CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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**Agenda Item 2** **CX/FL 13/41/2-Rev1**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON FOOD LABELLING**

**Forty-First Session**

**Charlottetown, Prince Edward Island, Canada, 14 - 17 May 2013**

**Matters referred to the Committee**

## A. Matters referred from the 35th Session of the Codex Alimentarius Commission

1. The texts that had been forwarded by the last session of the Committee to the Commission were adopted at Steps 8, 5A and 5, respectively, with the following discussion[1]:

***Draft Revision of the Guidelines on Nutrition Labelling (CAC/GL 2-1985) concerning a new definition of "nutrient reference values"***[2]

2. The Delegation of Malaysia, while not opposing the adoption of the new definition on "nutrient reference values", entered a reservation on the inclusion of the sentence "or with the reduction in the risk of diet-related non-communicable diseases".

3. The Commission adopted the definition as proposed by the CCFL, noting the reservation from Malaysia.

***Proposed Draft Revision of the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) concerning a new definition for "non-addition claim", conditions for free of salt claims, amendments to the section on comparative claims and conditions for non-addition of sugars claims***[3]

4. The Delegation of Malaysia reiterated their position that they did not support the addition of Section 6.4 on comparative claims for trans-fatty acids associated with saturated fatty-acids content. They maintained that any claims for trans-fatty acids should not be associated with saturated fatty acids or vice versa as these fatty acid components were not comparable in their definitions and their effects on health.

5. The Delegation of Malaysia also sought clarification on the status of Section 6.3 on comparative claims. They recalled that the CCFL had agreed to request advice from the CCNFSDU whether the condition for 10% of the NRV for comparative claims for micronutrient was still in line with current evidence-based guidance on micronutrients, particularly in light of the work being undertaken on NRVs The Delegation sought the Commission's advice on whether the procedure allowed to adopt this Section at Step 5/8 before receiving the advice from CCNFSDU.

6. The Delegation of Canada, speaking as Chair of the CCFL, noted there had been no support for the position of Malaysia on 6.4 in the Committee. Concerning the question on 6.3 he clarified that the revision proposed by the CCFL related to the fact that sodium had been explicitly included under the comparisons with a relative difference of 25%, however, no change to the existing text had been proposed to the part on micronutrients. If the advice of the CCNFSDU would eventually result in a change, this was not related to the present work but a separate amendment.

7. The Commission adopted the revision as proposed by the CCFL at steps 5/8 noting the reservations from Malaysia on 6.3 and 6.4.

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1 REP12/CAC Appendix III and Appendix IV
2 REP12/CAC paras 59 – 60
3 REP12/CAC paras 61 – 64

***Proposed/Draft amendment to the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999): use of ethylene for ripening of fruit (Step 8) and inclusion of new substances (Step 5A)***[4]

8. Some delegations commented that the use of ethylene in organic production should be re-examined in light of new findings on the risks to operators and other concerns. The Delegation of Egypt also mentioned that the use of ethylene for inhibiting sprouting in onions and potatoes should require special attention.

9. The Commission adopted the proposed draft/draft amendments at Steps 8 and 5A respectively and noted that further concerns on risks of ethylene could be addressed in the CCFL. The Commission noting also that the use of ethylene as sprouting inhibitor was still under discussion in the CCFL.

## B. Matters referred from other committees

### Committee on Fish and Fishery Products (CCFFP)

***Organic Aquaculture***[5]

10. The Committee considered a proposal of Norway as presented in CRD19 to request CCFL to consider in its work on organic aquaculture, the Code of Practice for Fish and Fishery Products, amongst others, to avoid duplication of work. The Secretariat clarified that the work on organic aquaculture was specifically focused on the requirements for organic production and that no duplication of work was foreseen. The Secretariat further indicated that the document was still under development at Step 2/3 and would be considered by the next session of CCFL in 2013, whereafter it would be sent to the CCFFP for information and/or comments. The Secretariat also stressed the need for coordination at the national level when considering the matter in CCFL.

11. In view of the concerns expressed, the Committee agreed to request CCFL to take into account the Code of Practice for Fish and Fishery Products, if relevant.

12. This matter will be considered under Agenda Item 5b.

### Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

***Comparative Claims***[6]

13. With regard to the request from CCFL about the condition for 10% of the NRV for comparative claims for micronutrients, the Committee clarified that 10% was the result of a pragmatic approach, rather than based on scientific evidence.

14. Some delegations were of the view that Section 6.3 in the Standard was confusing because the sentence included both macronutrients and micronutrients and suggested that the text should be made clearer.

15. Some delegations suggested that the increase in micronutrients should be based on the content of micronutrients between the compared foods as the requirement to base the comparison of increased micronutrients using the difference in NRV would complicate the implementation of this requirement and enforcement and for consistency with Section 6.3. Several delegations did not support the opinion as they used the current provisions for comparative claims for implementation purposes. Some delegations said that comparison should be based on substantial difference and that a 10% difference in micronutrient contents was too small.

