CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net

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PRINCIPLES AND CRITERIA FOR THE DEVELOPMENT OF NRVS FOR LABELLING PURPOSES FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NONCOMMUNICABLE DISEASES AT STEP 4

(Prepared by the United States with the assistance of Thailand and Chile and members of the electronic work group including Australia, Brazil, Canada, European Union, Indonesia, Japan, Malaysia, Mexico, New Zealand, Council for Responsible Nutrition, International Council of Beverages Associations, International Dairy Federation, and the World Sugar Research Organization)

Governments and interested international organizations are invited to submit comments on the above document at Step 3 (see Annex 2) in writing preferably be email to the Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, Fax +39-06-5705-4593, e-mail codex@fao.org with copy to Mr Georg **Müller,** Federal Ministry of Food, Agriculture and Consumer Protection, Rochusstraße 1, 53123 Bonn, Germany, Fax: +49 (228) 99 529 49 65, e-mail: ccnfsdu@bmelv.bund.de by **15 October 2010**.

I. BACKGROUND

31st (2009) CCNFSDU Session

1. At the 31st session, the United States and Thailand introduced a report of the physical working group and presented the discussion and recommendations. The report (CRD 1) included two annexes that addressed: 1) proposed draft principles for establishing Nutrient Reference Values for Nutrients Associated with Risk of Diet-Related Noncommunicable Diseases (NRVs-NCD) for the general population, and 2) a draft Project Document.

2. The Committee noted there was general support to initiate new work to establish NRVs-NCD for the general population and focused its efforts on finalizing the Project Document (ALINORM 10/33/26 para 125-154). The Project Document (ALINORM 10/33/26 Appendix VII) approved by the Commission in July 2010 identifies the relevance of this work to the WHO Global Strategy on Diet, Physical Activity and Health. Specifically, this new work aims to:

a) Establish Codex principles and criteria for the development of NRVs for labelling purposes for nutrients associated with risk of diet-related noncommunicable diseases for the general population aged older than 36 months; and

b) Establish NRVs for selected nutrients based on these principles and criteria.

3. Based on this work, the Committee will propose amendments to the listing of NRVs in Section 3.4.4 of the Codex Guidelines on Nutrition Labelling (hereafter referred to as the "Guidelines"), and include the principles and criteria in an Annex to the Guidelines.

4. In identifying nutrients to review with regard to whether NRVs-NCD should be established, the Project

Document stated that the first priority is nutrients that are referred to CCNFSDU by the CCFL[1]. The second priority is other nutrients that meet the criteria defined in the principles that the Committee establishes.

5. With regard to availability of scientific advice, the Project Document noted that expert scientific advice on diet-related noncommunicable disease is available through recent and comprehensive reviews by WHO/FAO and other recognized authoritative scientific bodies.

6. In a related agenda item, the Commission approved new work in 2008 for the Committee to develop general principles for the establishment of NRVs for vitamins and minerals in the Guidelines, and to revise and expand the vitamin and mineral NRVs in Section 3.4.4 based on these principles (ALINORM 03/31/rep, Appendix X). At its last session, the Committee agreed to forward proposed draft principles for the vitamin and mineral NRVs to the Commission for adoption at Step 5, and to return proposed draft revised and additional vitamin and mineral NRVs to Step 3 for further consideration. Also at the last session, the physical working group that began consideration of principles for establishing NRVs-NCD used the draft principles for the vitamin and mineral NRVs as a starting point. The aim was 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 the NRVs-NCD. Accordingly, this report continues efforts to closely coordinate work on these two sets of general principles for NRVs. In addition, it proposes that the Committee begin thinking about how best to present these two sets of NRVs in Section 3.4.4 of the Guidelines.

7. Additional background on the discussion at the 31st Session can be found in ALINORM 10/33/26, paras 125-154.

Charge and Conduct of the Electronic Working Group

8. At its 31st Session, the CCNFSDU agreed to establish an electronic working group (eWG) chaired by the United States of America (U.S.) and co-chaired by Thailand and Chile. This eWG was charged with preparing a revised document on principles and criteria for the development of Nutrient Reference Values for nutrients associated with risk of diet-related noncommunicable diseases for the general population for circulation at Step 3 and consideration at the next session. It was agreed that the eWG would work in both English and Spanish.

9. In February 2010, an invitation to participate in this eWG was extended to Codex members and observer organizations. Expressions of interest in participating were received from Australia, Belgium, Brazil, Canada, Chile, European Union, France, Ghana, Greece, Indonesia, Ireland, Japan, Latvia, Malaysia, Mexico, Netherlands, New Zealand, South Korea, Thailand, United States, European Committee of Sugar Manufacturers, Council for Responsible Nutrition, International Council of Beverages Associations, International Chewing Gum Association, International Dairy Federation, Institute of Food Technologists, and the World Sugar Research Organisation. In May 2010, a consultation document was circulated to eWG members in both English and Spanish[2] that attached the latest version of the draft principles from the 31st CCNFSDU session **(Annex 1)**, and posed questions about further development of the principles and criteria. It was noted that an interim summary is now available on the conclusions and recommendations from the Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition that was held November 10-14, 2008 in Geneva (http://www.who.int/nutrition/topics/FFA_human_nutrition/en/index.html).

10. Fifteen responses were received from eWG members which form the basis for this report. Given the numerous questions posed to the eWG and number of comments received, a brief summary of the comments to these questions is presented in this report with a *preliminary* response.

11. At the next session, a physical working group chaired by the U.S., Thailand, and Chile will meet immediately before the next session to consider this revised document and the comments received on it (CX/NFSDU 10/32/7-Add.1) with the aim to finalize recommendations for the plenary session.

