CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4a, 4b **CX/NFSDU 12/34/5**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-fourth Session

Bad Soden am Taunus, Germany
3 – 7 December 2012

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

CONSOLIDATION OF THE GENERAL PRINCIPLES FOR ESTABLISHING NRVS OF VITAMINS AND MINERALS AND THE GENERAL PRINCIPLES FOR ESTABLISHING NRVS-NCD

and

OTHER RECOMMENDATIONS

(Prepared by the United States of America with the assistance of Thailand and Chile and members of the electronic work group including Argentina, Australia, Brazil, Canada, Colombia, Costa Rica, European Union, Ghana, Japan, New Zealand, Nicaragua, Norway, European Committee of Sugar Manufacturers, European Salt Producers' Association, FoodDrinkEurope, Institute of Food Technologists, International Life Sciences Institute, and the World Sugar Research Organization)

Governments and interested international organizations are invited to submit comments on the Proposed Draft General Principles, as presented in Attachment B, 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 November 2012**.

I. BACKGROUND

Main Aspects, Importance, and Timeline for this Work

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 noncommunicable diseases (NCDs) 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.

(ALINORM 10/33/26, Appendix VII)

2. This work is deemed an important contribution to implementing the WHO Global Strategy on Diet, Physical Activity and Health (Global Strategy-DPAH) (WHA Resolution 57.17) in addressing the global burden of diet-related NCDs. It responds to a 2006 WHO and FAO draft action plan for implementing this Global Strategy that proposed that the CCNFSDU and the Codex Committee on Food Labelling (CCFL) consider the development of NRVs for nutrients that are associated with risk of NCDs (abbreviated hereafter as "NRVs-NCD") (CL 2006/44-CAC).

3. In identifying nutrients to review for these potential NRVs, the CCNFSDU's first priority was nutrients that the CCFL referred to the Committee for consideration of NRVs—which to date includes saturated fatty acids (SFA) and sodium (ALINORM 09/32/22, para 42). In a related action to implement this Global Strategy, in 2011 the Commission further recognized the relationship of these two nutrients to the global burden of diet-related NCDs in adopting amendments to the Guidelines that added SFA and sodium to the list of nutrients to declare in nutrition labelling (REP11/CAC, Appendix III).

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

5. The project document further identified 2013 as the target year for the Commission's final adoption of these NRVs and related general principles (ALINORM 10/33/26, Appendix VII). Accordingly, the CCNFSDU should keep these target dates in mind with the aim to complete this work in a timely manner.

Status of Work/Conduct of Electronic Working Group

6. At the 33rd (2011) CCNFSDU Session, the Committee made significant progress on the proposed draft general principles for establishing NRVs-NCD with the only remaining text in brackets in the first bullet of Section 3.1 (Appendix V, REP 12/NFSDU). This text addresses the strength of the scientific evidence for the relationship between a nutrient and risk of diet-related NCDs.

7. In addition, the Committee agreed to advance the proposed draft NRVs of 20 g for SFA and 2000 mg for sodium to Step 5/8 for adoption by the 35th Codex Alimentarius Commission (REP 12/NFSDU, para 76). One delegation expressed its reservation on the NRV for SFA. At the Commission meeting, this delegation expressed the view that the draft general principles should be fully resolved before adoption of these NRVs. In addition, the WHO noted related work. The Commission agreed to adopt the proposed draft NRVs for these two nutrients at Step 5 (REP12/CAC, paras 30-32).

8. At its last session, the CCNFSDU established an electronic working group (eWG) chaired by the United States (U.S.) and co-chaired by Thailand and Chile to work in English and Spanish[1] to prepare a revised document for consideration at the next session (REP12/NFSDU, para 65). The charge of this eWG was to:

1. Focus on text in brackets in the proposed draft Annex on general principles for NRVs-NCD (in Appendix V of the report).
2. Propose in a separate document for consideration a draft Annex to the Guidelines on Nutrition Labelling (CAC/GL 2-1985) that consolidates the Annexes on general principles for establishing vitamin and mineral NRVs and NRVs-NCD.
3. Further consider proposals for the need for one or more additional NRVs-NCD for other nutrients with a convincing level of scientific evidence.
4. Make proposals on additional issues for consideration in paragraphs 129 to 135 of CX/NFSDU 11/33/6 including:
    a. Whether more than one NRV could be set for certain nutrients;
    b. Proposed amendments to Section 3.4.4 of the Guidelines on Nutrition Labelling to refer to the CCFL that relate to the listing of the NRVs; and
    c. Evaluate the interest in proposing new work to develop NRVs for total fat, available carbohydrate and protein based on considerations other than diet-related NCDs such as energy balance.

9. In addition, this eWG considered comments received in response to Codex Letter (CL) 2011/24-NFSDU Part B[2] on the proposed draft general principles for establishing NRVs-NCD in Appendix V.

10. In February 2012, an invitation to participate in this eWG was extended to Codex members and international non-governmental organizations (INGOs) with observer status. In May, the Chair/Co-Chairs circulated a consultation paper to eWG members with a summary of the CL comments, which posed questions on issues in the eWG's terms of reference.[3]

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1 The eWG greatly appreciates Chile's substantial contributions to the work of this Committee and to broader eWG participation by translating the consultation paper into Spanish and translating all eWG comments into both English and Spanish.

2 This CL was issued in conjunction with REP12/NFSDU- November 11, 2011.

3 Please refer to CX/NFSDU 12/34/5-Add.1 for comments at Step 3.

11. Responses were received from 14 Codex member governments and six INGOs.[4] **This report presents a brief summary of 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:

II. GENERAL PRINCIPLES

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

12. The eWG's first term of reference was to focus on remaining bracketed text in Appendix V of REP12/NFSDU. This text addresses the strength of the scientific evidence for food label reference values established by Codex and governments, and related descriptors and definitions.

Below is relevant background and a summary of eWG comments on this unresolved text that form the basis for recommendations and new options for revised text in Attachment B.

Background on Terminology and Definitions for the Strength of the Evidence Descriptors in Section 3.1

13. At the last session, the Committee agreed that 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 (General Principle 3.2.1). Consequently, the Committee decided to consider the terminology used in relevant reports of joint FAO/WHO expert consultations to describe the strength of the scientific evidence for the relationship between a nutrient and NCD risk in the first bullet in Section 3.1. These reports are "FNP 91", the report of the 2008 joint FAO/WHO expert consultation on fats and fatty acids in human nutrition [5], and "TRS 916" , the report of the 2002 joint FAO/WHO expert consultation on diet, nutrition and the prevention of chronic diseases.[6] Both reports used the same criteria for "convincing" and "probable" evidence.

Definition of "Convincing Evidence"

14. At its last session, the Committee agreed that relevant "convincing/generally accepted" scientific evidence for the relationship between a nutrient and NCD risk should be considered in selecting nutrients for the establishment of a Codex NRV-NCD. In addition, the Committee previously agreed to place a footnote by "generally accepted" that states that "For these principles the terms convincing/generally accepted evidence are considered synonymous." A footnote was also placed by "convincing" with the definition from the two reports left in brackets for further consideration.

Definition of "Probable Evidence"

15. Given the lack of support for the definition of "probable evidence" used in these two reports, the Committee agreed to further consider a definition of "probable evidence" adapted from a 2007 World Cancer

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

5 FAO. *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 .

6 WHO. *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/ .

Research Fund (WCRF) report as it may apply to the two options identified in REP 12/ NFSDU, Appendix V, Section 3.1.

New WHO Terminology and Approach for Evaluating the Strength of the Scientific Evidence and Strength of a Recommendation

16. In finalizing recommendations for the text in the general principles that addresses strength of the scientific evidence for the relationship between a nutrient and NCD risk, the eWG was asked to keep in mind the relevance of specific terminology and definitions to potential work in the future to establish or update NRVs-NCD.

17. At the 2011 CCNFSDU session, the WHO representative indicated that in view of the guideline review process in WHO, it was no longer possible to convene ad hoc expert consultations, and that discussions were ongoing with FAO regarding the establishment of JEMNU[7] (REP 12/NFSDU para 25). In another update at the last session, the WHO representative indicated that new terms would replace the use of "probable" and "convincing" scientific evidence (in the development of WHO guidelines) (REP 12/NFSDU, para 47).

18. The most recent version of the WHO Handbook for Guideline Development explains the process WHO uses to develop WHO recommendations.[8] Separate components of this process include: 1) grading of the *quality of the evidence* of systematic reviews conducted to inform WHO guidelines in which the following descriptors are used to categorize the evidence ("high", "moderate", "low", or "very low"; and 2) "grading" the *strength of a recommendation.*[9] Thus, the eWG was asked to consider that new terminology may replace "convincing" and "probable" evidence in future reports of FAO/WHO scientific advice that are relevant to updating these NRVs-NCD or establishing new NRVs-NCD, and that the WCRF terminology and criteria may not be used in these future reports.

Text Options Identified at the Last CCNFSDU Session and in CL Comments for Addressing Strength of the Scientific Evidence

19. At the 2011 session, the Committee agreed to further consider two options for text on the suitability of probable evidence in a second sentence in 3.1 (REP12/NFSDU, Appendix V), and CL comments were received on this bracketed text. Most of the CL comments (nine) supported "convincing/generally accepted" evidence as the sole basis for Codex NRVs-NCD. Three CL comments supported consideration of "probable evidence" in addition to "convincing/generally accepted" evidence for a NRV-NCD. Additional proposals and options were identified in these CL comments. These formed the basis for questions posed to the eWG.

Expanded Approaches and Text Options for Addressing Strength of the Evidence

20. Based on the CL comments, three approaches were identified for addressing strength of the scientific evidence in the draft general principles. They included:

> **Approach A-"Convincing/Generally Accepted" evidence as the sole basis for an NRV-NCD and acknowledge government flexibility in the Preamble only.** This approach retains "convincing/generally accepted" scientific evidence as the sole basis for establishing a Codex NRV-NCD. In addition, it acknowledges only in the Preamble of the General Principles that governments have the flexibility to consider a lower level of evidence than "convincing/generally accepted".
>
> **Approach B-"Convincing/Generally Accepted" evidence as the sole basis for NRVs-NCD, and acknowledge government flexibility in both the Preamble and Section 3.1.** This approach retains "convincing/generally accepted" scientific evidence as the sole basis for establishing a Codex NRV-NCD. In addition, it acknowledges in a separate sentence in the first bullet of 3.1 that governments may consider the suitability of a lower level of evidence that "convincing/generally accepted" in establishing their own food label reference values.

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[7] In previous CCNFSDU reports, JEMNU has been identified as the abbreviation for "Joint FAO/WHO Expert Meetings on Nutrition."

[8] WHO Handbook for Guideline Development. 2012. Web reference (Accessed October 17, 2012): http://apps.who.int/bookorders/anglais/detart1.jsp?codlan=1&codcol=93&codcch=270

[9] The strength of a recommendation reflects the degree of confidence that the desirable effects of adherence to the recommendation outweigh the undesirable effects. WHO Handbook (Reference 8), p. 47.

<u>Approach C</u>-Additional Consideration of Evidence Lower than "Convincing/Generally Accepted" for NRVs-NCD and acknowledge government flexibility in Preamble. This approach retains "convincing/general accepted" scientific evidence as a basis for establishing a Codex NRV-NCD, and states or implies that the suitability of lower levels of evidence may also need to be considered in establishing a Codex NRV-NCD.

In addition, for each of these approaches, two options for proposed text were identified. These are included in Attachment A for reference.

21. The eWG was asked to consider relevant background and updates (including the CL responses) and to comment on which of the above approaches and text options they preferred most and least. The results for each approach are presented below:

- Approach A:
  - Preferred <u>most</u> by one member organization, five countries, and six INGOs
  - Preferred <u>least</u> by three countries
- Approach B:
  - Preferred <u>most</u> by five countries
  - Preferred <u>least</u> by one country
- Approach C:
  - Preferred <u>most</u> by four countries
  - Preferred <u>least</u> by one member organization, nine countries, and five INGOs

22. The eWG responses are consistent with CL responses in that most comments supported "convincing/generally accepted" evidence as the sole basis for an NRV-NCD with acknowledgement in the Annex that governments have the flexibility to consider a lower level of evidence than "convincing/generally accepted" (i.e., Approaches A and B). Approach C was least preferred by one member organization, nine countries, and five INGOs, whereas only one country preferred Approach B the least. One country that preferred Approach C stated that if the Committee ultimately supports Approach A or B, then it preferred that a government's prerogative to establish NRVs-NCD according to probable evidence be set out in Section 3.1—not only in the preamble.