16. One delegation considered that there was an inconsistency between the requirement for an absolute difference in nutrient content of 10% and the value for the claim for “source” of 15% of NRV per 100 g for vitamins and minerals. It was also suggested to use as the absolute minimum difference the value for “source” in the case of micronutrients as increased levels should be different versions of the same food or similar foods, which did not take into account fortification in the case of vitamins and minerals and proposed as an alternative solution to increase the relative difference to 25%.

17. The Committee noted that there were different views on possible approaches and at this stage it was not possible to go into further detail but that CCFL should clarify the text.

***Claim for “free” of trans fatty acids***[7]

18. The Committee recalled that CCFL had asked the Committee to provide advice on the establishment of conditions for claims for “free” of trans fatty acids.

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4 REP12/CAC paras 65 – 66
5 REP13/FFP paras 7 – 8
6 REP13/NFSDU paras 5 – 9
7 REP13/NFSDU paras 10 – 15

19. Some delegations supported the establishment of conditions for claims on free of trans fatty acids. One delegation proposed two different levels for fats and oils and fat emulsions and for ready-to-eat or other foods and did not support the claims for trans fatty acids associated with the levels of saturated fatty acids. Other delegations were of the view that the criteria associated with the levels of saturated fatty acids should be developed as in some products reducing trans fatty acid levels resulted in increasing saturated fatty acid levels.

20. Some delegations supported that the claims should be based on servings when serving size is regulated as this provides an important tool for consumers. Other delegations were of the view that the expression "per serving" was not appropriate because serving size might be misleading for consumers, especially in case the serving size was not regulated.

21. It was noted that the term "free" might be interpreted differently in each country.

22. One delegation expressed the view that trans fatty acids were of concern only in some countries, considering the previous discussion in CCFL and footnote in the Guidelines on Nutrition Labelling.

23. The Committee noted that CCFL had not concluded whether it would establish such a claim. The Committee therefore agreed that it would consider the conditions after CCFL concludes to establish the claim after considering the global importance of trans fatty acids.

**Principles for the Development and Review of NRVs for Labelling Purposes for Nutrients Associated with Risk of Diet-Related Non-Communicable Diseases**

Definitions of NRVs-R and NRVs-NCD (Section 2.6)[8]

24. CCNFSDU agreed to take Option 2, which was to propose to CCFL that the new definition of NRVs for inclusion in Section 2 of the Guidelines on Nutrition Labelling be revised, with replacement in the definition of Nutrient Reference Values of "include" with "comprise" to clarify that there are only two types of NRVs.

25. The Committee is invited to consider the proposal of CCNFSDU to amend definition (See Section 2.6 of Annex I)

Section 3.4.4 of the Guidelines on Nutrition Labelling[9]

26. CCNFSDU considered the proposal of the eWG to amend Section 3.4.4 of the Guidelines that relate to the listing of NRVs. The Committee agreed with the following amendments in addition to editorial and consequential amendments.

27. CCNFSDU agreed to replace "achieve overall healthful dietary intake" with "make choices that contribute to an overall…" in the third paragraph for consistency and remove square brackets in the fourth paragraph. The Committee also agreed to insert footnotes to saturated fatty acid and sodium with appropriate reference.

28. The Committee is invited to consider the proposal. (See Section 3.4.4 of Annex I)

Consolidation of the General Principles for Establishing NRVs of Vitamins and Minerals and General Principles for Establishing NRV-NCD[10]

29. CCNFSDU agreed to forward the consolidated text for consideration by the 41st Session of CCFL and to the 36th Session of the Commission for adoption.

30. The Committee is invited to consider the text (See Annex II).

**Committee on Methods of Analysis and Sampling (CCMAS)**

***Methods of Analysis for trans fatty acids (TFA)[11]***

31. One delegation informed the Committee that the work of NUGAG to review the definition of trans fatty acid was in progress and was of the view that the Committee should consider this matter after the review by NUGAG concluded.

32. The observer of IDF informed the Committee that IDF and ISO were developing a method for fatty acids, including TFA, for milk products, infant formulae and adult nutritionals. The method is expected to be published in 2014 and will also be published by AOAC.

33. The observer of AOCS noted that they had developed AOCS Ce 1J-07 for trans fatty acids and that collaborative study of the method for complex matrix was ongoing.

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8 REP13/NFSDU para 56, Appendix VI
9 REP13/NFSDU paras 67 – 69, Appendix VI
10 REP13/NFSDU para. 59, Appendix IV
11 REP13/MAS paras 10 - 13

34. Taking into account the information above, the Committee agreed not to endorse any new method for trans fatty acid at this session.