II. GENERAL COMMENTS

Presentation of General Principles and Revisions to Section 3.4.4

[1] Thus far, the CCFL has referred two nutrients to the CCNFSDU for consideration for NRVS for nutrients associated with risk of diet-related noncommunicable diseases---sodium and saturated fat (ALINORM 09/32/22, para 41).
[2] Appreciation is expressed to Chile for providing the Spanish translation.

12. There continues to be general agreement that the work on NRVs-NCD should be closely coordinated with the work on vitamin and mineral NRVs-NCD. In addition, at least one member government suggested that the Committee consider consolidating the two sets of principles wherever possible.

13. In response to the latter suggestion, we agree that the Committee should keep in mind the potential consolidation of at least some components of the two sets of principles as it continues work on these two topics, and strive for consistent language wherever applicable to facilitate consideration of potential consolidation at a later stage.

14. A member government suggested that the Committee consider as it proceeds in establishing both sets of NRVs:

1. the need for slight revisions to the introductory text in Sec. 3.4.4 in the Guidelines on Nutrition Labelling (CAC/GL 2-1985) so that this section is not limited to NRVs for vitamins and minerals (e.g.,"3.4.4 Numerical information on **nutrients** ~~vitamins and minerals~~ should be expressed…") and
2. whether subheadings and/or additional footnotes intended for governments would help clarify their basis and appropriate use.

15. In addition, an observer commented on the need for clarity in the Guidelines on the definition of an NRV (so that these are not confused with recommended intake values (e.g., INL_{98} values), and for the need to consider how consumers may interpret an expanded set of NRVs that extend beyond reference values aimed at meeting requirements.

16. In response, we note that a current agenda item of the Codex Committee on Food Labelling is to define "Nutrient Reference Values", and that any additional information regarding appropriate presentation of NRV information to the consumer could be considered under Sec. 3.4.4 of the Guidelines.

Terminology

17. One member government was of the view that the word "nutrient" is inappropriate to use as there are other components in food which are associated with risk of NCDs but are not considered as nutrients, as defined in Section 2.5 of *the Guidelines on Nutrition Labelling.* This comment cited *trans*-fatty acid, dietary fiber and sugar as examples. The commenter indicated that the use of the term "Nutrient Reference Value" is inappropriate for the same reason.

18. In response, the use of these terms is consistent with the scope of work approved by the Commission. While it is premature to conclude that any NRVs-NCD will be proposed for the food components identified above as examples since the principles are in development, we believe that the three examples above do meet the definition of "Nutrient" in these Guidelines (e.g., Section 2.5(a)).

III. CONSIDERATION OF REVISIONS TO PRINCIPLES AND CRITERIA FOR THE DEVELOPMENT OF NRVS-NCD

19. At the last session, there was general agreement to organize the principles as follows:

1. PREAMBLE
2. DEFINITION(S)
3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD
   - 3.1 Criteria for Selection of Nutrients
   - 3.2 Selection of Suitable Data Sources to Establish NRVs-NCD
   - 3.3 Selection of Appropriate Basis for Expressing NRVs- NCD

     (or alternatively, "Determining NRVs-NCD")

This organization has been maintained in Annex 2, but with an option to slightly revise the Sec. 3.3 heading to take into consideration the alternative heading above and new proposed text in this section.

20. **Annex 2** presents revised proposals for the principles and criteria based on eWG comments which are identified by bolded text. In this revision, a distinction is made between 1) text for which there was general

agreement at the 31st session, and 2) bracketed text and/or new proposed text which will be the primary focus of discussion at the physical working group meeting.

A summary of comments with preliminary recommendations and issues for discussion at the physical working group meeting are identified below by section.

TITLE

21. The eWG was asked to consider whether the title in Annex 1 should be revised to refer to "DRAFT **GENERAL** PRINCIPLES" and to identify the eventual placement of these principles in the Codex Guidelines on Nutrition Labelling in order to: 1) reflect the placement identified in the Project Document and 2) for consistency with the title of the vitamin and mineral NRV general principles at Step 5.

22. Most comments supported referring to "draft general principles" and identifying the placement of these principles in the Codex Guidelines on Nutrition Labelling. **The title in Annex 2 is revised accordingly.**

SECTION 1. PREAMBLE

NRVs-NCD—Target Population and Abbreviation

23. At the last session, the Committee agreed that these NRVs were for nutrients associated with diet-related noncommunicable diseases for the general population aged older than 36 months (ALINORM 10/33/26, para 133-134). There appeared to be general support in the physical working group to abbreviate these NRVs as "NRVs-NCD" as reflected in the headings of Section 3. The eWG was asked to comment on the removal of brackets from "NRVs-NCD" in the first sentence and third sentence in Annex 1, and on removal of the other brackets in the first sentence to clarify that the NRVs are for the general population identified as individuals older than 36 moths.

24. Most comments supported the removal of all brackets from the text in the preamble. One observer proposed, however, that the reference to "general population" be replaced with "healthy population", since recommended intakes of certain nutrients are different for populations with pre-existing NCDs, and expert committee recommendations used as a basis for estimating NRVs for NCDs usually relate to populations free of pre-existing disease.

25. In response the above comment, we would anticipate widespread agreement that intake recommendations for healthy populations should be the basis for establishing NRVs-NCD. However, clarification about the *nature of the recommendations* of interest would appear more appropriately addressed in Section 3.2 on "Selection of Suitable Data Sources to Establish NRVs-NCD".

26. **Based on all the above comments, in Annex 2 all brackets have been removed from the first sentence and from the abbreviation "NRVs-NCD" throughout the document. In addition, new text to refer to "intake recommendations for healthy populations" is proposed in Sec. 3.2 and discussed with the comments for this section.**

Other Bracketed Text

27. The only other bracketed text in the preamble of Annex 1 was in the second sentence, in which two alternatives have been proposed, "one way" and "a means". Note: In similar text used in the vitamin and mineral NRV general principles, the Committee decided to use the term "one way". Some eWG members preferred "one way" while others preferred "a means". A member organization commented that the impact of the alternative wording was not immediately clear, and three eWG members commented there was no difference or very little difference in their meaning.

28. **Given there appears little or no difference in their meaning and for consistency with the vitamin and mineral NRV general principles at Step 5, the revised text in Annex 2 refers to "one way" and the brackets have been removed so that the Committee can focus on more substantial issues.**

Additional Clarification in Preamble

29. In the May consultation document, it was noted that the third sentence in the preamble could be interpreted by some to indicate only that it is appropriate for governments to establish *different reference values for a nutrient* that has an NRV-NCD, but that it may not be appropriate to establish reference values for *additional nutrients*.

30. The eWG was asked if a sentence should be added to the Preamble to clarify that it may be appropriate for governments to establish additional food label reference values, and about their views on adding the following sentence after the third sentence:

> "In assessing the suitability of these principles and criteria, it is recognized that governments may appropriately establish additional reference values for labelling purposes."

31. Most eWG comments either supported or were not opposed to adding text to the preamble to clarify that it may be appropriate for governments to establish reference values for *additional nutrients*, with some comments supporting the proposed wording above, and others offering alternative wording.

32. One comment did not agree with the proposal to allow governments to establish additional reference values, and stated that this is not in the interest of international standardization and harmonization of labeling as emphasized in Section 3.4.4 of the Codex *Guidelines on Nutrition Labelling.*

33. In response to the latter comment, the revised introductory text to 3.4.4 in the report of the 31st CCNFSDU session (ALINORM 10/33/26) does not contain any text that refers to international standardization and harmonization. Moreover, the preamble for the general principles acknowledges that governments may select to use the NRVs, or alternatively, consider additional factors specific to a country or region in establishing their own nutrient reference values for labelling purposes.

34. **Based on general agreement to add this clarification and alternative suggested wording that would not require a new sentence, the following text is proposed in the third sentence in the Annex 2 preamble:**

> "A government may select to use the NRVs-NCD, or alternatively, consider the suitability of the general principles below and additional factors specific to a country or region in establishing their own reference values for labelling purposes, for these nutrients and for additional nutrients.

35. In addition, in response to one member government's question as to whether the term "NRVs-NCD" is intended to also encompass all food label reference values established by member governments (including but not limited to Codex values), our response is that this term is only intended to refer to Codex values.

Additional Comment on Preamble

36. One member organization proposed to provide in the Preamble an indication of the nutrients/dietary components that the principles are intended to cover to avoid any potential overlap between the NRVs for vitamins and minerals and those concerned with diet-related diseases.

37. In response to identifying specific nutrients in the preamble, it is noted that while specific nutrients may be proposed for consideration of NRVs-NCD (e.g., saturated fat and sodium were previously referred by the CCFL for consideration), it is the Criteria for Selection of Nutrients that focuses on public health importance and level of scientific evidence that the Committee identifies in Sec. 3.1 of these principles that should be the primary determinant of the specific nutrients for NRVs-NCD. Thus, to identify specific nutrients in the preamble in advance of finalizing the criteria on selection of nutrients would not appear appropriate. While an alternative is to consider referencing specific nutrients in the preamble after applying selection criteria, the Committee would need to discuss whether this would be appropriate given that the document concerns general principles, and is intended to apply to consideration of revised or expanded NRVs-NCD in the future.

38. With regard to the reference to "avoiding any potential overlap between NRVs for vitamins and minerals and those concerned with diet-related (noncommunicable) diseases", the Committee may wish to consider at a later stage whether there may be instances where overlap could be possible. For example, the Committee could consider whether it would be appropriate to consider two NRVs for a single nutrient if that nutrient met all criteria in both sets of principles but had substantially different recommended intake values established by recognized authoritative scientific bodies with one based primarily on requirements and the other value also taking into consideration chronic disease risk. For example, the Adequate Intake value for potassium established by the U.S. Institute of Medicine (IOM) of the National Academies of science is higher than certain other recommended intake values that are based primarily on meeting potassium requirements. This is because the IOM value considers the role of potassium from food sources in reducing adverse effects of sodium chloride intake on blood pressure and reducing risk of kidney stones. If any

nutrients met both criteria and the Committee decided to list two NRV values for the same nutrient, a government could then decide which value is most relevant to the public health needs of their population.

39. In addition, the above comments appear applicable to considering how the NRVs are presented in Sec. 3.4.4 of the Guidelines (noting also that provisions in this section encompass both information on presentation of nutrition information to the consumer and additional NRV reference information for governments). For example, one option for distinguishing between NRVs derived from the two sets of principles as a reference for governments is to consider separate subheadings for the listing of: 1) NRVs based on nutrient requirement levels and 2) NRVs based on risk reduction of diet-related noncommunicable diseases. Since the revision of Sec. 3.4.4 is not within the charge of this current eWG, however, it may be more appropriate to address such revisions in the plenary session or a subsequent eWG which explicitly incorporates this topic into its terms of reference.

SECTION 2. DEFINITIONS

NRVs-NCD

40. At the last session's physical working group meeting, there was general support to include the following definition of Nutrient Reference Values-Noncommunicable Diseases (abbreviated as NRVs-NCD):

> **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 [chronic] diseases**.**

However, last year's working group did not reach a conclusion on whether to include the term "chronic" to further clarify the term "noncommunicable".

41. The eWG was asked whether the term "chronic" should be added to the definition.

Several comments supported adding the term "chronic". Reasons included:

- "Noncommunicable chronic disease" is accepted and largely used;
- "Diet-related chronic noncommunicable diseases" is used in WHO publications, including the 2008-2013 Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases;
- To further clarify the nature of the diet-related noncommunicable diseases that are the subject of these NRVs (e.g., cardiovascular disease);
- To clarify that these NRVs do not encompass nutrient deficiency disease;
- To clarify that they are separate from short-term diseases that may be related to foods such as food-borne illness, infections and allergies.

A few comments opposed adding the term. Reasons included:

- The term "Noncommunicable diseases" is globally recognized, especially in WHO and in the Global Strategy, and the term "chronic" is not used in the Global Strategy on Diet, Physical Activity and Health;
- "Chronic" adds no additional information;
- Using the term "chronic" may not be appropriate given that NRVs-NCD should ultimately be considered in combination with NRVs for vitamins and minerals.

42. One comment proposed to include in the revised document a reference to the FAO/WHO definitions of at least 1) "chronic diseases" and 2) "non-communicable diseases" so that the scope of the principles would be clear that these NRVs will not cover vitamins and minerals and that the focus should be on nutrients that are consumed in excess. The comment did not identify the FAO/WHO definitions for consideration, or elaborate on how the FAO/WHO definitions would pertain to the scope of this work.

43. Another comment suggested not inserting "chronic" but clarifying disease exclusions with the following suggested edits:

> "Nutrient Reference Values – Noncommunicable Disease (NRVs-NCD) refer to Codex nutrient reference values….for nutrients that are associated with risk of diet-related noncommunicable diseases not including nutrient deficiency diseases.

44. **Given the majority of comments supported further clarifying the nature of diet-related noncommunicable diseases that are the subject of these NRVs with the addition of the term "chronic" or additional wording, it is proposed in Annex 2 that "chronic" be retained along with additional clarification that the diet-related chronic non-communicable diseases exclude nutrient deficiency diseases. The proposal to reference or include a definition for "noncommunicable disease" is discussed later in this document.**

45**.** One member government proposed adding the following text as a separate provision under Section 3.3: "The NRV-NCD represents the nutrient recommendations for the general population". In response, the physical working group may wish to consider whether to include this text in the Annex, and if so the most appropriate placement. Our preliminary recommendation is to consider whether this text should be added to the definition of "NRVs-NCD". **Accordingly the proposed text is included with the definition of NRV-NCD in Section 2 for consideration.**

Additional Terms

Nutrient Reference Values (NRVs)

46. At the last session's physical working group meeting, two delegations suggested using only one term, "NRVs", on the food label, while recognizing the value in retaining the term "NRVs-NCD" for use in the general principles for deriving these NRVs (CRD 1). In the plenary, the Committee agreed to recommend that the CCFL establish a definition for NRVs (as an overarching term applicable to vitamin and mineral NRVs and NRVs-NCD). It also agreed to forward to the CCFL the following proposed definition for consideration, *"Nutrient Reference Values are (a) set of numerical values established for purposes of nutrition labelling"*, and to recommend that the CCFL consider the following additions to the definition, *"and are based on scientific data on nutrient requirements"* and "*and/or nutrient levels associated with risk of diet-related noncommunicable diseases"* (ALINORM 10/33/26, para 147-148). One delegation noted that the definition of NRVs could be inserted in the definition section of the Codex Guidelines on Nutrition Labelling (ALINORM 10/33/26, para 145).

47. The eWG was asked to comment on whether a definition of "NRVs" should be included in these general principles in addition to the definition of "NRVs-NCD". The majority of comments did not believe it necessary to repeat the definition of "NRVs" in this Annex if it is to be included in the definition section of the Guidelines on Nutrition Labelling, but supported the inclusion of subsidiary definitions related to type of NRVs in the Annex (i.e., NRVs-NCD). **Accordingly, a definition of "NRV" is not proposed to be included in Annex 2 in addition to the subsidiary definition of NRV-NCD.**

Need for Definition(s) for Types of Values to Be Used to Establish NRVs-NCD

48. At the last session, the physical working group discussed whether to add a draft principle about upper levels of intake. Three delegations and the representative from WHO expressed support for including a principle on upper levels of intake, noting among other things, that this may be important for some nutrients such as sodium where there is both a requirement and a concern regarding excessive intake (CRD 1). Two observers commented that this addition seemed redundant (CRD 1), and at the plenary session, a member organization indicated that no agreement had been reached in the working group on inclusion of the concept of upper levels and asked for clarification on how the upper levels would be taken into account (ALINORM 10/33/26, para 131).

49. The May 2010 consultation document noted that if the committee decides to include a definition of "upper level of intake" in these draft principles that the following definition from the nutritional risk analysis principles in the Codex procedural manual could be considered, and that a slightly modified version is included in the draft principles for the vitamin and mineral NRVs (with the deletion of "or related substance").

> "**Upper Level of Intake** refers to 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."

50. In a related update, the recently posted interim summary of the Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition uses the following terms and *descriptions* that are related to upper level intakes:

- **Upper Level (UL)**; "This term was developed for instances where biochemical indicators are needed to confirm any adverse effects, measurable with a probability of occurrence. In the case of fatty acids, this only applied to *trans* fatty acids."
- **Upper Level of Acceptable Macronutrient Distribution Range (U-AMDR)**; Similar to the use of the upper bound of confidence intervals (UCI).

51. Additional terms used in the 2008 FAO/WHO Interim Summary to identify recommended dietary intakes for fats and fatty acids include:

- Adequate Intake (AI);
- Estimated Average Requirement (EAR);
- Acceptable Macronutrient Distribution Range (AMDR);
- Lower Level of Acceptable Macronutrient Distribution Range (L-AMDR).

52. Moreover, at the 31st CCNFSDU session, one or more delegations suggested defining the following additional terms as they relate to types of values to use in establishing NRVs-NCD:

- "daily intake reference value";
- "maximum nutrient level";
- "individual nutrient level".

53. The eWG was asked whether any terms relating to upper levels of intake should be defined in these draft principles, and about the need to define other terms.

Several comments supported defining Upper Level of Intake (UL) in these principles, with the majority favoring the definition in the Codex Procedural Manual. Reasons included:

- The importance of the UL for certain nutrients such as sodium where both a requirement and upper level have been established;
- The incorporation of the concept of scientific risk assessment in the Codex definition of the UL;
- Its usefulness in assessing whether there are any age-gender groups that might be adversely effected when setting NRVs-NCD;
- A definition may be needed to accompany any proposed principles that relate to Upper Levels of Intake;
- Support for its inclusion by three delegations and the WHO representative at the last session.

Other comments either opposed or were not convinced there was a need to define Upper Level of Intake. Reasons included:

- The question of whether definitions are required will depend on the final content of the document and can be reconsidered at a later stage;
- A principle referring to Upper Levels (for younger groups) is not needed for NRVs-NCD (based on older groups);
- It does not appear necessary, and if needed, the definition in the Codex nutritional risk analysis principles could be cited; instead a definition of "daily intake reference value" could be provided;
- One member was of the view that the scientific data to establish upper levels for many of these "nutrients' associated with NCDs are not sufficient or inconclusive at this time.

54. Based on these comments and considering also that sodium is one of two nutrients referred to the CCNFSDU for consideration of an "NRV-NCD", it would appear appropriate for the Committee to consider the need to include or refer to a definition of Upper Level of Intake as it continues it work, and to keep in

mind the support of several comments for the definition in the Codex procedural manual. **Accordingly, we have placed the Codex definition of Upper Level of Intake in brackets in the definition section of Annex 2, considering also a comment that the need for definitions that pertain to the type of values used to establish NRVs-NCD may depend on their use in these Principles.**

55. It is recognized that upper levels of intake that are established by recognized authoritative scientific bodies may be derived in different ways, and thus important for the Committee to understand the bases for these values. Likewise, it is possible that definitions for certain other terms (e.g., Upper Level of Acceptable Macronutrient Distribution Range) may vary among recognized authoritative scientific bodies, and again important to understand how such values were derived if proposed as a basis for an NRV-NCD.

56. Whereas it may not be appropriate at this stage to propose definitions for all the *specific* types of values that may be used to establish NRVs-NCD, we propose that the Committee consider defining the term "Daily Intake Reference Value" as an overarching term to refer to different types of values that may be considered in establishing NRVs-NCD, and as suggested by one member government since the term appears several times in the document and may not be clear to all.

57. The draft definition below takes into consideration wording proposed in the comment:

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

Note: Whereas the definition proposed in the comment incorporated additional criteria that would be applicable to selecting the most relevant daily intake values (e.g., values reflecting recommendations for healthy populations), we suggest that a reference to recommendations for healthy populations be incorporated as a criterion for selecting suitable values in Sec. 3.2 and the proposed wording above refer to the Sec. 3 principles and criteria in order to encompass all relevant criteria.

58. **Accordingly, the above draft definition has been added in square brackets to Annex 2 for the physical working group to consider.**

Need to Define Additional Terms

59. At the last session, there was a suggestion to define "noncommunicable disease" which was again proposed in eWG comments.

60. In response, given the additional clarification in the definition of NRVs-NCD that these reference values for food labelling purposes are for nutrients that are associated with a *subset* of noncommunicable diseases, it may not be necessary or appropriate to define "noncommunicable disease" in these principles. Moreover, it appears that the Global Strategy for Diet, Physical Activity and Health only provides examples of major noncommunicable diseases (e.g., cardiovascular disease, type 2 diabetes and certain types of cancer), but did not define the term.

61. In addition, another comment proposed including the following definition for "general population":

> "General population means a national population older than 36 months".

In response, we note that the first sentence of the preamble states that these principles apply to the establishment….of NRVs-NCD….for the general population identified as individuals older than 36 months.

62. **Thus, we have not proposed to include definitions for these or other terms in Annex 2. The Committee may wish to further consider the need for additional definitions as it proceeds in its work.**

SECTION 3. GENERAL PRINCIPLES FOR ESTABLISHING NRVS-NCD

3.1 CRITERIA FOR SELECTION OF NUTRIENTS

63. At the last session, there were different views on appropriate terms to use to characterize the required strength of the scientific evidence (in the first and third bullet in Section 3.1); whether the evidence should be characterized as "strong", "generally accepted", "convincing or probable" or some other term (CRD 1). One delegation did not agree with characterizing the evidence as "generally accepted", expressing concern that

there could be confusion about what "generally accepted" means. Another delegation expressed concern that characterizing the evidence as "convincing or probable" could have enormous impact on a number of issues including food label claims. After some discussion, it was agreed to retain the three draft criteria in Sec. 3.1 but to identify alternative wording for further consideration by the Committee.