Thus, approach B appears the most likely to result in Committee agreement on text at the next session. Among the two text options for Approach B, more countries supported option B1 (former Option 1 in Appendix V) which would retain a reference to "probable evidence".

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

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

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

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

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

New Proposal in CL Comment to Clarify Text in 3.1 Related to the Strength of the Scientific Evidence

25. A CL comment made a new proposal to address one reason some delegations may have supported consideration of evidence that is less than convincing in establishing an NRV-NCD. This comment noted that although an overall conclusion of scientific advice may be that there is convincing evidence for the relationship between a nutrient and NCD risk, further distinctions may be made in the level of evidence for specific population segments. For example, with regard to saturated fat, the report of the 2008 FAO/WHO expert consultation on fats and fatty acids in human nutrition identified in the summary of conclusions that there was convincing evidence that replacing SFA with polyunsaturated fatty acids decreases the risk of coronary heart disease, and recommended that total SFA intake not exceed 10% of energy (FNP 91. pp. 14-15). In addition to this overall conclusion, further distinctions were made in a report table in levels of evidence for recommended intakes for adults and children 2 to 18 years, with a "convincing" level identified for adults and a "probable" level identified for children.

26. Accordingly, the CL comment proposed that the underlined text identified below be added to the first bullet in 3.1 to clarify that the "convincing/generally accepted" scientific evidence for the nutrient-disease risk relationship would be for at least one major segment of the general population such as adults.

3.1 Criteria for Selection of Nutrients

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

- Relevant convincing[#]/generally accepted[#] scientific evidence for the relationship between a nutrient and noncommunicable disease risk, including validated biomarkers for relevant disease risk, [<u>for at least one major segment of the general population (e.g., adults)</u>].

27. The eWG was asked if it supported adding the above underlined text to clarify that convincing/generally accepted scientific evidence for the relationship between a nutrient and noncommunicable disease risk need only be for a major segment of the general population (e.g., adults).

The majority of comments supported adding this text, with the following views:

- The added text provides helpful clarification that the convincing evidence need not be for all segments of the general population.
- Relevant scientific evidence relating a nutrient to a NCD should be with the adult population.
- The added text is consistent with distinctions made in the level of scientific evidence for SFA for adults and children that were made by the 2008 FAO/WHO expert consultation on fats and fatty acids.
- The added text could lessen if not eliminate the need to explicitly refer to a lower level of evidence than "convincing/generally accepted" in these general principles, and thus contribute to finding a path forward for finalizing Section 3.1 text.

28. A few comments were undecided about the need for or wording of this added text with the following views:

- The wording should be clarified to indicate that the evidence needs to be strong for the general adult population.
- A comment acknowledged that convincing level of evidence for adults could be sufficient (for these NRVs-NCD), and noted that ethical reasons can also prevent the development of scientific evidence among subgroups. However, this comment stated that conditions of use of certain nutrition claims are based on NRVs, and a lower level of scientific evidence for these NRVs would also mean a lower scientific substantiation of these claims.
- This text should be kept under review because NRVs might ultimately be based on more recent recommendations that replace population nutrient intake goals and are divided at least between adults and children, in which case the text could be more explicitly and simply stated as adults.
- If the proposed edit is included, it is suggested that the term "healthy" be inserted before "general population" as population segments suffering from various NCDs are growing.

29. Two countries and two observer organizations did not support adding this text, with the following points of view:

- The criteria are clear and the added text is unnecessary.
- Only "convincing/generally accepted" scientific evidence for the general population as a whole will guarantee the use of the highest level of evidence in the framework of Codex.
- If the required scientific evidence refers to only one major segment of the population, the NRV-NCD might be misleading to parts of the population.

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

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

Definitions of "Convincing Evidence" and "Probable Evidence".

31. In Appendix V of the last CCNFSDU session report, additional bracketed text in 3.1 concerned definitions for "convincing evidence" and "probable evidence". As earlier noted, the draft definition of "convincing evidence" was from the two reports of joint FAO/WHO expert consultations that were used as primary sources for the proposed SFA and sodium NRVs-NCD. In addition, the Committee agreed to further consider a definition of "probable evidence" adapted from a 2007 World Cancer Research Fund (WCRF) report as it may apply to the two options identified in Appendix V—in which the first text option is proposed in Attachment B of this report.

Definition of "Convincing Evidence"

32. The eWG was asked whether the definition of "convincing evidence" in Appendix V should be retained with the general principles, or alternatively, whether only a reference to the source of the definition should be made in the Annex. Those who preferred the latter were asked to comment on the following proposed wording for a footnote in the General Principles suggested in one CL comment:

> "At the time these guiding principles were drafted, the definition and criteria for "convincing" evidence from the following FAO/WHO reports were used: 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."

33. Eleven countries and four INGOs supported retaining the definition of "convincing evidence" that was used in the FNP 91 and TRS 916 reports in the Guidelines, although there were different points of views on the definition's placement. Reasons for retaining the definition included:

- Reader access to the definition would be easier, and the document more "user-friendly".
- It would clarify the definition used and give traceability to the decision.
- If there are modifications of the definition, the values already validated should be re-evaluated according to the new definition for consistency in approach, and this re-evaluation would be more obvious if the definition were retained.

34. One member organization, two countries and one INGO supported only referencing the source of the definition in the Annex on general principles. Reasons for citing only the definition source included:

- The definition could in the future be subject to change, which would create the need to keep this text updated according to developments in other flora.
- It would be sufficient and save space to identify only the source of the definition in the Annex.

35. One country proposed that the definition of "convincing evidence" be included in the Definition section of the Annex. Another supported including the full definition of "convincing evidence" in Section 3.4.4 of the Guidelines so as to provide a link between specific NRV-NCD values and the actual definition used for these values (given that the definition could change in the future). In addition, this same country supported referencing the source of the definition in Section 3.1 of the Annex on NRV-NCD general principles using the proposed wording in paragraph 32 , which would foreshadow that the definition could change in the future with the preface, "At the time these guiding principles were drafted…". One comment that supported referencing only the source of the definition in Section 3.1 noted that the FNP 91 report refers to the WHO TRS 916 report as the source of the definition of convincing evidence used in both these reports, and thus a simple reference to the TRS 916 report should suffice.

NRV-NCD GP -- Definition of " Convincing Evidence"

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

Definition of "Probable Evidence"

37. Given the lack of support for the definition of "probable evidence" used in the FNP 91 and TRS 916 reports, the definition of "probable" evidence adapted from the 2007 WCRF report was included in Appendix V in brackets for further consideration as a footnote to the two text options in 3.1 that referred to "probable evidence". As earlier noted, based on eWG comments the first text option is proposed in Attachment B, which explicitly acknowledges in Section 3.1 that governments may consider "probable evidence" in addition to "convincing/generally accepted evidence" in establishing their own food label reference values.

38. Three eWG members who supported including a definition of "probable evidence" proposed that the Committee consider edits to the Appendix V draft definition. Edits proposed by one or more of these comments are identified below:

> [Probable Evidence 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 diet-related noncommunicable diseases ~~cancer~~.] [between a nutrient and diet-related noncommunicable disease risk, including validated biomarkers of the disease risk.] All of the following are generally required:
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> - 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.
>
> The definition of "probable evidence" 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** ~~The~~ 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 the scientific substantiation of ~~for~~ health claims~~. The latter is provided in the Annex on Recommendationon the Scientific Substantiation of Health Claims in the Guidelines for Use of Nutrition and Health Claims~~ (Annex**,** CAC/GL 23-1997).]

39. However, in paragraph 36, it is proposed to reference only the source of the definition(s) of the strength of the scientific evidence in the Annex (since the definition for any descriptor is subject to change), and to consider a proposal to reference the full definition of "convincing evidence" (with its source) in conjunction with specific NRVs-NCD in Section 3.4.4 of the Guidelines. Given that revised Section 3.1 in Attachment B (and C) would consider only convincing evidence for an NRV-NCD, it does not appear appropriate to include a definition of 'probable evidence" in Section 3.4.4.

NRV-NCD GP -- Definition of "Probable Evidence"

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

Placement of the Definition(s) for Subtype(s) of NRVs

41. At the last CCNFSDU session, the Committee agreed on a definition for NRV-NCD. This definition was included in Section 2 of the proposed draft Annex in Appendix V. However, with the consideration of a proposed consolidated Annex and amendments to Section 3.4.4 of the Guidelines, the need to distinguish between the two types NRVs became apparent. Consequently, the eWG was asked to comment on the need for additional terminology to identify NRVs based on levels of nutrients associated with nutrient requirements (i.e., "Nutrient Reference Values-Requirements", abbreviated as "NRVs-R". As discussed in more detail in paragraphs 61 to 65 in the following section, most comments agreed that this additional terminology was needed. Consequently, two options for placing definitions of both types of NRVs are identified in Attachments B and C.

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

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

Background

43. At its 2010 session, the Committee advanced the draft Annex on vitamin and mineral NRV general principles to the Commission for adoption at Step 8[10] after the Codex Secretariat clarified it would be possible, if the Committee agreed, to merge the two Annexes later (paras 35-36, REP11/NFSDU). Accordingly, in developing the NRV-NCD general 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 NRVs-NCD.

44. In the eWG consultation paper, a preliminary draft consolidation of the two Annexes offered in one of the CL comments was circulated for comment. It incorporated the draft text in Appendix V on NRV-NCD general principles and the adopted vitamin and mineral NRV general principles. **For the latter, please refer to the Annex in CAC/GL 2-1985; these adopted provisions are also identified in Attachment C**. In this draft consolidation, the aim was to be consistent with decisions previously made by the Committee, and to not modify or introduce new text except where needed in order to merge the two Annexes (with one exception to introduce the term, "Nutrient Reference Values-Requirements" which is addressed in paragraphs 61 to 65).

45. The eWG was asked whether they supported consolidating the two Annexes, and if so, whether they agreed with the proposed organization, including the headings and subheadings. Based on eWG responses which are summarized below, a revised proposed draft consolidation of the two Annexes is proposed in Attachment D, which also incorporates the proposed revisions to the NRV-NCD principles in Attachment B.

Support for Consolidating the Two Annexes

46. Most comments supported consolidating the two Annexes with the following views:

- Two Annexes could result in inconsistencies and potential confusion.
- The subject matter has considerable compatibility, and consolidation would streamline text and avoid many repetitions.
- A consolidated Annex would be easier to understand and facilitate identification of similarities and differences in general principles for establishing the two types of NRVs.
- Since the approved text and current draft text under discussion is quite similar, no considerable delay should occur in finalizing the consolidated text.

[10] The Commission adopted the Annex at its 34th (2011) session.

One country that supported consolidation further commented that it makes sense to consolidate the Annexes before the NRV-NCD general principles are finalized because the consolidation could necessitate certain revision in wording.

47. One country supported retaining separate Annexes with the view that they are based on different principles, and suggested that the Annexes be located in one place sequentially for easy reference. In addition, one INGO considered that consolidation would present a problem with the view that the purpose of the two sets of NRVs are diametrically opposite.

Consolidated GP- Support

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

Proposed Organization for a Consolidated Annex

49. The draft consolidated Annex circulated to the eWG was organized according to the following headings and subheadings:

1. PREAMBLE
2. DEFINITIONS
3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs
3.1 Selection of Suitable Date Sources to Establish NRVs
3.2 Selection of Nutrients and Appropriate Basis for Determining and Expressing NRVs
3.2.1 Selection of Appropriate Basis [for NRVs Based on Levels of Nutrients Associated with Nutrient Requirements] [for NRVs-R]
3.2.1.1….
3.2.1.2…
Etc.
3.2.2 Selection of Nutrients and Appropriate Basis for NRVs-NCD
3.2.2.1 Criteria for Selection of Nutrients
3.2.2.2 Selection of Appropriate Basis for Determining and Expressing NRVs-NCD
3.2.2.2.1…..
3.2.2.2.2…
Etc.
3.3 Consideration of Daily Intake Values for Upper Levels

50. The eWG was asked if they agreed with the above proposed organization for a consolidated Annex. All eWG members who supported consolidation generally supported the above organization. However, one country suggested that the headings and subheadings in Section 3.2 be slightly revised to be shorter and more consistent, and to avoid 5-digit numbers as follows:

3.2 Selection of Nutrients and Appropriate Basis for ~~Determining and Expressing~~ NRVs
3.2.1 Selection of Appropriate Basis [~~for NRVs Based on Levels of Nutrients Associated with Nutrient Requirements] [for~~ NRVs-R~~]~~
3.2.1.1…
3.2.1.2…
Etc.
3.2.2 Selection of Nutrients and Appropriate Basis for NRVs-NCD
~~3.2.2.1 Criteria for Selection of Nutrients~~
3.2.2.1 The following criteria should be considered in the selection of nutrients…..
~~3.2.2.2 Selection of Appropriate Basis for Determining and Expressing NRVs-NCD~~
~~3.2.2.2.1~~ Relevant and peer-reviewed scientific evidence…
~~3.2.2.2.2~~ Daily intake reference values …
Etc.

Consolidated GP-- Proposed Organization

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

Proposal for New Terminology with Definition

61. As previously noted, an aim in consolidating the two Annexes was to be consistent with decisions previously made by the Committee, and to not modify or introduce new text except where necessary to merge the two Annexes. The one exception to this approach was to ask the eWG whether they supported adding the following new term and definition to Section 2 of the consolidated Annex:

> "2.1 *(new)* **Nutrient Reference Values-Requirements (NRVs-R)** refer to NRVs that are based on levels of nutrients associated with nutrient requirements.

The proposal to consider this new term stemmed in part from the need to distinguish between NRVs related to nutrient requirements and those related to diet-related NCDs in proposed amendments to Section 3.4.4 of the Guidelines.

62. It was further noted that the proposed definition of "Nutrient Reference Values- Requirements" was consistent with certain text in the definition of Nutrient Reference Values (NRVs), which the Commission adopted at its 35th (2012) session for inclusion in Section 2 (Definitions) in the Guidelines. This definition is:

> "**Nutrient Reference Values (NRVs)*** are a set of numerical values that are based on scientific data and established for purposes of nutrition labelling and relevant claims. NRVs are based on levels of nutrients associated with nutrient requirements, or with the reduction in the risk of diet-related non-communicable diseases."
>
> * See also the Annex for the General Principles for the Establishment of Nutrient Reference Values.

63. Most comments agreed that there was a need to provide for a separate term and definition for nutrient reference values related to nutrient requirements in a consolidated Annex, and supported the proposed definition for "Nutrient Reference Values (NRVs-R)". Reasons included:

- It would be useful since each type of NRV would have a suffix reflecting its particular type.
- The presence of the NRV-NCD definition necessitates a corresponding definition for NRV-R.
- These are different categories of values, with different evidentiary bases and different implications on health, and as such should be distinguished from one another. However, this should not imply that countries should necessarily differentiate these different types of NRVs on their labels.
- Certain nutrients may have more than one NRV established using estimated requirements and/or reduction on diet-related NCDs, while others will have only one.

An INGO that supported defining NRVs-R suggested that the text "in a balanced diet" be added to the end of the definition.

64. A few comments did not agree that a separate term was needed. Instead, they considered that the definition of "Nutrient Reference Values" in Section 2 of the Guidelines should suffice.

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

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

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

Other Comments on the Content of the Annex

66. Certain eWG comments suggested that additional edits to certain provisions in the General Principles be considered at the next session, with one country proposing specific edits. However, the terms of reference for this eWG was only to focus on the remaining bracketed text in Section 3.1 and on revisions that would be needed in consolidating the two Annexes.

67. With regard to suggested edits to the Preamble as a result of consolidating the two Annexes, two comments proposed that the term "nutrient" be deleted in two places because it did not appear to be needed and to better distinguish between food label values established by Codex and by governments. In addition, with regard to the last sentence of the Preamble which identifies pregnant women as an example of a specific segment of the general population for which separate food label reference values may be established for specific segments of the general population, one country noted that this example is not included in the NRVs-NCD general principles in Appendix V, and did not consider it necessary to provide an example in the consolidated Annex.

Consolidated GP—Edits to Preamble

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

III. NEED FOR ADDITIONAL NRVs-NCD

69. The eWG's third term of reference was to consider the need for one or more additional NRVs-NCD for other nutrients with a convincing level of scientific evidence.

Considerations

70. In considering this need, the eWG was asked to refer to the proposed draft Annex on general principles in REP 12/NFSDU, Appendix V. In addition to the principles in Section 3, the Preamble acknowledges governments' flexibility in establishing their own food label reference values. It may also be noted that the CCFL has referred only two nutrients to the CCNFSDU for consideration of NRVs-NCD: SFA and sodium. Another important consideration is whether an NRV-NCD should be considered for any nutrient that is not in the recently expanded list of nutrients in 3.2.1.2 of the Guidelines that should always be declared in nutrition labelling when nutrient declaration is applied.[11] This list now includes SFA and sodium in addition to protein, available carbohydrate (i.e., dietary carbohydrate excluding dietary fibre), fat, and total sugars.

71. Prior to posing questions to the eWG on the need for additional NRVs-NCD with a convincing level of evidence, the eWG was asked about the following related issues:

- Suitable data sources for identifying additional nutrients with convincing evidence;
- Global public health importance of nutrients assessed to have convincing evidence; and

[11] The expanded list of nutrients in CAC/GL 2-1985, Section 3.2.1.2 was adopted by the Commission in 2010.

- Additional issues with macronutrients.

EWG views on these issues are summarized below.

Suitable Data Sources for Identifying Additional Nutrients with Convincing Evidence

Assessment of Evidence—FAO/WHO Data Sources

72. General Principle 3.2.1 in Appendix V is:

> "Relevant and recent 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."

Accordingly, the eWG was asked if the two reports of joint FAO/WHO expert consultations that were considered in proposing NRVs-NCD for SFA and sodium (i.e., "FNP 91"[12] and "TRS 916"[13]) should be an initial starting point to identify additional nutrients that were assessed to have a convincing level of evidence for NCD risk.

73. Most comments agreed these reports were suitable for this purpose. A few commented that while useful as a starting point, more recent data from recognized authoritative scientific bodies should also be taken into account. An INGO commented that the FNP 91 report based on a 2008 FAO//WHO expert consultation reflects more recent evidence that the TRS 916 based on a 2002 consultation, and that the former may be more suitable for evidence grading. Another INGO considered that TRS 916 may be a suitable starting point for consideration of certain nutrients other than sugars.

74. The eWG did not identify any additional suitable data sources from FAO/WHO for assessing strength of the evidence for additional nutrients. In this regard, a country noted comments by the WHO representative at the last CCNFSDU session that indicated that in view of the WHO guidelines review process, it was no longer possible to convene joint FAO/WHO expert consultations, and that consultations were ongoing with FAO on establishing a new procedural arrangement for "Joint Expert Meetings on Nutrition (JEMNU)" (REP 12/NFSDU, para 25).

75. In addition, two countries cited work by a WHO Nutrition Guidance Expert Advisory Group (NUGAG) subgroup on Diet and Health to review the scientific evidence for the relationship between certain nutrients and NCD risk and to update intake recommendations through the WHO guidelines process (REP 11/NFSDU, para 19, REP 12/NFSDU, para 22). One of these comments noted a WHO progress report at the last CCNFSDU session on updating potassium intake recommendations that clarified that although systematic literature reviews form the main base of a WHO final recommendation, additional information on costs, feasibility, value preferences and ethical considerations are also considered (CX/NFSDU 11/33/4-Add.1).

Assessment of Evidence—FAO and/or WHO Data Sources

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

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

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

[12] Chapter 2 in FNP 91 (pp. 9 to 20) identifies nutrients assessed to have a convincing level of evidence, the nature of that evidence, and recommended intakes for these nutrients.

[13] Chapter 5 in TRS 916 identifies nutrients assessed to have a convincing level of evidence and the nature of that evidence. In addition, quantitative recommendations expressed as population nutrient intake goals are summarized on p. 56 in Chapter 5 which include but is not limited to nutrients with a level of convincing evidence.

Assessment of Evidence—Recognized Authoritative Scientific Bodies

79. General Principle 3.2.2 in Appendix V is:

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

80. The eWG was asked about additional suitable data sources from recognized authoritative scientific bodies that could be considered in identifying nutrients with convincing evidence. One country recommended that the Committee develop a working definition/criteria for "recognized authoritative scientific body". In this regard, a country noted that this year's eWG on revised and additional vitamin and mineral NRVs addressed the meaning of the term "recognized authoritative scientific body" (abbreviated "RASB") and invited eWGs to nominate organizations with substantiation.

81. In the conduct of the NRV-NCD eWG, two countries provided substantiation for their view that the Institute of Medicine of the National Academies of sciences in the U.S. (IOM) is a RASB. A number of additional eWG comments identified reports from both the IOM and the European Food Safety Authority (EFSA) as relevant to assessing whether nutrients have convincing evidence. A variety of additional data sources (and references) were suggested by one or more eWG members (Attachment E).

Assessment of Evidence—Recognized Authoritative Scientific Bodies

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

Global Public Health Importance of Nutrients Assessed to Have Convincing Evidence

83. A Section 3.1 principle is that the public health importance of the nutrient-NCD risk relationship(s) among Codex member countries should be considered in selecting nutrients for the establishment of NRVs-NCD. In 2011, the CCFL referred SFA and sodium to CCNFSDU to consider the establishment of an NRV-NCD after confirming their global public health importance with new Codex provisions for their declaration in nutrition labelling.

84. The eWG was asked if additional nutrient(s) assessed to have convincing evidence in FNP 91 and TRS 916 met the criterion in general principle 3.1 for global public health importance. Views were mixed. A member organization considered that SFA and sodium should remain the primary targets as they concentrate the convincing scientific evidence of a link between excess consumption and increased NCD risk. Other comments supported the view that for the time being CCNFSDU should focus on consideration of major nutrients identified in the WHO Global Strategy-DPAH.[14] In contrast, one country considered that all nutrients with convincing evidence in FNP 91 and TRS 916 are of global public health importance. Another country considered that not all nutrients assessed to have convincing evidence for a nutrient-NCD risk relationship may meet the principle in 3.3.1 in Appendix V for sufficient scientific evidence for a quantitative daily intake value to reduce NCD risk. Several comments expressed the view that one or more of the following nutrients had convincing evidence for NCD risk and were of global public health importance: minerals (potassium, calcium, vitamin D); macronutrients (sugars/free sugars, linoleic acid, omega-3 polyunsaturated fatty acids (n-3 PUFA), trans fatty acids) and dietary fibre. However, there was no general agreement among eWG members of the global public importance of any of these specific nutrients in relation to NCDs.

[14] WHO. *WHO Global Strategy on Diet, Physcial Activity and Health*. WHO, 2004. Web reference (Accessed September 28, 2012): http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy_english_web.pdf

85. One country suggested that the CCFL determine global public health importance since it determined the list of nutrients that should always declared on that basis. As discussed below, it seems appropriate for the CCNFSDU to take into account CCFL decisions with regard to the global public health importance for nutrients that should be declared in nutrition labeling, which include but are not limited to NCD risk. However, as illustrated with SFA and sodium, it has been the role of CCNFSDU to apply all the draft general principles (including global public health importance) in assessing whether one or more additional NRVs-NCD should be established.

Adopted Codex Nutrition Labelling Provisions Pertaining to Global Public Health Importance

86. With regard to the global public health importance of nutrients, another consideration identified earlier is whether an NRV-NCD should be considered for any nutrient that is not in the recently expanded list of nutrients in 3.2.1.2 of the Guidelines that should always be declared in nutrition labeling (Refer to paragraph 70 for this list). The eWG was asked if consideration of any additional NRVs-NCD should be limited to only these nutrients.

87. A member organization, four countries and an INGO responded yes with the following reasons:

- The nutrients in 3.2.1.2 have already been prioritized and discussed in Codex in the context of the global public health agenda.
- An NRV-NCD for a nutrient should not stand alone, but should be linked to and complement the content of a nutrient declared in nutritional labeling.
- If another nutrient (not listed in 3.2.1.2) is considered for an NRV-NCD, it would be necessary to include the content on the nutrition label. This raises a question of whether the content could reliably be defined at this stage.

88. Five countries and an INGO responded no with the following reasons:

- The nutrients in 3.2.1.2 do not necessarily include all convincing nutrient-NCD risk relationships that are of global public health importance.
- The establishment of vitamin and mineral NRVs does not require that a nutrient be listed in 3.2.1.2.
- Consideration of NRVs-NCD should support future innovation and not be unduly restrictive.
- Interest in having an NRV-NCD established for one or more specific additional nutrients.

Global Public Health Importance of Additional Nutrients and their Prioritization

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

Additional Issues in Considering NRVs-NCD for Macronutrients

90. In proposing a SFA NRV-NCD at the last session, the Committee considered the recommendation in FNP 91 that total intake of SFA not exceed 10% E, and that SFA be replaced with PUFA in the diet.[15] In addition, the conclusions from a 2010 EFSA Scientific Opinion and 2002 IOM expert panel provided additional support for *increased* risk of CHD with SFA intake, and for limiting intake of this nutrient. In contrast, in considering the need for additional NRVs-NCD, it may be noted that the *decreased* risk of CHD for PUFA and MUFA in FNP 91 is based on replacing SFA with these fatty acids.

91. The eWG was asked whether they supported considering one or more *additional* NRVs-NCD for a macronutrient based on substitution effects. Six countries and two INGOs responded yes with the majority further specifying one or more of the following conditions:

- Convincing evidence for NCD risk is available for either a direct effect or a substitution effect.
- An expected desirable substitution is highly likely, and the food supply supports the wide practice of that dietary substitution.

[15] FNP 91, p. 15.

92. A member organization, two countries, and two INGOs responded that they did not support consideration of *additional* NRVs-NCD for macronutrients with substitution effects. Reasons included:

- Evidence to support an NRV-NCD for macronutrients other than SFA is not convincing.
- Evidence may be insufficient that an expected substitution is highly likely.
- The effect of substitution is, by definition, the effect of a lower consumption of a nutrient the excess of which is detrimental to health rather than the effect of a higher consumption of a nutrient replacing the first one. Based on substitution, NRV-NCDs are therefore redundant when added to the message provided by the NRV-NCDs based on nutrients consumed in excess.
- The proliferation of NRVs-NCD may be counterproductive by diluting the message given by key NRVs-NCD.
- Such NRVs should not substitute for food based guidelines that are easier to understand messages, like the one on the substitution of animal fat by vegetable fat in the diet.
- Mixing NRV-NCDs for nutrients whose consumption should be reduced with NRV-NCDs for nutrients whose consumption should be increased may be very confusing for consumers.

Additional Considerations with Macronutrients

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

eWG Views on the Need for One or More Additional NRVs-NCD

94. Based on consideration of all proposed draft principles in Appendix V and other considerations, the eWG was asked if there was a compelling reason for the Committee to consider establishing an NRV-NCD for one or more additional nutrients with convincing evidence for a nutrient-NCD risk relationship.

95. A majority of comments (a member organization, six countries and five INGOs) did not propose additional NRVs-NCD for any specific nutrient(s) at this time with proposed value(s). Although two of these comments suggested that nutrients in the Global Strategy-DPAH might be further considered, another commented that the nutrients listed in 3.2.1.2 of the Guidelines are well targeted and offer the largest margins of improvement when considering current and advised intakes. Another country was of the view that the CCFL should consider the need for one or more additional NRVs-NCD and how the values would be used in nutrition labelling.

96. Five countries (CO) and an INGO proposed one or more specific nutrients for consideration of additional NRVs-NCD, but without apparent widespread support for any one. These proposals are categorized below according to: a) nutrients listed in 3.2.1.2, and b) other nutrients.

PROPOSED NUTRIENT	PROPOSED BY:	PROPOSED DATA SOURCE(S)	PROPOSED LABELLING VALUE FROM DATA SOURCE(S)
A. Nutrients Listed in 3.2.1.2 of the Guidelines			
Protein	1 CO	TRS 916, Chapter 5	10-15% E
Total Fat	1 CO	TRS 916, Chapter 5	15-30% E
Total Sugars	1 CO	--	--
B. Other Nutrients			
Potassium	2 CO	TRS 916, Chapter 5 and updates from FAO/WHO & RASB	--
Trans fatty acids[16]	3 CO	FNP 91, Chapter 2	<1%E (2 CO)
Cholesterol	1 CO	TRS 916, Chapter 5	< 300 mg day
Total PUFA	1 CO	FNP 91, Chapter 2	6-11% E (AMDR)
n-6 PUFA	1 CO	FNP 91, Chapter 2	2.5-9% E (AMDR)
Linoleic Acid	1 CO	--	--
n-3 PUFA	1 CO	FNP 91, Chapter 2	0.5-2% E (AMDR)
n-3 PUFA (EPA+DHA)	2 CO; 1 INGO	FNP 91, Chapter 2	0.250-2 g/day(AMDR)-1 CO; 1 INGO
)nounsaturated Fatty Acids	1 CO	FNP 91, Chapter 2	By Difference: Total fat [%E]-SFA [%E]-PUFA [%E]-TFA [%E] Can be up to 15-20% E, according to total fat intake
Total Carbohydrate	1 CO	TRS 916, Chapter 5	55-75% E
Dietary Fibre	1 CO	--	--
Free Sugars	1 CO	TRS 916, Chapter 5	<10% E

97. With regard to the nutrients in 3.2.1.2, protein, total fat, and available carbohydrate are addressed later in this report with another term of reference for this eWG to evaluate interest in proposing new work to develop NRVs for these nutrients based on considerations other than diet-related NCDs such as energy balance. In addition, protein, total fat, available carbohydrate were not assessed to have convincing evidence for NCD risk.

98. Total sugars is the only other nutrient in the 3.2.1.2 list for which an NRV has either not been referred by the CCFL for consideration of an NRV or is not identified explicitly in a term of reference for this eWG. One country proposed that an NRV be considered for total sugars, but did not propose a specific value. Two other countries commented that the scientific evidence was insufficient for the Institute of Medicine to set a Tolerable Upper Intake Level or a recommended intake level for total (or added) sugars. A country further noted that although total sugars was recently added to the 3.2.1.2 list, the CCFL did not request that the CCNFSDU consider an NRV for total sugars as it did for SFA and sodium.

99. In addition, one country considered that, before setting further NRVs-NCD for nutrients to be limited in the diet, the Committee should consider asking FAO/WHO to provide scientific advice on the appropriate

[16] Trans fatty acids are not included in the 3.2.1.2 list of nutrients. Instead a footnote in 3.2.1.4 indicates that "Countries where the level of trans fatty acid intake is a public health concern should consider declaration of trans fatty acids in nutrition labelling."

derivation of dietary intake reference values for upper levels related to NCD risk in situations where there is no apparent threshold level of intake for NCD risk.

Need for One or More Additional NRVs-NCD

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

IVA. POTENTIAL FOR MORE THAN ONE NRV FOR CERTAIN NUTRIENTS

101. Another term of reference for this eWG was to consider whether more than one NRV could be set for the same nutrient.

Background

102. In last year's eWG report on this agenda item, two countries commented that for certain nutrients such as sodium and potassium there could potentially be more than one basis to establish an NRV, that is: 1) an NRV based on nutrient requirements; and/or 2) an NRV based on NCD risk (that would also meet requirements).

103. In this year's eWG consultation paper, sodium was used to illustrate this issue. For example, the 1998 joint FAO/WHO expert consultation on *Vitamin and Mineral Requirements in Human Nutrition*[17] did not establish Individual Nutrient Level 98 values for sodium based on estimated average nutrient requirements. Thus, if an NRV based only on requirements were to be considered, scientific advice would need to be requested from FAO/WHO and/or values considered from RASB in accordance with the general principles. However, this Committee has not established a need for a sodium NRV based only on requirements, and daily intake reference values based only on requirements from RASB may not be globally relevant. Also, in the past decade, there appears to be more FAO/WHO interest in establishing recommendations for sodium intake that not only meet sodium requirements but also reduce NCD risk. At its 2011 meeting, the CCNFSDU further recognized the importance of a labeling value for sodium aimed at reducing NCD risk in proposing an NRV-NCD for sodium.

104. In related work, the Australia, as Chair for the 2012 vitamin and mineral NRV eWG, asked in its first consultation paper whether sodium and potassium should be excluded from the work of that eWG. Given that nearly all members responded yes, Australia decided not to conduct further work in the 2012 eWG on NRVs for sodium and potassium based on nutrient requirements.

eWG Views

105. The eWG was asked if they supported consideration of more than one (basis for an) NRV for certain nutrients.[18]

106. Comments that supported more than one NRV expressed the following views:

- Two types of NRVs for the same nutrient could be considered on a case by case basis. This country and another considered that an alternative basis for certain NRVs might be appropriate given the wide diversity of some nutrient intakes and other country or region specific factors.
- Two types of NRVs could be considered if there is strong evidence they will be useful to consumers.
- More than one NRV should be required for any nutrient that is both essential and likely to be consumed in excess.

107. Other comments considered that a nutrient should only have one basis for an NRV. Reasons included:

- Two types of NRVs for the same nutrient would be difficult for consumers to understand and confusing.

[17] World Health Organization/Food and Agriculture Organization. 2004. *Vitamin and mineral Requirements in Human Nutrition.* 2nd edition. Geneva. WHO.

[18] Whereas the intent of the question and summary of responses focus on whether an NRV for a nutrient such as sodium should be established based on requirements in addition to NCD risk, a few members interpreted the question differently (e.g., whether separate NRV values should be established for different age groups).

- Sodium and potassium NRVs that address NCD risk (that would also meet requirements) would have more global public health relevance than NRVs based only on minimum requirements. For example, whereas FAO/WHO has not established daily intake reference values for sodium or potassium based on requirements, the WHO has initiated work to develop guidelines on recommended intakes for these two nutrients based on NCD risk.
- Governments can establish their own food label reference values based on nutrient requirements or NCD risk, if a Codex NRV is unsuitable.
- More than one NRV for a nutrient could necessitate developing additional guidance for governments on the appropriate choice of NRV(s).

108. A few comments further suggested that multiple NRVs for certain nutrients be considered to target different groups (e.g., children, pregnant and lactating women, and persons who are salt sensitive and/or have hypertension).

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

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

Consideration of Separate NRVs for Population Segments for Certain Nutrients

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

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

111. Another term of reference for this eWG was to propose amendments to Section 3.4.4 of the Guidelines to refer to the CCFL that relate to the listing of NRVs. A separate eWG was charged with recommending revised and additional vitamin and mineral NRVs for the general population for the CCNFSDU to consider at its next session. Consequently, this eWG focused on recommending text and format amendments to 3.4.4 to encompass the draft NRVs-NCD for SFA and sodium, which can be used to incorporate revised and new NRVs at the 34th CCNFSDU Session.

The eWG was asked about proposed amendments to the introductory text and listing of values in Section 3.4.4. Responses provided a basis for proposed draft amendments to Section 3.4.4 in Attachment D.

3.4.4 Introductory Text

112. In the eWG consultation paper, a few preliminary draft amendments were identified to the 3.4.4 introductory text that included consideration of the discussion at the 31st (2009) CCNFSDU session on vitamin and mineral NRVs. The eWG was also asked to comment on additional proposed amendments that aimed to clarify the uses of NRVs, distinguish between NRVs that relate to nutrient requirements and those relate to diet-related NCDs, and refer to the Annex(es) on general principles.

113. As additional context for the 3.4.4 provisions, 3.4.2 and 3.4.3 are related provisions for the declaration of nutrient content that refer to: 1) energy content, and 2) protein, carbohydrate and fat content. **Accordingly, in Attachment D it is proposed to retain the reference to "vitamins and minerals" in the first sentence of 3.4.4, but to propose amendments to the third sentence to provide for NRVs for additional nutrients. In addition, the eWG generally agreed that the footnote in the third sentence that indicates that NRVs should be kept under review is not needed, and consequently deletion of this footnote is proposed in Attachment D.**

114. At the 2009 CCNFSDU session, the Committee proposed that the underlined text below be added to the first sentence in 3.4.4 to clarify that NRVs were expressed for ready to use foods:

> "3.4.4 Numerical information on vitamins and minerals should be expressed in metric units and/or as a percentage of the Nutrient Reference Value per 100 g or per 100 ml <u>on the ready to use product</u> or per package if the package contains only a single portion."

(ALINORM l0/33/26, para 82 and Appendix IV)

115. Two countries and a member organization did not support adding the underlined text to clarify that NRVs are expressed for ready to use foods. Reasons included:

- The current Codex standard refers to the product as sold, and the Codex Standard on the Labelling of Prepackaged foods foresees only an exemption for listing ingredients for dehydrated or condensed foods that are reconstituted by adding water only (CODEX STAN-1-1985, para 4.2.1.6).
- The added text could imply that nutrition information should *only* be based on a product after preparation according to manufacturer instructions (e.g., after the addition of water for dehydrated products). This would be a major change from the current provisions which refer to the product as sold in 3.4.4 as well as in preceding paragraphs in 3.4.2 and 3.4.3.
- Nutrient information based on ready to use forms of food can be misleading because foods may not be prepared according to package instructions.
- Governments should decide whether nutrient information should be based on the ready to use form of the product.
- The introduction of a new basis for expressing NRVs would need further clarification to distinguish rules applying to the product as sold and those applying to "ready to use"/reconstituted products (and would necessitate changes to other sections such as 3.4.2 and 3.4.3).

Another country agreed that the CCNFSDU should not propose to add this text and suggested that the question of declaration of nutrient content of foods on a ready to use basis be referred to the CCFL.

116. **Based on the above comments, an amendment to 3.4.4 to refer to "ready to use foods" is <u>not</u> included in Attachment D.**

117. The fourth sentence in 3.4.4 of the Guidelines currently reads:

> "The following Nutrient Reference Values should be used for labeling purposes in the interests of international standardization and harmonization:"

At the 2009 session, the Committee proposed to delete "in the interests of international standardization and harmonization" in the above sentence because it was considered superfluous, and instead proposed to clarify that these NRVs are for the general population identified as individuals older than 36 months (ALINORM 10/33/26 para 82 and Appendix IV). **These amendments are proposed in Attachment D based on the eWG's general support.**

118. In the consultation paper, the eWG was asked whether they supported adding the following new sentence to 3.4.4 to identify the uses of NRVs:

> "<u>They should be used for labelling purposes to help consumers achieve overall healthful dietary intake</u>".

119. The eWG generally supported this proposed amendment. One country considered that the sentence could be placed earlier in the Guidelines (e.g., in 3.1.1 or at the front of the Guidelines under "Principles for Nutrition Labelling") and another suggested modifying the text to refer to consumers *making choices that contribute* to an overall healthful dietary intake. One country did not consider the text to clarify NRV uses

was needed. **Based on the eWG's general support for the new sentence, it is included in Attachment D for the Committee's consideration.**

120. The eWG was asked whether they supported adding the following two sentences to 3.4.4 to 1) distinguish between NRVs that relate to nutrient requirements and those relate to diet-related NCDs, and 2) refer to the Annex(es) on general principles.

> "They include NRVs based on levels of nutrients associated with nutrient requirements (NRVs-R), and NRVs based on levels of nutrients associated with reduction of risk of diet-related noncommunicable diseases (NRVs-NCD). The general principles and definitions used in establishing these NRVs are identified in [*Identify Annex or Annexes*]."

121. Most comments supported adding a sentence in 3.4.4 to distinguish between the two types of NRVs, with certain of these suggesting further discussion of proposed text. In addition, it is relevant to note that with the option to define NRVs-R and NRVs-NCD in Section 2 of the Guidelines (as identified in Attachments B and C, the first sentence could simply read:

> "They include two types of NRVs: Nutrient Reference Values-Requirements (NRVs-R) and Nutrient Reference Values – Noncommunicable Disease (NRVs-NCD).

In addition, comments generally supported referring to the Annex(es) on general principles with one country proposing that this sentence be placed as a footnote and also refer to the definitions.

122. **Based on the above comments, the two options for text in paragraphs 120 and 121 are included in brackets in Attachment D to distinguish between the two types of NRVs with a footnote that refers to the general principles and related definitions.**

Listing of NRVs

Listing of NRVs in 3.4.4 for Reference by Governments

123. In the eWG consultation paper, a separate listing of NRVs was proposed for NRVs-R (*new 3.4.4.1*) and for NRVs-NCDs (*new 3.4.4.2*). In addition, it was proposed to present conversion factors for vitamin equivalents in the form of a table with NRV listing, rather than in footnotes, based on preliminary comments from the eWG on vitamin and mineral NRVs. Also, in new proposed 3.4.4.2 for the listing of NRVs-NCD, the proposed draft NRVs-NCD for SFA and sodium were identified, with a footnote by SFA to indicate that this value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories.

124. The eWG was asked to comment on the proposed amendments in the eWG consultation paper. Most comments supported the proposals. One country suggested further distinguishing between NRVs-R (for which consumers are encouraged to aim) and NRVs-NCD (for which consumers are encouraged not to exceed). Another country considered that the listing of NRVs-NCD in 3.4.4 should distinguish between nutrient intake that should be limited and nutrient intake that should be increased to reduce NCD risk. With regard to this latter comment, it may be noted that to date the Committee has not proposed any NRVs-NCD for nutrients to increase.

Listing of NRVs in 3.4.4 for Reference by Governments

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

Presentation of NRVs in Nutrition Labelling for Reference by Consumers

126. Whereas the listing of NRVs in 3.4.4 by the subtypes NRV-R and NRV-NCD clarifies their basis for reference by governments, a member organization raised a question about whether there is a need to clarify in the Guidelines how NRVs should be presented in nutrition labeling to the consumer to ensure understanding. As an example, this organization considered that the overaraching term "NRVs" might be sufficient to use in nutrition labeling.

Presentation of NRVs in Nutrition Labelling for Reference by Consumers

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

IVC. INTEREST IN PROPOSING NEW WORK RELATED TO NRVs FOR PROTEIN, TOTAL FAT AND/OR AVAILABLE CARBOHYDRATE

128. This eWG's final term of reference is to evaluate interest in proposing new work on NRVs for protein, total fat and available carbohydrate based on considerations other than diet-related NCDs such as energy balance. These macronutrients are included in the 3.2.1.2 list of nutrients in the Guidelines in which amounts (expressed in grams for these nutrients) should always be declared in nutrition labelling when nutrient declaration is applied. An NRV is currently provided only for protein (Section 3.4.4). In addition, the Preamble in the two Annexes on general principles for establishing NRVs provides for governments to establish their own reference values for labelling purposes that take into account factors specific to a region or country.

129. The eWG was asked if they supported consideration of new work on NRVs for protein, total fat, and available carbohydrate. If an eWG member supported new work, additional questions were asked including whether there would be a need to develop new general principles in a separate Annex to the Guidelines.

A. Interest in New Work to Review the Protein NRV

Background on Protein NRV

130. In 1993, the Commission adopted a protein NRV of 50 grams. This value was recommended by the 1988 Joint FAO/WHO Expert Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes held in Helsinki, Finland. The basis for this value is described in the report of the 1988 consultation as follows:

> "The Consultation considered the recommendations of the (1985 Joint FAO/WHO Expert Consultation on Energy and Protein Requirements).[19] It considered the *safe level of intake of 0.75 g/kg per day* recommended by that Consultation as being acceptable for both sexes at all ages and body weights as a basis for establishing a Codex NRV. Taking into account its conclusion concerning a uniform figure for use in all labelling, the Consultation arrived at a NRV of 50 g per day (rounded from 52.5 g). based on the intake of a 70 kg man. It was noted that for most populations this was consistent with several national recommendations that the energy intake from protein should be from 10 to 15 percent of total energy intake. The Consultation further concluded that for food labelling purposes differences in protein quality would not be considered. It was noted that for infants and children the absolute value given above would exceed the requirement calculated on a body weight basis."

The 1985 Consultation defined the protein requirement *of an individual* as "the lowest level of dietary protein intake that will balance losses of nitrogen from the body in persons maintaining energy balance at modest levels of physical activity" (Section 2.1, Definitions). For children and pregnant or lactating women, it was considered to include "the needs associated with the deposition of tissues or the secretion of milk at rates consistent with good health". The *safe level of intake* for protein was defined as an amount that meets or exceeds the requirements of practically all individuals in a group (i.e., the average requirement plus 2 standard deviations). Thus, this daily intake reference value corresponds with the Individual Nutrient Level 98 (INL_{98}) which serves as the primary basis for the vitamin and mineral NRVs (CAC/GL 2-1985 Annex on general principles).

FAO/WHO Scientific Update on Protein Requirements

131. A scientific update on protein requirements is available from FAO/WHO. Specifically, a joint WHO/FAO/UNU Expert Consultation was held in 2002 on Protein and Amino Acid Requirements in Human Nutrition.[20] Chapter 14 provides a summary of protein requirements, including safe levels of intake by age and sex group. For adults, the value accepted for the safe level of intake is 0.83 g/kg per day (or 58 g per day for a 70 kg adult), for proteins with a protein digestibility-corrected amino acid score value of 1.0. The report identifies a separate approach for calculating protein requirements for infants, children and

[19] WHO. *Energy and protein requirements. Report of a joint FAO/WHO/UNU expert consultation.* WHO Technical Report Series 724. 1985. Web reference (Accessed 22, 2012). http://www.fao.org/DOCREP/003/AA040E/AA040E00.HTM

[20] WHO. *Protein and amino acid requirements in human nutrition; Report of a joint WHO/FAO/UNU expert consultation.* WHO Technical Report Series 935. 2007. Web reference (Accessed April 22, 2012). http://whqlibdoc.who.int/trs/WHO_TRS_935_eng.pdf

adolescents (with safe levels of intake for children age 3 to 18 years ranging from 0.84 to 0.92 g/kg per day), and identifies adjustments for protein quality of the diet.

Additional Scientific Updates

132. In commenting on whether to support new work to review the protein NRV, the eWG was asked to consider additional scientific updates from other recognized authoritative scientific bodies that meet the criteria identified in the general principles for the other NRVs. For example, in a 2012 scientific opinion of the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies, the Population Reference Intake[21] for protein for adults of all ages was estimated to be 0.83 g per kg body weight per day, which is applicable to both high quality protein and to protein in mixed diets.[22] In addition, a 2002 report of the Institute of Medicine of the National Academies of science in the U.S. (IOM) identified the Recommended Dietary Allowance for adults to be 0.80 g of good quality protein per kg body weight per day.[23]

eWG Support for New Work to Review the Protein NRV

133. The majority of comments supported new work to review the protein NRV in light of scientific updates, and to consider whether the 50 g value for the general population should be revised. Reasons for supporting new work included:

- This work is appropriate given that the NRVs for other nutrients are under review.
- Suitable scientific updates are available to assess the need to revise the protein NRV.
- It would help in evaluating the appropriateness of current Codex member government values.
- It could consider differences in protein quality as they relate to establishing a protein NRV for food labeling purposes.
- It could consider the lower protein requirement for children compared to adults.

134. A member organization and one country did not consider the review of the protein NRV to be a priority, with the former indicating that protein intakes are in the recommended range and are not a public health issue in Europe.

eWG Support for New Work to Review the Protein NRV

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

General Principles for Establishing a Protein NRV

136. The eWG was asked if a new set of general principles would need to be developed to review the protein value (if the two existing annexes are not consolidated); or alternatively whether the proposed consolidation of the two Annexes on general principles could apply to protein. The eWG generally agreed that the proposed consolidated Annex could apply to protein. One country considered that the separate Annexes on general principles could apply.

General Principles for Establishing a Protein NRV

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

[21] "Population Reference Intakes" (and "Recommended Dietary Intakes") are other terms for the INL_{98}.

[22] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on Dietary Reference Values for protein. EFSA Journal 2012;10(2):2557 [66 pp.] Web reference (Accessed May 3, 2012). http://www.efsa.europa.eu/en/efsajournal/pub/2557.htm .

[23] 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. p. 589. Web reference (Accessed May 3, 2012). http://www.iom.edu/Activities/Nutrition/DRIMacronutrients.aspx

eWG Views on Suitable Data to Consider in Reviewing the Protein NRV

138. The eWG was asked about potential suitable data sources that meet criteria identified in the general principles for other NRVs that could be considered in any work to review the protein NRV. At a minimum, comments generally supported consideration of the three reports identified in the consultation paper that provide scientific updates for INL_{98} values for protein. These include: 1) a 2007 report of a 2002 joint WHO/FAO/UNU Expert Consultation on Protein and Amino Acid Requirements in Human Nutrition[24], 2) a 2012 scientific opinion on Population Reference Intakes for protein from the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies[25], and 2) a 2002 report of the Institute of Medicine of the National Academies of science in the U.S. (IOM) on Recommended Dietary Allowances for protein.[26]

139. In addition, a country considered that the INL_{98} value should be retained as the basis for a Codex NRV given its scientific and public health basis and clear meaning, and because the Committee had already identified the INL_{98} value as an appropriate basis for vitamin and mineral NRVs.

Suitable Data to Consider in Reviewing the Protein NRV

140. Relevant scientific updates on INL_{98} values for protein are available from WHO/FAO and other recognized authoritative scientific bodies that could be considered in potential new work.

B. Interest in New Work to Establish an NRV for Total Fat

Background

141. With regard to diet-related NCDs, the 2008 joint FAO/WHO expert consultation on fats and fatty acids in human nutrition concluded that there is no probable or convincing evidence for significant effects of total dietary fats on coronary heart disease or cancers (FNP 91, p. 13). In addition, the consultation concluded that it was not possible to determine at a probable or convincing level the causal relationship of excess percent energy (% E) intake from fat and unhealthy weight gain given insufficient evidence and conflicting interpretation of results on the nature of the relationship between %E fat and adult body weight (FNP 21, p. 13). It was further noted that in populations with inadequate total energy intake, dietary fats are an important macronutrient that contribute to increasing energy intake to more appropriate levels.

This consultation concluded that better evidence was needed upon which to base a globally applicable recommendation for the acceptable macronutrient distribution range for %E fat. It did, however, suggest the following minimum and maximum intakes (pp. 11-14):

1) Adults

Minimum total fat intake

- 15%E to ensure adequate consumption of total energy, essential fatty acids and fat soluble vitamins for most individuals;
- 20%E for women of reproductive age and adults with BMI <18.5, especially in developing countries in which dietary fat may be important to achieve adequate energy intake in malnourished populations.

Maximum total fat intake

- 30-35% E for most individuals.

2) Children 2-18 years

Minimum total fat intake: 25%E

Maximum total fat intake: 35%E

[24] WHO. *Protein and amino acid requirements in human nutrition; Report of a joint WHO/FAO/UNU expert consultation.* WHO Technical Report Series 935. 2007. Web reference (Accessed April 22, 2012). http://whqlibdoc.who.int/trs/WHO_TRS_935_eng.pdf

[25] "Population Reference Intakes" (and "Recommended Dietary Intakes") are other terms for the INL_{98}.

[26] 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. p. 589. Web reference (Accessed May 3, 2012). http://www.iom.edu/Activities/Nutrition/DRIMacronutrients.aspx

eWG Support for New Work to Establish an NRV for Total Fat

142. The eWG views were mixed regarding support for new work to establish an NRV for total fat. A member organization, 5 countries and two INGOs supported consideration of this new work with the following views:

- Total fat is among the nutrients to be declared in nutrition labelling (in 3.1.2.1).
- An NRV would inform consumers about levels of total fat in foods, including the selection of a low fat diet if desired.
- Such information allows consumers to know both an adequate fat daily intake and the contribution of food to that intake.
- It is important to public health.
- Some governments may not have food label reference values for total fat, or their values may not have sound bases.
- It is good as much as possible to have a value harmonized among Codex member governments.

143. Six countries and two INGOs did not support the establishment of an NRV for total fat with the following views:

- It would appear that total fat does not meet the draft criteria for establishing an NRV.
- There is not a strong scientific basis and public health need for an NRV:
    - The scientific evidence is insufficient for a relationship between total fat and coronary heart disease, cancers, and unhealthy weight gain.
    - Better evidence is needed to base a globally applicable recommendation for an acceptable macronutrient distribution range for % energy fat. In addition, even if better evidence became available, it may be difficult to reach consensus on a globally relevant single NRV from an acceptable range.
- The types of fatty acids are more important in influencing coronary heart disease risk than the total amount of fat in the diet.
- This is not be a priority at this stage. The NRVs on SFA and sodium should be used as a test for their usefulness.
- This does not preclude governments from establishing their own food label reference values for total fat.

144. One country preferred that CCFL decide whether total fat and available carbohydrate should be considered for an NRV. In this regard, if CCFL referred another nutrient for consideration of an NRV, CCNFSDU would still need to consider whether an NRV should be established based on the general principles, as it did for SFA and sodium.

General Principles for Establishing a Total Fat NRV

145. Certain comments considered that the general principles for establishing vitamin and mineral NRVs and/or those for establishing NRVs-NCD would be applicable to establishing a total fat NRV, whereas others considered that these would not apply. For example, it is unclear how these general principles would be used for total fat given that vitamin and mineral NRVs are based primarily on INL_{98} values and total fat did not have either convincing or probable or evidence for a relationship to NCD risk in FNP 91.

Another eWG member considered that until there is sufficient evidence to derive an NRV for total fat at the Codex level, that food label reference values for total fat should only be derived at the national level.

eWG Support for New Work to Establish a Total Fat NRV

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

C. Interest in New Work to Establish an NRV for Available Carbohydrate

Background

147. Section 3.2.1.2 of the Guidelines provides for the declaration in nutrition labelling of amounts of *available* carbohydrate (which is identified as dietary carbohydrate excluding dietary fibre).

In evaluating whether a Codex NRV for available carbohydrate is needed, a consideration identified in the eWG consultation paper is how a percentage NRV for 'available carbohydrate" on the nutrition label that excludes dietary fibre could help consumers plan healthful diets. The eWG was also asked to consider if it would be possible to establish a Codex NRV for available carbohydrate, given that the Codex definition of dietary fibre in the Guidelines leaves two issues to national authorities (and thus the definition may vary among countries), which in turn affects what would be measured by available carbohydrate.

148. It was further noted that FAO/WHO data sources appear to provide recommendations for total carbohydrate rather than for available carbohydrate over a wide range of intake. For example, both the 1997 joint FAO/WHO expert consultation on carbohydrates in human nutrition and the 2002 expert consultation on diet, nutrition and the prevention of chronic diseases recommended that total carbohydrate in the diet provide 55-75% of energy.[27] In addition, a conclusion of a 2006 FAO/WHO scientific update on carbohydrates was that a lower limit of around 50% energy was acceptable.[12] However, with this scientific update it was noted that it is more important to be prescriptive with regard to the nature of carbohydrate—especially when total carbohydrate intakes are at the upper end of the recommended range—with the need for carbohydrate to be derived principally from whole-grain cereals, fruits, vegetables and legumes.

eWG Support for New Work to Establish an NRV for Available Carbohydrate[28]

149. eWG views were mixed regarding support for new work to establish an NRV for available carbohydrate, with much similarity to comments on the total fat NRV. A member organization, six countries and three INGOs supported consideration of this new work with the following views:

- Available carbohydrate is among the nutrients to be declared in nutrition labelling (in 3.1.2.1).
- An NRV would inform consumers about levels of available carbohydrate in foods.
- Such information allows consumers to know both an adequate available carbohydrate daily intake and the contribution of food to that intake.
- This nutrient is a key nutrient to ensure a healthy diet.
- To include the amount of sugar would give more information to the consumer.
- Some governments may not have food label reference values for available carbohydrate, or their values may not have sound bases.
- It is good to have a value harmonized among Codex member governments as much as possible.

One country that supported new work to establish an NRV cited a paper submitted for the FAO/WHO Scientific Update on Carbohydrates in Human Nutrition.that stated that carbohydrates are among the macronutrients the provide energy and can thus contribute to excess energy intake and subsequent weight gain.[29] In this regard, this paper and a related one on conclusions of the scientific update also stated that there is no clear evidence that altering the proportion of total carbohydrate in the diet is an important determinant of energy intake.

150. Five countries and one INGO did not support the establishment of an NRV for available carbohydrate with the following views:

- No data are available for available carbohydrate that would meet the general principles in Sections 3.1.1 and 3.1.2.
- There is not a strong scientific basis and public health need for an NRV.
- Available carbohydrates vary widely in their physical properties and physiological effects.

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[27] Mann J, Cummings JH, Englyst HN, Key T et al. FAO/WHO scientific update on carbohydrates in human nutrition: Conclusions. European Journal of Clinical Nutrition (2007) 61 (Suppl 1, S132-S137. 2007. Web Reference. Accessed April 24, 2012. http://www.nature.com/ejcn/archive/index.html

[28] In question 15b in the consultation paper, there was an error in referring to "total carbohydrate" instead of available carbohydrate in one place, with most eWG recognizing this error in their responses.

[29] Van Dam RM and Seidell JC. Carbohydrate intake and obesity. European Journal of Clinical Nutrition (2007) 61 (Supp 1), S75-299. Web Reference. Accessed October 9, 2012. http://www.nature.com/ejcn/journal/v61/n1s/pdf/1602939a.pdf

- It is unclear how a percentage NRV for available carbohydrate on the nutrition label would help consumers plan healthful diets.
- It would be difficult to establish an NRV for available carbohydrate, given that the definition of dietary fibre may vary among countries.
- This is not be a priority at this stage. The NRVs on SFA and sodium should be used as a test for their usefulness.
- This does not preclude governments from establishing their own food label reference value for available or total carbohydrate.

General Principles for Establishing an NRV for Available Carbohydrate

151. Certain comments considered that the general principles for establishing vitamin and mineral NRVs and/or those for establishing NRVs-NCD would be applicable to establishing an NRV for available carbohydrate, whereas others considered that these would not apply.

Another eWG member considered that until there is sufficient evidence to derive an NRV for carbohydrate at the Codex level, food label reference values for this nutrient should only be derived at the national level.

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

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

Attachment A

OPTIONS PRESENTED TO THE EWG FOR FINALIZING TEXT PERTAINING TO STRENGTH OF THE SCIENTIFIC EVIDENCE IN THE PROPOSED DRAFT GENERAL PRINCIPLES FOR NRVs-NCD IN APPENDIX V OF REP 12/NFSDU

Note to CCNFSDU: For reference, below are expanded approaches and options for text in the proposed draft general principles for NRVs-NCD that is related to the strength of the evidence for the relationship between a nutrient and NCD risk (in Section 3.1). The eWG was asked which of these three approaches and six text options they preferred most and least. Based on these comments, the report recommendation is to use text option B1 (highlighted below), which is incorporated into the proposed revision of Appendix V in Attachment B and into the proposed draft consolidated Annex in Attachment C.

APPROACHES AND OPTIONS

Approach A-"Convincing/Generally Accepted" evidence as the sole basis for an NRV-NCD and acknowledge government flexibility in Preamble only. This approach retains "convincing/generally accepted" scientific evidence as the sole basis for establishing a Codex NRV-NCD. In addition, it acknowledges only in the Preamble of the General Principles that governments have the flexibility to consider a lower level of evidence than "convincing/generally accepted".

Preamble

Option A1 considers that sufficient flexibility is already provided in the following text in the 3rd sentence for governments to consider a lower level of evidence and that this is implicit.

Option A1 proposed text:

"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."

Option A2 considers that the preamble could refer more specifically to levels of evidence.

Option A2 proposed text:

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

Approach B-"Convincing/Generally Accepted" evidence as the sole basis for NRVs-NCD, and acknowledge government flexibility in both the Preamble and Section 3.1. This approach retains "convincing/generally accepted" scientific evidence as the sole basis for establishing a Codex NRV-NCD. In addition, it acknowledges in a separate sentence in the first bullet of 3.1 that governments may consider the suitability of a lower level of evidence that "convincing/generally accepted" in establishing their own food label reference values.

Section 3.1, Second sentence in first bullet

Option B1 *(Former Option 1 in Appendix V).* **This option explicitly acknowledges in 3.1 that governments may consider "probable evidence" in establishing their own food label reference values.** With this option, a definition for "probable evidence" could be included (or a citation for a definition provided), but it may not be required since it would not apply to Codex NRVs-NCD.

Option B1 proposed text:

[In addition, governments may consider the suitability of probable evidence[30] in conjunction with other bases in establishing their own food label reference value(s).]

[30] *With Option B1, a decision would need to be made on whether to include or refer to a definition of "probable evidence".*

Option B2. This option acknowledges in 3.1 that governments may consider lower levels of evidence in establishing NRV-NCDs *without* identifying specific descriptors for levels of evidence or definitions.

Option B2 proposed text:

[In addition, governments may consider the suitability of ~~probable evidence~~ **[**additional/different levels of evidence] in conjunction with other bases in establishing their own food label reference value(s).]

Approach C-Additional Consideration of Evidence Lower than "Convincing/Generally Accepted" for NRVs-NCD and acknowledge government flexibility in Preamble. This approach retains "convincing/general accepted" scientific evidence as a basis for establishing a Codex NRV-NCD, and states or implies that the suitability of lower levels of evidence may also need to be considered in establishing a Codex NRV-NCD.

Option C1- This option allows consideration of "probable" evidence in establishing NRVs-NCD with a specific descriptor and definition (*Former Option 2 in REP 12/NFSDU, Appendix V).* There was general agreement that the criteria for probable evidence used in FAO/WHO data sources currently available for this work (i.e., FNP 91 and TRS 916) was unsuitable. Consequently, Option 2 in Appendix V includes a footnote to an "updated" draft definition adapted from a 2007 World Cancer Research Fund/American Institute for Cancer Research Report (WCRF/AICR Report).

Option C1 proposed text:

[In addition, the suitability of probable evidence may need to be considered.]

Option C2- This option allows consideration of lower levels of evidence in establishing NRV-NCDs without identifying specific descriptors for levels of evidence or definition(s). (*Former Option 1 in Appendix V with edits below).* This option considers that the FAO/WHO values based on "probable evidence" currently available for this Committee's work did not use the definition in the 2007 WCRF/AICR report, and that the WHO representative indicated at the last CCNFSDU session that a new term would replace "probable" evidence (as well as "convincing evidence").

Option C2 proposed text:

[In addition, the suitability of ~~probable~~ [additional/different] levels of evidence may need to be considered.]

Attachment B

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

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

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

1. PREAMBLE

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

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

2. DEFINITION(S)

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

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

Or

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

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

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

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

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

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

2.# **Upper Level of Intake (UL)**[31] is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans**.**

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

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 Criteria for Selection of Nutrients

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

Relevant convincing[32]/ generally accepted[33] scientific evidence for the relationship between a nutrient and noncommunicable disease risk, including validated biomarkers for relevant disease risk

[, for at least one major segment of the population (e.g., adults).] In addition, governments may consider the suitability of probable evidence[34] in conjunction with other bases in establishing their own food label reference value(s).

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

3.2 Selection of Suitable Data Sources to Establish NRVs-NCD

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

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

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

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

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

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

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

[32] At the time these guiding principles were drafted, the definition and criteria for "convincing evidence" from the following FAO/WHO reports were used: 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.

[33] For these General Principles the terms convincing/generally accepted evidence are considered synonymous.

[34] Where applicable, the definition and criteria for "probable evidence" from the following World Cancer Research Fund/American Institute for Cancer Research (AICR) report may be adapted by governments for this purpose: *Food, Nutrition, Physical Activity, and the Prevention of Cancer: a Global Perspective.* Washington DC: AICR, 2007, p.60.

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

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

3.3.5 Where a daily intake reference value is based on a percentage energy intake, the single 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 *8370* kilojoules/*2000* kilocalories, or may derive their own reference values for nutrition labelling based on another reference energy intake that considers factors specific to their country or region.

3.4 Consideration of Daily Intake Values for Upper Levels

The establishment of general population NRVs-NCDs should take into account daily intake reference values for upper levels established by FAO/WHO or other recognized scientific authoritative bodies where applicable (e.g., Upper Level of Intake, Acceptable Macronutrient Distribution Range).

Attachment C

*Note to the CCNFSDU:: Below is **a proposed draft consolidation** of the: 1) adopted Annex on general principles for establishing vitamin and mineral NRVs (Annex, CAC/GL 2-1985), and 2) revised proposed draft general principles for establishing NRVs-NCD in Attachment B. In this consolidation, sections are renumbered and certain headings are simplified. In addition, provisions in the adopted Annex are clearly identified by "VM NRV GP". With a goal to finalize the NRV general principles at the next session, the Committee may wish to focus their review in particular on the bracketed text [.....] and proposed new underlined text. Note: Shaded/highlighted identifies additional minor edits that would result from consolidating the two Annexes.*

PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES ON NUTRITION LABELLING:

GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR THE GENERAL POPULATION

1. PREAMBLE

(Slight proposed revision of adopted text in VM NRV GP as a result of consolidation)

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

For example, at the national level, population-weighted values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group. In addition, governments may establish ~~nutrient~~ reference values for food labelling that take into account country or region specific factors that affect nutrient absorption, utilization, or requirements. Governments may also consider whether to establish separate food label reference values for specific segments of the general population [such as pregnant and lactating women].

2. DEFINITIONS

*[**Option 1**: Define NRVs-R and NRVs-NCD in Section 2 of this Annex as identified below:*

> **2.1***(new term and definition)* **Nutrient Reference Values- Requirements (NRVs-R)** refer to NRVs that are based on levels of nutrients associated with nutrient requirements.]
>
> **2.2 Nutrient Reference Values - Noncommunicable Disease (NRVs-NCD)** refer to NRVs for nutrients that are associated with risk of diet-related noncommunicable diseases not including nutrient deficiency diseases or disorders.

Or

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

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

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

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

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

2.4 *(adopted definition- VM GP)* **Individual Nutrient Level 98 (INL_{98})**[35] is the [daily nutrient intake value] [daily intake reference value] that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in a specific life stage and sex group.

2.5 *(adopted definition- VM GP)* **Upper Level of Intake (UL)**[36] 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.

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

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs

Note to CCNFSDU: The draft proposal below for consolidating principles in Section 3 in the two Annexes addresses selection of suitable data sources first, then selection of nutrients and the appropriate basis for NRVs, and finally consideration of daily intake reference values for upper levels.

3.1 Selection of Suitable Data Sources to Establish NRVs

3.1.1 *(adopted VM NRV GP)* 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.

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

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

3.2 *(proposed revised heading)* Selection of Nutrients and Appropriate Basis for NRVs

3.2.1 *(new subheading)* Selection of Nutrients and Appropriate Basis for NRVs-R

3.2.1.1 *(adopted VM NRV GP)* The NRVs-R should be based on Individual Nutrient Level 98 (INL_{98}). In cases where there is an absence of an established INL_{98} for a nutrient for a specific sub-group(s), it may be appropriate to consider the use of other reference values or ranges that have been established by recognized authoritative scientific bodies. The derivation of these values should be reviewed on a case-by-case basis.

3.2.1.2 *(adopted VM NRV GP)* The general population NRVs-R should be determined by calculating the mean values for a chosen reference population group older than 36 months. [Nutrient Reference Values] [NRVs-R] derived by the CCNFSDU are based on the widest applicable age range for each of adult males and females.

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[35] *(adopted footnote in VM NRV GP)* Different countries may use other terms for this concept, for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), or Population Reference Intake (PRI).

[36] *(adopted footnote in VM NRV GP)* Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range.

3.2.1.3 *(adopted VM NRV GP)* For the purpose of establishing these NRVs-R, the values for pregnant and lactating women should be excluded.

3.2.2 *(Revised shortened heading)* **Selection of Nutrients and Appropriate Basis for NRVs-NCD**

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

- Relevant convincing[37]/ generally accepted[38] scientific evidence for the relationship between a nutrient and noncommunicable disease risk relationship, including validated biomarkers for relevant disease risk [, for at least one major segment of the population (e.g., adults).] In addition, governments may consider the suitability of probable evidence[39] in conjunction with other bases in establishing their own food label reference value(s).
- Public health importance of the nutrient-noncommunicable disease risk relationship(s) among Codex member countries.

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

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

3.2.2.4 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.

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

3.2.2.6 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 8370 kilojoules/2000 kilocalories, or may derive their own reference values for nutrition labelling based on another reference energy intake that considers factors specific to their country or region.

3.3 Consideration of Daily Intake Values for Upper Levels

(NRV-NCD GP agreed on at last session) The establishment of general population NRVs should also take into account daily intake reference values for upper levels established by FAO/WHO or other recognized authoritative scientific bodies where applicable (e.g., Upper Level of Intake, Acceptable Macronutrient Distribution Range).

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[37] At the time these guiding principles were drafted, the definition and criteria for "convincing evidence" from the following FAO/WHO reports were used: 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.

[38] For these General Principles the terms convincing/generally accepted evidence are considered synonymous.

[39] Where applicable, the definition and criteria for "probable evidence" from the following World Cancer Research Fund/American Institute for Cancer Research (AICR) report may be adapted by governments for this purpose: *Food, Nutrition, Physical Activity, and the Prevention of Cancer: a Global Perspective.* Washington DC: AICR, 2007, p.60.

Attachment D

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

Note to CCNFSDU: Below are proposed draft amendments to Section 3.4.4 of the Guidelines on Nutrition Labelling to refer to CCFL. These amendments consider eWG comments and proposed draft amendments to the 3.4.4 introductory text in 2009 (ALINORM 10/33/26, Appendix IV).

Proposed new text is underlined. Proposed deletions are identified by strikeout. Text in italics provides additional explanatory notes for CCNFSDU reference.

3.4 Presentation of nutrient content

3.4.4 Numerical information on vitamins and minerals should be expressed in metric units and/or as a percentage of the NRV ~~Nutrient Reference Value~~ per 100 g or per 100 ml or per package if the package contains only a single portion. In addition, this information may be given per serving as quantified on the label or per portion provided that the number of portions contained in the package is stated.

In addition, information on protein and additional nutrients may also be expressed as percentages of the NRV ~~Nutrient Reference Value~~.[40] where an NRV has been established.

The following NRVs ~~Nutrient Reference Values~~ are for the general population identified as individuals older than 36 months. They should be used for labelling purposes to help consumers achieve overall healthful dietary intake. ~~in the interests of international standardization and harmonization.~~

Option 1

[They include NRVs based on levels of nutrients associated with nutrient requirements (NRVs-R), and NRVs based on levels of nutrients associated with reduction of risk of diet-related noncommunicable diseases (NRVs-NCD).[41]]

Or

Option 2 (if the terms and related abbreviations and definitions for NRVs-R and NRVs-NCD are introduced earlier in the Guidelines in Section 2)

[They include two types of NRVs: Nutrient Reference Values-Requirements (NRVs-R) and Nutrient Reference Values – Noncommunicable Disease (NRVs-NCD).[41]]

3.4.4.1 NRVs-R

Note to CCNFSDU: In new proposed section 3.4.4.1, NRVs associated with nutrient requirements and related footnotes that reflect the outcome of discussion at the next CCNFSDU session would be listed. One option presented in the vitamin and mineral eWG consultation paper is to identify conversion factors in a table rather than in footnotes. This option is presented below.

Protein (g) 50

[*Vitamin A unit value*

Etc.]

[40] ~~In order to take into account future scientific developments, future FAO/WHO and other expert recommendations and other relevant information, the list of nutrients and the list of nutrient reference values should be kept under review.~~

[41] The general principles and related definitions used in establishing these NRVs are identified in [*Identify Annex or Annexes*].

Table of conversion factors for vitamin equivalents

Vitamin	**Dietary Equivalents**	
Vitamin A	*To be determined (TBD)* *[e.g., 1 µg retinol equivalents (RE) =*	*1 µg retinol* *6 µg ß-carotene* *Etc.]*
Vitamin E	*TBD*	*TBD*
Niacin	*TBD*	*TBD*
Folate	*TBD*	*TBD*

3.4.4.2 NRVs-NCD

Note to eWG: In new proposed section 3.4.4.2, NRVs-NCD would be listed with related footnote(s).

Saturated fatty acids 20g[42] [43]

Sodium 2000[43] mg

[42] The selection of these nutrients for the establishment of an NRV was based on "convincing evidence" for a relationship with NCD risk using the following definition:

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

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

[43] This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories.

Attachment E

Potential Suitable Data Sources for Assessing Convincing Evidence in Addition to FAO/WHO Data Sources[44]

In addition to the reports of the two relevant FAO/WHO expert consultations (i.e., FNP 91 and TRS 916), one or more eWG members identified the following potential data sources/references that might be considered in assessing whether there is convincing evidence for a nutrient-NCD relationship with regard to the first criterion for selection of nutrients for NRVs-NCD in REP 12/NFSDU, Appendix V, Section 3.1.

European Food Safety Authority (EFSA)

- EFSA Nutrition and health claims. http://www.efsa.europa.eu/en/topics/topic/nutrition.htm .
- EFSA Scientific Opinion on Dietary Reference Values Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, *trans* fatty acids, and cholesterol. EFSA Journal 2010; 8(3):1461. http://www.efsa.europa.eu/en/efsajournal/doc/1461.pdf .
- EFSA. Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. The EFSA Journal, 2010; 8(3):1462. http://www.efsa.europa.eu/en/efsajournal/doc/1462.pdf .

Institute of Medicine of the National Academies of sciences in the United States (IOM)

- IOM reports. http://www.iom.edu/Reports.aspx?page=1&Series={508F5CFF-EE88-4FF6-92BF-8D6CAB46F52E} .
- Institute of Medicine (IOM) Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and aminoacids (macronutrients), 2005 http://www.nap.edu/openbook.php?isbn=0309085373 .

Other Potential Data Sources/References by Country[45]

Canada

- Health Canada http://www.hc-sc.gc.ca/fn-an/index-eng.php .

France

- AFSSA (Agence Française de Sécurité Sanitaire des Aliments), Opinion of the French Food Safety Agency on the update of French population reference intakes (ANCs) for fatty acids, 2010, Summary in English Web reference http://www.anses.fr/Documents/NUT2006sa0359EN.pdf .
- ANSES (Agence Nationale de Sécurité Sanitaire Alimentation, Environnement, Travail, Actualisation des apports nutritionnels conseillés pour les acides gras; Rapport d'expertise collective, Mai 2011, Complete Report in French Web reference http://www.anses.fr/Documents/NUT2006sa0359Ra.pdf .

United States

- National Institute of Health http://health.nih.gov/ .

Spain

- AESAN:http://www.aesan.msc.es/ ,

Additional Cited References

- ILSI http://www.ilsi.org/Pages/HomePage.aspx .
- World Cancer Research Fund (WCRF)
- Harvard School of Public Health (trans fats): http://www.hsph.harvard.edu/research/index.html#projects .
- Brunner E, Rees K, Ward K, Burke M, Thorogood M, Dietary advice for reducing cardiovascular risk (Review), Cochrane library. 2009, issue 1.
- Hooper L, Summerbell CD, Thompson R, Sills D, Roberts FG, Moore H, Davey Smith G, Reduced or modified dietary fat for preventing cardiovascular disease (Review), Cochrane library 2011, issue 7.
- Puska P, et al., Can we turn back the clock or modify the adverse dynamics? Programme and policy issues influencing public nutrition for NCDs prevention: from community intervention to national programme- Experiences from Finland, Public Health Nutrition 2010, 5(1a):245-251.

[44] Suitable data sources for SFA and sodium were considered in the 2011 eWG.

[45] Note: The countries identified indicate the source of the *data*, not necessarily the source of the *comment.*

Attachment F

DRAFT PROJECT DOCUMENT

PROPOSAL TO REVIEW THE NUTRIENT REFERENCE VALUE FOR PROTEIN IN THE GUIDELINES ON NUTRITION LABELLING (CAC/GL 2-1985) IN LIGHT OF SCIENTIFIC UPDATES

1. PURPOSE AND SCOPE OF THE NEW WORK

Codex nutrition labelling provisions recognize the importance of obtaining adequate amounts of protein in the diet. Section 3.2.1.2 of the Guidelines on Nutrition Labelling (CAC/GL 2-1985) (hereafter referred to as "the Guidelines") provides for amounts of protein expressed in grams to always be declared in nutrition labelling when nutrient declaration is applied. Section 3.4.4 of the Guidelines provides for the additional listing of protein amounts as percentages of a Nutrient Reference Value (NRV) established for protein to help consumers make informed food choices. Moreover, the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997, Section 5) identify conditions for protein content claims based on specified percentages of the protein NRV.

The protein NRV of 50 g is based on recommendations at least 25 years old. This value is assumed to be applicable to the general population based on the additional background below, although current Section 3.4.4 does not explicitly identify the applicable population.[46] A footnote in Section 3.4.4 of the Guidelines recognizes the need to keep the list of NRVs under review and to take into account scientific developments. The purpose of this proposed new work is to review the protein NRV in light of scientific updates and general principles for establishing NRVs, and to assess the need to revise this NRV. This proposed work would complement current CCNFSDU work to consider revised and additional NRVs for other nutrients, including vitamins and minerals and nutrients associated with risk of diet-related noncommunicable diseases.

Basis for Current Protein NRV

The protein NRV of 50 grams was adopted by the Commission in 1993. This value was recommended by the 1988 Joint FAO/WHO Expert Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes held in Helsinki, Finland, which in turn considered the recommendations of the 1985 Joint FAO/WHO Expert Consultation on Energy and Protein Requirements.[47] The 1988 consultation considered the *safe level of intake of 0.75 g/kg per day* recommended by the 1985 Consultation as being acceptable for both sexes at all ages and body weights as a basis for establishing a Codex NRV. Taking into account its conclusion concerning a uniform figure for use in all labelling, the Consultation arrived at a NRV of 50 g per day (rounded from 52.5 g). based on the intake of a 70 kg man. The Consultation further concluded that for food labelling purposes differences in protein quality would not be considered. It was noted that for infants and children the absolute value given above would exceed the requirement calculated on a body weight basis."

The *safe level of intake* for protein was defined as an amount that meets or exceeds the requirements of practically all individuals in a group (i.e., the average requirement plus 2 standard deviations). This daily intake reference value corresponds with the Individual Nutrient Level 98 (INL_{98}) which serves as the primary basis for the vitamin and mineral NRVs (CAC/GL 2-1985 Annex).

2. RELEVANCE AND TIMELINESS

A review of the protein NRV is timely given that the recommendations upon which it is based are more than 25 years old, and recent and relevant scientific updates are available from FAO/WHO and other recognized authoritative scientific bodies. A review is also timely given recent and current CCNFSDU work to develop general principles for establishing NRVs and to consider revised and additional NRVs for other nutrients.

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[46] By comparison, recent CCNFSDU work on general principles for establishing NRVs for other nutrients clarify that these NRVs are for the general population older than 36 months. In addition, the project document for the vitamin and mineral NRVs anticipate future CCNFSDU work to establish separate vitamin and mineral NRVs for individuals 6 to 36 months of age.

[47] WHO. *Energy and protein requirements. Report of a joint FAO/WHO/UNU expert consultation.* WHO Technical Report Series 724. 1985. Web reference (Accessed 22, 2012). http://www.fao.org/DOCREP/003/AA040E/AA040E00.HTM

3. MAIN ASPECTS TO BE COVERED

This work would consider scientific updates on INL_{98} values for protein from FAO/WHO and other recognized authoritative bodies and general principles for establishing NRVs for the general population identified as over 36 months that are based on nutrient requirements. As a result of this review, the Committee would propose either to retain the protein NRV of 50 g for the general population in Section 3.4.4 of the Guidelines, or alternatively, propose amendments to 3.4.4 to revise the protein NRV.

4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

4.1 General criterion

This work meets Codex criteria for the establishment of work priorities, and would enhance protection of consumer health, help ensure fair practices in international food trade, and take into account identified needs of developing countries.

4.2 Criteria applicable to general subjects

a) Diversification of national legislations and apparent resultant or potential impediments to international trade.

This work would enhance protection of consumer health, encourage the use of the protein NRV, and facilitate fair food trade by ensuring that the protein NRV is not outdated and takes into consideration recent and relevant scientific updates from FAO/WHO and other recognized authoritative scientific bodies.

b) Scope of work and establishment of priorities between the various sections of the work.

The scope of work relates to previously undertaken work by CCNFSDU to establish a protein NRV and current related work to establish revised and additional NRVs for other nutrients.

c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

Relevant scientific updates on INL_{98} values for protein are available from WHO/FAO and other recognized authoritative scientific bodies to consider in this work. They include at a minimum: 1) a 2007 report of a 2002 joint WHO/FAO/UNU Expert Consultation on Protein and Amino Acid Requirements in Human Nutrition[48], 2) a 2012 scientific opinion on Population Reference Intakes for protein from the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies[49], and 2) a 2002 report of the Institute of Medicine of the National Academies of science in the U.S. (IOM) on Recommended Dietary Allowances for protein.[50]

d) Amenability of the subject of the proposal to standardization.

This work is intended to encourage the use of the Codex protein NRV by member governments by taking into account recent and relevant scientific updates.

e) Consideration of the global magnitude of the problem or issue.

As previously noted, current Codex provisions recognize the public health importance of obtaining adequate amounts of protein in the diet through provisions for nutrition labeling and for nutrition content claims.

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[48] WHO. *Protein and amino acid requirements in human nutrition; Report of a joint WHO/FAO/UNU expert consultation.* WHO Technical Report Series 935. 2007. Web reference (Accessed April 22, 2012). http://whqlibdoc.who.int/trs/WHO_TRS_935_eng.pdf

[49] "Population Reference Intakes" (and "Recommended Dietary Intakes") are other terms for the INL_{98}.

[50] 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. p. 589. Web reference (Accessed May 3, 2012). http://www.iom.edu/Activities/Nutrition/DRIMacronutrients.aspx

5. RELEVANCE TO CODEX STRATEGIC GOALS

This work would contribute to the following goals identified in the Codex Alimentarius Commission Strategic Plan 2008-2013:

- Goal 1: Promoting sound regulatory frameworks (specifically 1.3-review and develop Codex standards and related texts for food labeling and nutrition)
- Goal 2: Promoting widest and consistent application of scientific principles and risk analysis
- Goal 5:Promoting maximum and effective participation of members

6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING DOCUMENTS

A. Adopted Codex provisions that relate to this proposed work include:

Guidelines on Nutrition Labelling (CAC/GL 2-1985)

- Section 3.4.4: Protein NRV
- Annex: General Principles for Establishing NRVs for Vitamins and Mineral for the General Population

Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)

- Section 5: Conditions for protein content claims based on specified percentages of the protein NRV

B. Current CCNSFDU work that relates to this proposed work include:

- Establishment of revised and additional NRVs for other nutrients

7 IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

Expert scientific advice on protein requirements is available through recent and comprehensive reviews by FAO/WHO and other recognized authoritative scientific bodies.

8 IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

None foreseen.

9 PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK

Subject to approval, the proposed time line for completion of the new work is as follows:

December 2012	CCNFSDU endorsement of new work proposal and review of the protein NRV by an electronic working group
2013 CAC	CAC approval of new work
2013 CCNFSDU	CCNFSDU decision to retain protein NRV or propose an amendment; If latter, advance proposed draft amendment to Step 3

If Decision is to Amend:

2014 CCNFSDU	CCNFSDU considers proposed draft amendment at Step 3 and advances proposed amendment to Step 5/8
2014 CAC	CAC adoption of draft amendment at step 5/8