**FAO/WHO Coordinating Committee for the Near East (CCNEA)**

***Discussion Paper on a Standard for Halal Food***[12]

35. At the 7th Session of the Committee the delegation of Egypt introduced a discussion paper outlining first the growing trade volume of halal products world wide due to several factors i.e. that the number of Muslims is growing and the term "halal food products" is no longer restricted to meat from animals slaughtered in accordance with Islamic law, but has come to include numerous other products as well. They also outlined current efforts on standardization done by the Organization of Islamic Cooperation, that has 57 member States on four continents and has in 2009 approved final drafts of three fundamental documents in the domain of halal food products, namely: OIC Standard – general guidelines on halal foods, Guidelines for bodies providing halal certification, and Guidelines for the authorized accreditation body accrediting halal certification bodies. They reported also of other efforts for harmonization in addition to many existing national regulations for halal foods and considered that it is essential for Codex to develop standards, directives and guidelines for halal food products. This would help lower barriers to intraregional trade among Codex member States, not only at the regional level but also at the international level. They suggested that Codex work should start where OIC work had ended and to use the results of the OIC work.

36. The Representative of WHO/EMRO presented the WHO document on halal, which had been announced at the 6th session of the Committee. He reiterated that the issues related to halal were ethical and religious issues and also related to fair practices in trade and labelling but were not related to food safety. The Representative also was of the opinion that in any discussion on halal, the existing Codex halal guidelines and the Arab halal guidelines 2012-2563 produced by Arab Industry and Standardization should be taken into account.

37. Several delegations reported on their experience with regulating halal foods and supported the general idea for Codex work on halal especially to prevent fraud in this growing market area and said that the existing criteria were not sufficient to ensure this. It was mentioned that what had originally been a religious issue had now also become a promotional label to which consumers attributed a certain quality. It was mentioned that all current international work should be taken into account.

38. The Codex Secretariat recalled that if the existing Codex General Guidelines for the Use of the Term Halal were considered inadequate, a relevant project document should be drafted in accordance with the Codex procedural manual, outlining the need for revision of the guidelines.

39. After some discussion the Committee agreed that the delegation of Egypt taking into account the OIC documents and other relevant documents would prepare a project document for submission to the next session of the Executive Committee of the Codex Alimentarius Commission outlining the gaps in the current General Guidelines for Use of the Term Halal (CAC/GL 24-1997) and the scope for a revision to update them to include any relevant new guidance. When drafting the scope care should be taken that an international consensus could be reached on the issues in question.

[12] REP13/NEA., paras 111 -117

**ANNEX I**

**PROPOSED AMENDMENT TO THE GUIDELINES ON NUTRITION LABELLING (CAC/GL 2-1985)**

**2.6 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 comprise the following two types of NRVs:

**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 for the General Principles for the Establishment of Nutrient Reference Values.

**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~~.[~~13~~] 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 make choices that contribute to an ~~achieve~~ overall healthful dietary intake. ~~in the interests of international standardization and harmonization.~~

[They ~~include~~ comprise two types of NRVs: Nutrient Reference Values-Requirements (NRVs-R) and Nutrient Reference Values – Noncommunicable Disease (NRVs-NCD). [1] ~~]~~

**3.4.4.1 NRVs-R**

To be included later; see results agenda item 5

**3.4.4.2 NRVs-NCD**

| | |
|---|---|
| Saturated fatty acids | 20 g[2,3] |
| Sodium | 2000 mg[3] |

~~[13] 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.~~

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

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

[3] The selection of these nutrients for the establishment of an NRV was based on "convincing evidence" for a relationship with NCD risk as defined in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003.

**ANNEX II**

**PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES ON NUTRITION LABELLING – CONSOLIDATED VERSION:**

**GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR THE GENERAL POPULATION**

## 1. PREAMBLE

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 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 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.

## 2. DEFINITIONS

**2.1 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 general population or to a segment of the population (e.g., recommendations for a specified age range).

**2.2 Individual Nutrient Level 98 ($INL_{98}$)**[14] is the 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.

**2.3 Upper Level of Intake (UL)**[15] is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.

**2.4 Acceptable Macronutrient Distribution Range (AMDR)** is a range of intakes for a particular energy source that is associated with reduced risk of 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

### 3.1 Selection of Suitable Data Sources to Establish NRVs

**3.1.1** 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.

**3.1.2** 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.

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

### 3.2 Selection of Nutrients and Appropriate Basis for NRVs

#### 3.2.1 Selection of Nutrients and Appropriate Basis for NRVs-R

**3.2.1.1** 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

[14] 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).

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

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** The general population NRVs-R should be determined by calculating the mean values for a chosen reference population group older than 36 months. NRVs-R derived by the CCNFSDU are based on the widest applicable age range for each of adult males and females.

**3.2.1.3** For the purpose of establishing these NRVs-R, the values for pregnant and lactating women should be excluded.

### 3.2.2 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[16]/ generally accepted[17] scientific evidence or the comparable level of evidence under the GRADE classification[18] for the relationship between a nutrient and noncommunicable disease risk relationship, including validated biomarkers for the disease risk , for at least one major segment of the population (e.g., adults).
- 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 determine 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 Reference Values for Upper Levels

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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[16] At the time these guiding principles were drafted, the definition and criteria for “convincing evidence” from the following FAO/WHO report were used Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 96. WHO, 2003.

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

[18] WHO’s Guidelines Review Committee. WHO Handbook for guideline development. Geneva, World Health Organization (WHO) , 2012 (http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf).