.3.1, that there should be "Relevant peer-reviewed scientific evidence for a quantitative reference value for daily intake' is fulfilled in the case of SFA. This comment noted that the EFSA concluded in 2010 that it was not possible to establish a specific figure for SFA intake and recommended that the intake should be as low as possible within the context of a nutritionally adequate diet.

96. The EWG generally agreed to further consider 10% E from SFA as a basis for a proposed

NRV-NCD. In addition, the Committee is requested to consider whether 3.3.1 has been met in the case of SFA.

Potential SFA NRV-NCD Based on a Reference Energy Intake

97. In the consultation document, it was noted that if the draft criteria in 3.3 are applied to 10% of energy from SFA, the resulting single NRV-NCD based on a reference daily energy intake of 2000 kilocalories/8370 kilojoules would be 22 grams (or 20 grams if rounded). EWG members who supported further consideration of 10% of energy as a basis were asked whether the resulting potential NRV-NCD for consideration should be the unrounded number of 22 grams, or alternatively, the rounded number of 20 grams.

98. The EWG did not agree on whether a potential SFA NRV-NCD should reflect an unrounded or rounded number. In addition, one member country further clarified that whereas 10% of 2000 kilocalories yields 22.2g (assuming an energy density of 9 kcal/g), 10% of 8370 kilojoules yields 22.6 g which rounds to 23 g (assuming an energy density of 37 kJ/g).

99. Reasons for considering the unrounded number of 22 (instead of 20) included:

- The unrounded number reflects the 2008 FAO/WHO expert consultation recommendation that total SFA not exceed 10% E.
- Whereas 10% of 2000 kilocalories yields 22.2g (assuming an energy density of 9 kcal/g), 10% of 8370 kilojoules yields 22.6 g which rounds to 23 g (assuming an energy density of 37 kJ/g).
- Consideration of a rounded number might necessitate discussion of whether specific rounding rules would need to be developed more generically (e.g., that would apply to all potential NRVs-NCD).
- Consistency with a specific country's food label reference value.

Reasons for considering the rounded number of 20 (which is about 9 % E from SFA) included:

- It is consistent with evidence that suggests further health benefit below 10% E.
- The rounded number is simpler to work with.

Potential SFA NRV-NCD

100. Based on EWG support to further consider 10% E from SFA as a basis for an NRV-NCD, the Committee may wish to further consider 22 g (or 20 g if rounded) as a potential NRV-NCD based on the reference daily intake 8370 kilojoules/2000 kilocalories. (Refer to Annex 2).

Potential Application of the Draft Principle in 3.4

101. The EWG was asked whether the draft principle in 3.4 on "Consideration of Daily Intake Values for Upper Levels" applied to the establishment of an NRV-NCD for SFA, taking into consideration suitable data sources from FAO/WHO and other recognized authoritative bodies.

102. The majority of comments were of the view that the draft principle in 3.4 applies to the establishment of an NRV-NCD for SFA. Reasons included:

- The 2008 joint FAO/WHO expert consultation concluded that total intake of SFA in the diet should not exceed 10% E.
- The SFA intake recommendation from the 2008 expert consultation is expressed as an Upper Value of the Macronutrient Distribution Range.

A few comments were of the view that the draft principle in 3.4 does not apply. Reasons included:

- A 2010 EFSA scientific opinion concluded it was not possible to set a Tolerable Upper Intake Level for SFA because no threshold of SFA intake can be defined below which there is no adverse effect.
- ULs for SFA and sodium are based on NCD end points which have a continuous dose response relationship and as such differ from the basis of ULs for vitamins and minerals.

103. With regard to the comments that were of the view that the 3.4 draft principle does not apply, these comments appear to assume that the 3.4 draft principle applies only to the UL and not to the U-AMDR. However, the 3.4 draft principle refers to daily intake values for upper levels (with the UL given as one example) and thus can be interpreted to also encompass the U-AMDR. Additionally, the second comment referred to a UL for SFA but we are unaware that a UL for SFA has been established by FAO/WHO or another recognized authoritative scientific body. Thus, this comment does not appear applicable to this nutrient.

3.4 Draft Principle on Upper Levels

104. Based on the above comments, the Committee may wish to further discuss at its next session whether the 3.4 draft principle applies to the U-AMDR for SFA established by the 2008 FAO/WHO expert consultation.

B. Sodium

Application of Section 3.1 Draft Criteria for Selection of Nutrients

105. With regard to the 3.1 criterion on strength of the scientific evidence for the nutrient-disease risk relationship, the 2002 joint WHO/FAO expert consultation on Diet, Nutrition and the Prevention of Chronic Diseases (TRS 916) concluded that there is convincing evidence that high sodium intake is related to increased risk of cardiovascular disease. This report identified *population* nutrient intake goals rather than recommended intakes for individuals. It stated that "Population nutrient intake goals represent the population average intake that is judged to be consistent with the maintenance of health in a population", and "Health, in this context is marked by a low prevalence of diet-related diseases in the population" (TRS 916, p. 54). The expert consultation recommended a population nutrient intake goal of less than 2 g of sodium per day (TRS 916, p. 56).

As earlier noted, the second criterion refers to the public health importance of the nutrient-noncommunicable disease risk relationship among Codex member countries.

106. The EWG was asked whether they agree that sodium meets the two criteria in Section 3.1 of the draft principles. All comments from member countries agreed that sodium met these two draft criteria. As additional comments on the scientific evidence, one member organization noted that a 2005 EFSA Scientific Opinion concluded that there was generally accepted evidence of a relationship between sodium (as sodium chloride) and risk of increased blood pressure.[12] Another member country cited conclusions in a 2004 IOM report that on average blood pressure rises progressively with increased sodium intake.[13] An observer organization was against continuing work on NRV-NCD proposals because the principles were not set. This organization opposed the development of a sodium NRV-NCD, stating among other things, that many core foods that contain intrinsic sodium levels are associated with diets that reduce hypertension.

107. With regard to the second criterion, a member country again commented that cardiovascular disease is a leading cause of death globally, and considered that TRS916 and the Global Strategy on Diet, Physical Activity and Health provide a sufficient case to take action to reduce sodium intake.

3.1 – Criteria for Selection of Nutrients

108. The EWG generally agreed that the criteria were met for sodium.

[12] EFSA Journal **(**2005) 209, 1 (http://www.efsa.europa.eu/en/efsajournal/doc/209.pdf). Language English

[13] Institute of Medicine. Food and Nutrition Board. *Dietary Reference Intakes: Water, Potassium, Sodium, Chloride and Sulfate.* Washington DC: National Academies Press, 2004. p. 270, summary section on sodium and chloride. http://www.nap.edu/openbook.php?record_id=10925&page=269 .

Application of Section 3.2 Draft Principles for Selection of Suitable Data Sources for NRVs-NCD

3.2.1 (Suitable Data Sources from FAO/WHO) and 3.2.3 (Recommendations for Healthy Populations)

109. The EWG was asked if they agreed that the daily intake recommendation for sodium intake in TRS 916 meets the first and third criteria in 3.2. They were also asked whether any other report with recent and relevant FAO/WHO scientific advice is available to consider in proposing a sodium NRV-NCD.

110. Most comments agreed that the sodium intake recommendation in TRS 916 met the first and third criteria in 3.2. No additional FAO/WHO scientific advice was identified in comments.

111. One member country proposed that the Committee consider the 2003 WHO/International Society of Hypertension Statement on Management of Hypertension, but no specific sodium daily intake reference value was identified from this reference. In addition, this WHO statement focuses on treatment recommendations for hypertensive patients, and thus does not appear to meet the criterion in 3.2.3.

112. Another member country was of the view that TRS 916 no longer provides up-to-date evaluation of the evidence and should not be used as the basis of the decision if suitable more recent evaluations are available, including from the parent organizations. It further commented that it was premature to derive sodium NRVs because: 1) the WHO/FAO report on vitamin and mineral intake recommendations at the next CCNFSDU session is relevant to a broader issue of what to do when a nutrient has both a reference value for dietary adequacy and risk of reduction of noncommunicable disease; and 2) the Committee should await the outcome of a review of salt and sodium recommendations by (a subgroup of) the WHO Nutrition Guidance Expert Advisory Group (NUGAG) rather than rely on TRS 916 or other data, given that the NUGAG approach incorporates a systematic review of the evidence now adopted by WHO.

113. With regard the above comment, it may be noted that the Committee charged this EWG to make proposals for NRV-NCDs for sodium and SFA for consideration at the next session, not to finalize recommendations. Moreover, the Committee's project document for this new work stated that "expert scientific advice on diet-related noncommunicable diseases is available through recent and comprehensive reviews by WHO/FAO and other recognized authoritative bodies"; no request was made at that time for additional FAO/WHO scientific advice. Nonetheless, the comment raises a question as to whether the Committee believes that more recent scientific data should be considered and/or additional FAO/WHO scientific advice requested. Related questions that could be addressed at the next session include: 1) the progress made by FAO and WHO since the last session on procedural arrangements for the "Joint FAO/WHO Expert Meetings on Nutrition"; and 2) how the Committee should regard NUGAG and other reports from only one of the Codex parent organizations, taking into consideration Codex risk assessment principles as addressed in CRD 5 at the last session.

3.2.1 and 3.2.3

114. The EWG generally agreed that the first and third criteria in 3.2 were met for sodium. The Committee may also wish to consider the need for obtaining additional scientific advice as it relates to this work, and FAO and WHO updates on mechanisms for providing scientific advice on nutrition issues.

3.2.2 - Suitable Data Sources from Other Recognized Authoritative Scientific Bodies

115. With regard to draft principle 3.2.2, the EWG was asked if there was a compelling reason to also consider relevant and recent sodium values that reflect an independent review of the science from other recognized authoritative bodies. If so, information was requested about the reason, how the full report and scientific review could be accessed, the specific daily intake value(s), and information needed to interpret the value(s), including how it was derived, the type of daily intake value(s), and associated definition.

116. Two member countries considered that in addition to the TRS916 recommendation for sodium intake, there was a compelling reason to consider dietary reference intake values for sodium from the 2004 U.S. Institute of

Medicine report, which include "Tolerable Upper Intake Levels (UL)" "and "Adequate Intake values".[14] These values and their definition and derivation are identified in Annex 2 for reference. One country was of the view that while the TRS 916 meets the criteria for selection as a data source, the rationale for the specific sodium recommendation is not clear. This country commented that the 2004 IOM report should also be considered because it makes clearer linkages between the scientific evidence and reference intakes. The other country supported consideration of the IOM daily intake reference values to support the goal that the sodium NRV-NCD have a sound scientific basis and be applicable globally to helping consumers construct healthful diets. This country considered that the IOM definition of Tolerable Upper Intake Level (UL) is similar to the Codex definition of Upper Level of Intake (UL) (and to the definition from a 2005 FAO/WHO workshop on nutrient risk assessment[15]). It further noted the applicability of the UL to diverse population groups and its global relevance as identified in the 2005 FAO/WHO workshop report (pp. 15-16). However, the other country considered that the definition of a UL for sodium is problematic as increases in blood pressure continue with increasing sodium intakes without an apparent threshold.

In addition, both these countries identified the IOM sodium "Adequate Intake" values[16] as relevant to these countries' consideration of a sodium food label reference value. One commented that the AI level is thought to meet or exceed requirements of almost all individuals. The other commented that the IOM sodium AI values were based on meeting sodium needs of apparently healthy individuals as well as to ensure that an overall Western-type diet provides an adequate intake of other important nutrients. Thus, unlike the UL, the IOM sodium AI values do not appear applicable globally. Highly variable sodium intake recommendations established by governments is further suggested in a table that compared recommended daily intakes in the U.S. and Europe that was included in a 2003 scientific opinion by the European Scientific Committee on Food.[17]

117. The Committee may also wish to consider dietary reference intakes for sodium from the IOM that may be relevant to this work, either as a sole basis for a sodium NRV-NCD or as supplementary information to consider in proposing an NRV-NCD in conjunction with other daily intake reference values that meet the criteria in the draft principles. The derivation of these values is important to consider in assessing their global relevance to establishing a sodium NRV-NCD.

Application of Section 3.3 Draft Principles for Selection of Appropriate Basis for Determining and Expressing NRVs-NCD

Background

118. In the EWG consultation document, it was noted that the 2002 expert consultation recommended a population nutrient intake goal of less than 2 g of sodium per day. If the draft criteria in 3.3 are applied, the single NRV-NCD value for the general population would be 2 g (or 2000 mg).

119. The EWG was asked if they support further consideration of 2 g (or 2000 mg) as a proposed NRV-NCD (in addition to further consideration at the next session of any additional suitable data sources based on responses to the consultation document). They were also invited to comment on whether a proposed NRV-NCD for sodium should be expressed in grams or milligrams.

[14] Institute of Medicine. Food and Nutrition Board. *Dietary Reference Intakes: Water, Potassium, Sodium, Chloride and Sulfate.* Washington DC: National Academies Press, 2004. p. 268, summary section on sodium and chloride.

[15] *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances: Report of a Joint FOA/WHO Technical Workshop on Nutrient Risk Assessment, 2-6 May 2005*. WHO, 2006.

[16] The IOM established an "Adequate Intake" value for a nutrient when a Recommended Dietary Allowance[16] cannot be determined because of insufficient data to establish an estimated average requirement. "Recommended Dietary Allowance" is the U.S. term for an Individual Nutrient Level 98 (INL[98]).

[17] European Commission. *Opinion of the Scientific Committee on Food on the Revision of Reference Values for Nutrition Labelling.* SCF/CS/NUT/GEN/18 Final. 6 March 2003.

Units for Expressing a Sodium NRV-NCD

120. All EWG comments that commented on recommended units for a potential sodium NRV-NCD supported its expression in milligrams rather than grams. Reasons included:

- The amount of sodium in a food is more likely to be reported or calculated in milligrams. It would make the percentage calculation easier and less prone to error if the reference value in the same units.
- Milligrams is consistent with the units used for certain other nutrients in nutrition labelling (e.g., calcium, magnesium, iron and zinc).
- The larger number may help convey the message that the value represents a substantial amount of sodium. If expressed in grams, differences in sodium content may be less apparent to the consumer.

121. Another member country noted that the Guidelines on Nutrition Labelling specify units for certain nutrients when declared on the label (e.g., in 3.4.2, 3.4.3, 3.4.6 and 3.4.7). By comparison, 3.4.4 implies but does not explicitly require that the metric units of the listed NRVs be reflected in the label declaration of protein and vitamin and mineral amounts. This country commented that the Committee could recommend that CCFL specify a labeling unit for sodium as well as consider explicitly linking the NRV units of vitamins, minerals and protein in paragraph 3.4.4 to their units for labelling declaration.

Units for Expressing a Sodium NRV-NCD

122. The EWG generally agreed that a proposed NRV-NCD should be expressed in milligrams. When the Committee is ready to make recommendations to CCFL that pertain to labelling aspects for NRVs, it could also consider the above recommendation by a country to clarify in the Guidelines appropriate labelling declaration units for protein, vitamins and minerals..

Potential NRV-NCD for Sodium

123. Most EWG comments supported further consideration of the 2002 FAO/WHO expert consultation recommendation of 2000 mg as a proposed NRV-NCD. In addition, one member country noted a statement in TRS 916 that "Current evidence suggests that an intake of no more than 70 mmol or 1.7 g of sodium per day is beneficial." Two member countries supported consideration of other suitable data sources that meet the criteria in 3.2 such as the 2004 IOM report on sodium dietary reference intakes. Another commented that TRS 916 should not be used as the basis of (an NRV-NCD) if more recent suitable evaluations are available, and proposed that forthcoming sodium intake recommendations by a WHO NUGUG subgroup be considered. A member organization requested further consideration of whether criterion 3.3.1, that there should be "Relevant peer-reviewed scientific evidence for a quantitative reference value for daily intake", is fulfilled in the case of an upper level of intake for sodium. This comment noted that the EFSA concluded in 2005 that it is not possible to determine a threshold level of habitual sodium consumption below which there is unlikely to be any adverse effect on blood pressure.

Potential NRV-NCD for Sodium

124. The EWG generally agreed to further consider 2000 mg as a basis for a proposed NRV-NCD, in addition to other suitable data sources that meet the criteria in 3.2. In addition, the Committee is requested to consider whether 3.3.1 has been met in the case of sodium. (Refer to Annex 2).

Potential Application of the Draft Principle in 3.4

125. The EWG was asked whether the draft principle in 3.4 on "Consideration of Daily Intake Values for Upper Levels" applies to the establishment of an NRV-NCD for sodium, taking into consideration suitable data sources from FAO/WHO and other recognized authoritative scientific bodies.

126. Five member countries considered that this principle applies in the case of sodium. One indicated that it is difficult to know whether the principle applies to the FAO/WHO recommendation of 2000 mg without knowing

more about how this value was derived. Another commented that the IOM UL is also appropriate to consider in establishing an NRV-NCD given that a UL is globally relevant and the 2004 IOM report reflects a recent independent review of the scientific evidence. Two other countries sought additional information before offering an opinion.

127. A member organization did not consider that this draft principle applies given that the 2005 EFSA opinion concluded it was not possible to establish a Tolerable Upper Intake Level. Another country again indicated that they preferred that the draft principle in 3.4 be deleted. However, they noted that if the basis for a NRV for sodium were dietary adequacy, then consistent with other mineral, a comparison against the UL for young children might be appropriate. Two other countries sought additional information before offering an opinion.

3.4 Draft Principle on Upper Levels

128. Based on the above comments, the Committee may wish to further discuss at its next session whether the 3.4 draft principle applies in the case of sodium.

IV. ADDITIONAL ISSUES FOR THE COMMITTEE'S CONSIDERATION

Multiple Types of Daily Intake Values for Certain Nutrients

129. In the course of this Committee's work on NRVs-NCD, at least two member countries commented that for certain nutrients there is more than one basis to establish a potential NRV. Last year, one country noted that the IOM Adequate Intake values for potassium—which consider the role of potassium from food sources in reducing adverse effects of sodium chloride on blood pressure as well as kidney stone risk—are higher than recommended intake values established by other government(s) that are based on meeting potassium requirements. This country suggested that the CCNFSDU discuss 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 FAO/WHO and/or other recognized authoritative scientific bodies, with one based primarily on requirements and the other also taking into consideration NCD risk. A government could then decide which value is most relevant to the public health needs of their population. In a related matter, the Committee noted at its last session that WHO may wish to consider the establishment of daily intake values for potassium on the basis of dietary adequacy and/or reduction of NCD risk as part of its work on salt and sodium recommendations (Appendix III, REP11/NFSDU).

130. Another country noted that FNP91 assigns more than one type of daily intake reference value for certain macronutrients such as n-6 PUFA (linoleic acid) that may be considered for an NRV (i.e., for adults—an AMDR, an estimated average requirement (EAR/INL_{50}), and an Adequate Intake (AI)). This country commented that one way to address the issue of nutrients having more than one type of reference value is to include introductory, high level principles in a merged Annex that guide the choice of an NRV by a government.

Protein NRV

131. A protein NRV of 50 grams is identified in Section 3.4.4 of the Guidelines. Two EWG members commented that it will be important when finalizing the list of NRVs that a reference value for protein continues to be included in the list. One of these commented that the Committee will probably need to review the placement of the value and need for a review of the value.

132. Another country stated in its CL comments that the (NRV-NCD) principles need to allow for an NRV for protein to be established on the basis of its INL_{98} rather than percentage dietary energy, and that a decision on the basis for a protein NRV should precede any consideration of the percentages of energy from fat and carbohydrate given that protein also contributes to dietary energy and that the sum of energy from protein, carbohydrate and fat should total 100 percent. However, a member organization did not agree that the energy associated with reference values for fats, carbohydrates and protein would need to equal 100 % of a reference

value for energy. This respondent stated that other components can contribute to the energy intake and noted that the Guidelines include energy conversion factors for alcohol (ethanol) and organic acid.

133. With regard to the above comments, the Committee may wish to discuss the need to review the protein NRV at its next session. However, this topic falls outside of the current work approved by the Commission to establish NRVs for nutrients associated with risk of diet-related noncommunicable diseases.

Consolidation of Annexes on NRV-NCD and vitamin and mineral NRV principles

134. More than one member country commented on the potential consolidation of the two annexes. One strongly encouraged that the two work items be brought together as soon as possible. This comment appears to have merit. For example, it does not appear logical for the Committee to proceed in finalizing the NRV-NCD principles if certain text would need to be reviewed again if the two Annexes are merged. Consequently, at the next session it is suggested the Committee discuss the consolidation of the Annexes.

Presentation of Information on NRVs in the Guidelines on Nutrition Labelling

135. At the last session, the Committee noted that as a result of this work, Section 3.4.4 of the Guidelines would need to be revised, and asked the Codex Committee on Food Labelling if it had any comments for the CCNFSDU to consider in developing proposed text (para 114, REP11/NFSDU). In this regard, it may be helpful to consider that the current text in 3.4.4 encompasses both: 1) presentation of nutrient content information to the consumer in nutrition labelling; and 2) information that relates to governments' use and interpretation of NRVs (i.e., the actual NRV values and related footnotes). Given this approved work mainly focuses on the latter, the Committee may wish to discuss its appropriate role with regard to CCFL on labeling issues that arise in the course of work. A few issues related to potential amendments to 3.4.4 are identified below.

Listing of NRVs-NCD. This section currently identifies NRVs for protein and 14 vitamins and minerals with footnotes for certain of these values. If NRVs-NCD are added to this list, the Committee could consider whether to propose separate listings of: 1) NRVs based on nutrient requirements; and 2) NRVs based on reduction of risk of diet-related noncommunicable diseases, with corresponding subheadings and/or footnotes to clarify their basis. For example, the basis for a proposed NRV-NCD for SFA from recommendations in the 2008 joint FAO/WHO expert consultation on fats and fatty acids in human nutrition is the substitution of SFA with PUFA or MUFA.

Information on the Nutrition Label. If NRVs-NCD are established for any macronutrients, the first paragraph in Section 3.4.4 on how nutrient content information should be expressed in nutrition labelling will need to be slightly revised given that the text currently only addresses vitamins, minerals, and protein. Another issue identified in the course of this EWG is the identification of a reference energy intake on the nutrition label in conjunction with an NRV-NCD based on this reference intake. The Committee could consider whether it would be preferable to refer NRV-related labeling issues (with possible suggested text) to CCFL as these issues arise, or alternatively, wait until more progress has been made on the NRVs-NCD.

Annex 1

PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES ON NUTRITION LABELLING: GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NONCOMMUNICABLE DISEASES FOR THE GENERAL POPULATION

(At Step 3 of the Procedure)

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 choose**]** **[Governments are encouraged]** 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 nutrients associated with noncommunicable diseases.

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

2. DEFINITION(S)

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

2.2 Daily Intake Reference Values as used in these principles refer to reference nutrient intake values provided by FAO/WHO or other recognized authoritative scientific bodies that may be considered in establishing an NRV-NCD based on the principles and criteria in Section 3 **[and include values that are recommended intakes and values that are upper levels of intake]** ***OR*** **(e.g., Acceptable Macronutrient Distribution Range or Upper Level of Intake, where applicable.)].** 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.

[2.3 Upper Level of Intake (UL)[18] is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.**]**

[**2.4 Acceptable Macronutrient Distribution Range (AMDR) is a range of intakes for a particular energy source that is associated with reduced risk of chronic diseases while providing adequate intakes of essential nutrients.]**

[2.5 Convincing Evidence[19] **is evidence based on epidemiological studies showing consistent associations between exposure and disease, with little or no evidence to the contrary. The available evidence is based on a substantial number of studies including prospective observational studies and where relevant,**

[18] [**Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range.]**

[[19] **1) This definition was used in the following FAO/WHO reports that were considered in establishing NRVs-NCD for these nutrients:[***specify nutrients***]: 1)** ***Fats and Fatty Acids in Human Nutrition: Report of an Expert Consultation.*** **FAO Food and Nutrition Paper 91. Rome. FAO, 2010. and 2)** ***Diet, Nutrition and the Prevention of Chronic Diseases*****. WHO Technical Report Series 916. WHO, 2003.]**

randomized controlled trials of sufficient size, duration and quality showing consistent effects. The association should be biologically plausible.]

[2.6 Probable Evidence[20] is evidence strong enough to support a judgement of a probable causal relationship [,which would generally justify goals and recommendations designed to reduce the incidence of cancer]. All of the following are generally required:

- **Evidence from at least two independent cohort studies, or at least five case control studies.**
- **No substantial unexplained heterogeneity between or within study types in the presence or absence of an association or direction of effect.**
- **Good quality studies to exclude with confidence the possibility that the observed association results from random or systematic error, including confounding, measurement error and selection bias.**
- **Evidence for biological plausibility.]**

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 Criteria for Selection of Nutrients

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

- Convincing/ Generally accepted[21] ~~[or Probable]~~ [and relevant] **strength of** scientific evidence for the nutrient-noncommunicable disease risk relationship **[,which includes validated biomarkers for disease risk.] [In addition, governments may consider the suitability of probable evidence as defined in Section 2 in conjunction with other relevant bases in establishing their own food label reference value(s) .]**
- Public health importance of the nutrient-noncommunicable disease risk relationship**(s)** among Codex member countries.

3.2 Selection of Suitable Data Sources to Establish NRVs-NCD

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

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

3.2.3 [These values] [**The NRVs-NCD]** should reflect intake recommendations for healthy populations.

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

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

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[20] [This definition may be used in future FAO/WHO reports. The definition is [adapted] from the World Cancer Research Fund/American Institute for Cancer Research (AICR) report: *Food, Nutrition, Physical Activity and the Prevention of Cancer: a Global Perspective.* Washington, DC: AICR, 2007, p. 60. This definition and application of "probable evidence" is specific to consideration of an appropriate basis for food label reference values by governments, and is not applicable to Codex recommendations on scientific substantiation for health claims. The latter is provided in the Annex on Recommendations on the Scientific Substantiation of Health Claims in the Guidelines for Use of Nutrition and Health Claims (CAC-GL 23-1997).]

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

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 energy intake.

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

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

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

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

[3.3.4 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).]

Annex 2

Daily Intake Values from FAO/WHO and Other Recognized Authoritative Scientific Bodies that May Be Relevant to CCNFSDU's Consideration of NRVs- NCD for the General Population for Saturated Fatty Acids and Sodium

A. SATURATED FATTY ACIDS

1. FAO/WHO Data Source(s)

Data Source	Year(s): Scientific Review/ Publication	Type of Daily Intake Reference Value	Numeric Amount for Specific Population Group(s)	Nature of Convincing Evidence
FNP 91[22]	2008/2010	U-AMDR	10% E for Adults (convincing evidence)	Replacing SFA (C12:0-C16.0) with PUFA and cis MUFA decreases LDL cholesterol concentration and total/HDL cholesterol ratio

2. Other Recognized Authoritative Scientific Bodies

It is suggested that the Committee discuss at its next session whether there are any other daily intake reference values for SFA from recognized authoritative scientific bodies that could also be considered in proposing a SFA NRV.

[22] Fats and Fatty Acids in Human Nutrition: Report of an Expert Consultation. FAO Food and Nutrition Paper 91. FAO 2010. Rome. Web reference (Accessed April 17, 2011): http://www.fao.org/docrep/013/i1953e/i1953e00.pdf

B. SODIUM

1. FAO/WHO Data Source(s)

Data Source	Year(s): Scientific Review/ Publication	Type of Daily Intake Reference Value	Numeric Amount for Specific Population Group(s)	Nature of Convincing Evidence
TRS 916[23]	2002/2003	Population nutrient goal (for average intake)	2000 mg	Blood pressure reduction

2. Other Recognized Authoritative Scientific Bodies

It is suggested that the Committee discuss at its next session whether there are other daily intake reference values for sodium from recognized authoritative scientific bodies that could also be considered in proposing a sodium NRV-NCD—either as the sole basis of the NRV-NCD or in conjunction with other daily intake reference values. EWG members identified the following values for consideration.

Recognized Authoritative Scientific Body/Data Source	Year(s): Scientific Review/ Publication	Type of Daily Intake Reference Value/ Definition and Deriviation	Numeric Amount for Specific Population Group(s) (sodium in mg)
Institute of Medicine/report on dietary reference intakes for electrolytes and water[24]	18 month study ~ 2003-04/2004	**Tolerable Upper Intake Level (UL)** "The highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential of adverse effects may increase." (p. 3 of this DRI report).	**1) Tolerable Upper Intake Level** Males, Females 1-3 y 1500 4-8 y 1900 9-13 y 2200 14 + y 2300

[23] *Diet, Nutrition and the Prevention of Chronic Diseases*: *Report of a Joint WHO/FAO Expert Consultation.* WHO Technical Report Series 916. WHO, 2003. Web reference (Accessed April 17 2011): http://www.who.int/dietphysicalactivity/publications/trs916/en/ .

[24] Institute of Medicine. Food and Nutrition Board. *Dietary Reference Intakes: Water, Potassium, Sodium, Chloride and Sulfate.* Washington DC: National Academies Press, 2004. pp. 269-423.Accessed July 10 2011. http://www.nap.edu/openbook.php?isbn=0309091691 .

Recognized Authoritative Scientific Body/Data Source	Year(s): Scientific Review/ Publication	Type of Daily Intake Reference Value/ Definition and Deriviation	Numeric Amount for Specific Population Group(s) (sodium in mg)
		Derivation of UL Values: The adverse effects of higher levels of sodium intake on blood pressure provide the scientific rationale for setting the UL.	
Institute of Medicine/report on dietary reference intakes for electrolytes and water	18 month study ~ 2003-04/2004	**Adequate Intake (AI):** "The recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy populations that are assumed to be adequate—used when a Recommended Dietary Allowance cannot be determined " (because of insufficient data to establish an Estimated Average Requirement) (p. 3 of this DRI report). **Derivation of Adequate Intake Values:** - For adults 19-50 y, the AI is set at 1500 mg based on meeting sodium needs of apparently healthy individuals as well as to ensure that an overall Western-type diet provides an adequate intake of other important nutrients. - For children and adolescents, the AI was extrapolated down from the adult AI of 1500 mg/d using relative energy intake (i.e., the average of median energy intake levels of the age groups for adults and children as the basis for extrapolation). - For older adults, the AI was extrapolated from younger adults based on the combined average for men and women of median energy intakes (which decrease with age).	**2) Adequate Intake Values** Males, Females 1-3 y 1000 4-8 y 1200 9-50 y 1500 51-70 y 1300 > 70 y 1200