64. In a related update, the experts who participated in the 2008 Joint FAO/WHO expert consultation on fats and fatty acids agreed to use the criteria from the report, *Diet, Nutrition, and the Prevention of Chronic Diseases; Report of a Joint WHO/FAO Expert Consultation* (WHO TRS 916, Geneva 2003), to judge the levels and strength of the evidence required to conclude that fat and fatty acids affect major health and disease outcomes. The four levels of judgment were: 1) Convincing, 2) Probable, 3) Possible, and 4) Insufficient. They also acknowledged other equally valid criteria that exist.

1) The criterion for "convincing evidence" is:

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

2) The criterion for "probable evidence" is:

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

65. The eWG was asked to comment on the term(s) to use to describe the level of scientific evidence in the first and third bullets in Section 3.1. Moreover, it was noted that some may regard "convincing evidence" and "strong evidence" as comparable terms based on the review of the criterion for "convincing evidence". Thus, the eWG was asked to consider whether the level of scientific evidence needed to establish an NRV-NCD for a nutrient should be limited to "convincing evidence", rather than to "convincing or probable" evidence.

Sec. 3.1 (1st Bullet)

66. With regard to options in brackets for describing the strength of the evidence for the nutrient-noncommunicable disease risk relationship, different views were expressed on preferred terminology with five member governments and three observers supporting "convincing" or "strong"; four member governments supporting "convincing or probable" or "at least probable"; and one member organization supporting "generally accepted". The comment that supported "generally accepted" indicated that this wording is in line with existing Codex texts. However, it did not provide citations for these Codex texts initially, but in the review of the final draft report, the commenter indicated that the term is used in Section 7 of the Codex *Guidelines on the Use of Nutrition and Health Claims.* This comment also noted that macronutrients are an integral part of ingredients in foods, and therefore difficult to treat in isolation, so that the overall balance of the diet would need to be considered.

67. In response to the comment that preferred "generally accepted", we are not aware of any existing Codex provisions that use "generally accepted" in the context of defining and describing the ***strength*** of the scientific evidence for a nutrient-noncommunicable disease relationship which is the subject of the first bullet in 3.1. Moreover, taking into consideration one delegation's comment at the last session that there could be confusion about what "generally accepted" means, it would be helpful to have further clarification on the criteria behind "generally accepted" as is provided with the FAO/WHO terminology, and whether the "generally accepted" terminology would more closely approximate the criterion for "convincing", or alternatively, for "probable or convincing".

68. In response to comments that supported characterizing the strength of the evidence as "probable or convincing" or "at least probable", it is possible that some (but not all) member governments have an interest in providing food label reference values for nutrients for which the strength of the scientific evidence for a

nutrient-disease relationship is "probable", in addition to providing values for nutrients where the evidence is "convincing". Consequently, the Committee would have to find agreement, which may be more difficult, on certain values that are based only on a "probable" relationship. In addition, the new proposed text in the preamble in Annex II of these general principles would make it explicit that governments can establish *additional* food label reference values. Another rationale for proposing "at least probable" in the comments could be to encompass additional macronutrients for which member governments currently have food label reference values (e.g., total fat) and which are identified as nutrients to always be declared in the Codex *Guidelines for Nutrition Labelling*, which may not be based on convincing evidence for a nutrient-noncommunicable disease relationship, but rather on other criteria such as overall balance of macronutrients in the diet. We believe these other criteria fall outside of the scope of work and principles to establish NRVs-NCD.

69. In response to comments that supported characterizing the level of scientific evidence in the first bullet as "convincing" and/or "strong", we propose that the Committee further consider "convincing" since this term is used by FAO/WHO and appears comparable to the term "strong".

70. **Based on the above comments, it would appear preferable to use FAO/WHO terminology to characterize the level of scientific evidence in the first bullet. The preliminary recommendation is to consider using the term "convincing". However, we have also retained the FAO/WHO term "or probable" as well as the term "generally accepted" in brackets for further discussion at the physical working group meeting.**

71. One or more eWG comments suggested inserting text to refer to "relevant peer-reviewed scientific evidence" or "relevant available scientific evidence. **In Annex 2, we have retained these suggestions in brackets for further discussion.**

72. In addition, one comment suggested reordering bullet one and two. In response, this can be considered at the physical working group meeting, but no change was made as all three criteria might be considered together.

Sec. 3.1 (2nd Bullet)

73. One comment asked for clarification as to whether the intended meaning of the second bullet is that a Codex NRV would only be proposed if (the nutrient-noncomunicable disease risk relationship) is of public health importance for a significant proportion of member countries. In response, that is our understanding of the intent, since the preamble acknowledges that governments can establish additional food label reference values.

Sec. 3.1 (3rd Bullet)

74. Different points of view were expressed on how to characterize the level of scientific evidence in the third bullet, with the following terms most comments suggesting one of the following terms: "strong", "convincing", or "convincing or probable" . In addition, two comments were of the view that the third principle should not be included with one indicating that it would not necessarily be applicable or possible for all nutrients, and the other commenting that that they were not aware of possible source documents assigning strength of evidence to a specific numeric value.

75. In response, we believe the third principle is important to include as a criterion for establishing an NRV-NCD and should be applicable to all nutrients considered for NRVs-NCD. While we recognize that source documents may not assign strength of evidence to a specific numeric value, a description of a desired level of evidence for a quantitative reference value for daily intake would still appear to be an appropriate criterion to consider in selecting nutrients for NRVs-NCD. **Accordingly, we have retained the third criterion in Annex 2.**

76. In addition, FAO/WHO terminology is proposed in the third bullet to describe the level of evidence, noting again that "convincing" appears to be a term that is comparable to 'strong". **Specifically, Annex 2 identifies three options for further discussion based on eWG comments: 1) "convincing" only; 2) "convincing or probable" and 3) "probable" only.**

77. As with the first bullet, one comment suggested inserting text to refer to "relevant peer-reviewed scientific evidence". **In Annex 2, we have retained this suggestion in brackets for further discussion.**

78. **In addition, Annex 2 includes a proposal to delete the phrase "of Codex member" countries in the thirst bullet as it does not appear necessary.**

CONSIDERATION OF SUBSTITUTION EFFECTS

79. The eWG was asked if the Committee should consider an NRV-NCD for a nutrient if its main effect is based on substituting for another nutrient in the diet. As an example, it was noted that in the FAO/WHO interim summary on fats and fatty acids, the experts identified the level of evidence for monounsaturated fatty acids based on its effect when substituting for saturated fatty acids. An additional question was posed as to whether it would be appropriate to clarify in any final Codex provisions that the nature of the evidence is for a substitution effect.

80. One comment noted that a substitution effect would be applicable to energy-contributing macronutrients. While a majority of comments appeared to support considering an NRV-NCD if its main effect is based on substituting for another nutrient in the diet and the nutrient met other criteria for an NRV-NCD, one observer did not agree stating that including substitution effects is based on assumptions on substitution patterns which includes uncertainty. Another observer suggested clarifying in the Guidelines that the NRV should only be used when an expected substitution is highly likely, and raised the issue of potential inappropriate substitutions of macronutrients. Comments appeared divided on whether there was a need to clarify the *nature* of the substitution effect in the Guidelines on Nutrition Labelling (e.g., in Section 3.4.4).

81. **In response, the Committee may wish to further consider whether the issue of a main effect being based on substitution of another nutrient should be addressed in some way in these General Principles and/or Section 3.4.4 of the Guidelines.**

3.2 SELECTION OF SUITABLE DATA SOURCES TO ESTABLISH NRVS-NCD

82. The Committee was asked to comment on whether the same principles apply for selection of suitable data sources to establish NRVs-NCD as for vitamin-mineral NRVs, and invited to suggest any additional edits to 3.2.

83. The majority of comments agreed that the same principles should apply, and to align the two sets of principles. **Accordingly, the text in Annex 2 was slightly revised and reformatted to align with Section 3A in the Proposed Draft General Principles for Establishing NRVs for Vitamins and Minerals at Step 5 (ALINORM 10/33/26, Appendix II). As part of this alignment and in response to eWG comments, it was clarified in 3.2.1 that FAO/WHO should be taken into consideration as primary sources in establishing NRVs-NCD.**

84. **Moreover, in response to earlier comments that proposed clarifying that the daily intake values used to establish NRVs-NCD should reflect intake recommendations for healthy populations, a new sentence is proposed in 3.2.1 to provide this clarification.**

85. **In response to comments, 3.2.2 has been slightly revised to clarify that higher priority should be given, as appropriate to values that have been based on a systematic review of the scientific evidence, *regardless of whether there is "substantial new evidence"*. Moreover, the reference to "recent" values was removed since it does not appear necessary since the provisions in 3.2.1 refer to recent values.**

86. With regard to FAO/WHO reference values, one member government suggested amendments to the text in 3.2 that would identify criteria for when FAO/WHO daily intake reference values would not be appropriate to use and when alternative values from recognized authoritative scientific bodies could be considered. **This proposal can be further discussed at the physical working group, including consideration of whether it is possible to identify a comprehensive list of criteria that would apply in all situations.**

3.3 SELECTION OF APPROPRIATE BASIS FOR EXPRESSING NRVS-NCD

87. The eWG was asked whether to retain 3.3.3 with its associated text as a separate section or to include the text as a subsection of 3.3.2.

88. Comments were divided on whether to retain 3.3.3 as a separate section or to include it as a subsection of 3.3.2. **Accordingly, we have retained it as a separate section for further discussion at the physical working group as needed.**

89. In addition, another comment proposed keeping these sections separate but changing 3.3.2 to 3.3.1 to first identify the point(s) relating to the source documents followed by point(s) on how an NRV-NCD is derived or expressed. **The latter proposal may be a more logical presentation, and thus the reordering of 3.3.1 and 3.3.2 is proposed in Annex 2.**

90. With regard to 3.3.3, two comments proposed slight edits to clarify that "the single NRV-NCD should be expressed in grams or milligrams….". **This edit is proposed in Annex 2.**

91. In addition, two comments were of the view that the second sentence in 3.3.4 that acknowledges that governments can establish a food label reference value "based on another reference energy intake that considers factors specific to their country or region" was not necessary, with one comment stating it is redundant with text in the preamble. **The proposal to delete this text can be discussed at the physical working group.**

92. One comment proposed adding the following new provision in Section 3.3 that relates to the determination of NRVs-NCD:

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

93. In response, a slightly modified version of this proposal is included in new 3.3.4 for the Committee to consider, which also acknowledges that the daily intake reference value(s) may be for the general population.

94. The eWG was asked whether the heading for Section 3.3 should be retained which uses similar wording as the vitamin and mineral NRV general principles, or whether it should be replaced with the heading, "Determining NRVs-NCD" as suggested by one delegation at the last session.

95. The majority of comments appeared to support retaining the heading of "Selection of Appropriate Basis for Expressing NRVs-NCD. With the proposal to add a provision in 3.3 that is related to the determination of NRVs-NCD, however, **it is proposed in Annex 2 that the physical working group consider referring to both the determination and expression of NRVs-NCD in the Section 3.3 heading.**

NEED FOR ADDITIONAL PRINCIPLE(S) RELATED TO UPPER LEVELS

96. At the last session, there was some support for including a principle on upper levels of intake, noting among other things, that this may be important for some nutrients such as sodium where there is both a requirement and a concern regarding excessive intake (CRD1). It was also noted that there is a principle that addresses consideration of upper levels of intake in the draft general principles for vitamin and mineral NRVs.

97. Some eWG comments supported including a principle related to Upper Levels of Intake and/or Upper Level of Acceptable Macronutrient Distribution Range. Other comments did not support adding a principle. Accordingly, the following draft text for a principle that takes into consideration the wording in the vitamin and mineral NRV general principles is included in square brackets in Annex 2 for the physical working group to further consider.

> *New Sec.3.4* **Consideration of Daily Reference Intake Values for Upper Levels**
>
> The establishment of general population NRVs-NCDs should take into account daily intake reference values for upper levels established by recognized authoritative bodies where applicable (e.g., Upper Level of Intake).

OTHER SUGGESTED TEXT FOR THE ANNEX

98. At the last session, one Codex member suggested adding the following sentence to Section 3.3 as identified in parentheses at the end of Annex 1:

> "For daily intake reference values expressed in absolute amounts for each nutrient, the NRV should be based on the mean for the general population."

The eWG was asked to comment on the need to include the above principle or any additional principles in Section 3.

99. A number of comments stated that that the intent of this proposed sentence was unclear and did not support its inclusion as written. However, certain comments supported consideration of a principle about

the method of calculating an NRV-NCD, and considering whether the concept of "a chosen reference population" which is included in the vitamin and mineral NRV general principles is applicable to the determination of NRVs-NCD.

100. **In response, the physical working group can further consider the need for any additional principles related to the basis of NRVs-NCD, considering also the new proposed text in 3.3.4.**

Annex 1

*Note: Below is the **November 4 2009** version of the draft principles that the eWG used as a **starting point** for its work to further elaborate these principles. We provide this as a reference to compare with the revised draft in Annex 2 since these draft principles were not included as an appendix in the 31st CCNFSDU session report, and for the Codex members and observers who did not participate in the eWG.*

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

1. PREAMBLE

These principles apply to the establishment of Codex Nutrient Reference Values for labelling purposes for nutrients associated with risk of *(noncommunicable diseases NRVs-NCD) (for the general population identified as 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 *(a means/one way)* to compare the nutrient content between products. A government may select to use the *(NRVs-NCD)*, or alternatively, consider the suitability of the general principles below and additional factors specific to a country or region in establishing their own reference values for labelling purposes. Governments may also consider whether to establish separate food label reference values for specific segments of the general population.

2. DEFINITION(S)[3]

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 (chronic) diseases**.**

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 Criteria for Selection of Nutrients

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

- (Strong) / (Generally accepted) and relevant (Convincing or probable)/ (Available) scientific evidence for the nutrient-noncommunicable disease risk relationship
- Public health importance of the nutrient-noncommunicable disease risk relationship among Codex member countries
- (Strong) / (Convincing or probable) and relevant scientific evidence for a quantitative reference value for daily intake that is applicable to the general population older than 36 months of Codex member countries.

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

3.2.1 Relevant and recent daily intake reference values provided by FAO/WHO should be taken into consideration in establishing NRVs-NCD. Relevant and recent values from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration.

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

- The sources should reflect independent review of the science by recognized authoritative scientific bodies;
- Higher priority should be given, as appropriate, to more recent values from recognized authoritative scientific bodies provided that there is substantial new evidence that has been evaluated through a systematic review.

[3] At the 31st CCNFSDU session, one or more Codex members suggested considering definitions for the following terms: “NRVs”, “daily intake reference value”, “general population”, “special needs”, “noncommunicable disease”, “risk”, “upper level of intake”, “maximum nutrient level”, “daily intake reference value” and “individual nutrient level”.

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

(Or: Determining NRVs-NCD)

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

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

3.3.3 (? or subsection to 3.3.2?) Where a daily intake reference value is based on a percentage energy intake, the single NRV-NCD should be in grams or milligrams based on a reference intake for the general population of 2000 kilocalories/8370 kilojoules.

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

Additional proposed text by one delegation:

(For daily intake reference values expressed in absolute amounts for each nutrients, the NRV should be based on the mean for the general population.)

Annex 2

*Note: Below is the **updated** version of the draft principles that takes into consideration eWG comments and that serve as the basis for further elaboration by the physical working group at the 32nd session. New recommendations within each section are identified by underlined text.*

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

(At Step 3 of the Procedure)

1. PREAMBLE

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

2. DEFINITION(S)

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

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

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

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD

3.1 Criteria for Selection of Nutrients

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

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

3.2 Selection of Suitable Data Sources to Establish NRVs-NCD

3.2.1 Relevant and recent daily intake reference values provided by FAO/WHO should be taken into consideration **as primary sources** in establishing NRVs-NCD. Relevant and recent values **that reflect independent review of the science,** from recognized authoritative scientific bodies other than FAO/WHO

could also be taken into consideration. **These values should reflect intake recommendations for healthy populations.**

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

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

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

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

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

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

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

[3.4 Consideration of Daily Intake Values for Upper Levels

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