

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 7

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES Thirtieth Session

Cape Sun Hotel, Cape Town, South Africa  
3 – 7 November 2008

#### ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN CODEX GUIDELINES ON NUTRITION LABELLING AT STEP 3

(Prepared by Republic of Korea with the assistance of FAO, Australia, Brazil, China, European Community, Malaysia, New Zealand, United States of America, CRN, and NHF)

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Principles at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, sixteenth Edition*) preferably by email to: to Dr Rolf Grossklaus, Chairman of the Committee, Bundesinstitut für Risikobewertung (BfR), P.O. Box 33 00 13, 14191 Berlin, Germany; Email: [ccnfsdu@bmelv.bund.de](mailto:ccnfsdu@bmelv.bund.de) (Fax: +49 228 99529 4965), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (fax:+39 06 570 54593; email: [codex@fao.org](mailto:codex@fao.org)) **by 15 October 2008.**

### Background

Section 3.4.4 of the *Codex Guidelines on Nutrition Labelling* provides the list of Nutrient Reference Values (NRVs) for several nutrients for labelling purposes in the interests of international standardization and harmonization. The Principles for Nutrition Labelling included in the Codex Guidelines state that the information supplied should be for the purpose of providing consumers with a suitable profile of nutrients contained in the food and considered to be of nutritional importance and that such information should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health. The Purpose of Guidelines is to ensure that nutrition labelling is effective in providing the consumer with information about a food so that a wise choice of food can be made, in addition to encouraging the use of sound nutrition principles in the formulation of foods, which would benefit public health.

Codex Reference Recommended Daily Allowances were first introduced in 1985 and were renamed Nutrient Reference Values and amended once in 1993 according to the recommendations of FAO/WHO Expert Consultation (Helsinki, Finland, 12-16 September 1988). According to Section 5.0, nutrient labelling should be reviewed periodically in order to maintain the list of nutrients, to be included in composition information, up-to-date and in accord with public health facts about nutrition. Such revision of the NRVs should consider new scientific data and thus the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was requested to develop general principles to guide the choice and methods to amend NRVs.

CCNFSDU took up consideration of the addition or revision of NRVs at the 25<sup>th</sup> Session in 2003. At the 29<sup>th</sup> Session, the Committee agreed that the scope of the work should be limited to vitamins and minerals. The Committee also agreed that this work would involve a process to develop the general principles for establishment of NRVs for the general population as a first step. The next step would be a process to review all available reference values and their scientific basis by the principles agreed upon and, if appropriate, update and extend the current list of vitamin and mineral NRVs in the *Guidelines on Nutrition Labelling*. Once the above is completed, the Committee would establish the principles and NRVs for individuals 6 months to 36 months of age, using as a basis the principles identified for NRVs for the general population and modifying them as appropriate (ALINORM 08/31/26, paras 128-129).

The Committee agreed to request the 31<sup>st</sup> Session of the Commission to approve new work on the revision of NRVs of Vitamins and Minerals for Food Labeling Purposes (ALINORM 08/31/26, para 132 and Appendix V) and the Commission agreed to the Committee's proposal (ALINORM 08/31/REP, Appendix X).

### Timeframe

- First draft to be considered at the 30<sup>th</sup> Session of CCNFSDU, November, 2008;
- Proposed to advance to Step 5 following the development of the general principles and the updating and extending of the current NRVs for the general population by the 32<sup>nd</sup> Session of CCNFSDU scheduled for 2010;
- Proposed to advance for adoption by Commission following modification as needed of draft general principles and development of NRVs for individuals 6 months and 36 months of age by the 34<sup>th</sup> Session of CCNFSDU scheduled for 2012.

### Recommendations

That the Committee:

1. Decides if the purposes of NRVs are properly described at para 9 and the preamble of the proposed draft annex.
2. Discuss para 7 and 8 to determine if the Committee needs to continue including specific international food labeling values in these guidelines as opposed to identifying only general principles for governments to derive their own set of food labeling values, considering the extent to which NRVs are used by member countries.
3. Discuss to revise the introductory text and any other applicable provisions to be consistent with the annex.
4. Decides appropriate options for (1) the selection of the basis and (2) the approaches to use to consider age-sex specific nutrient intake values<sup>1</sup> in determining a single nutrient intake value for use in the general population<sup>2</sup>.
5. Decides the criteria for suitable data sources from which to extract NRVs and identifies the list of nutrients to be included on a scientific basis.
6. Considers and provides comments on whether the proposed draft annex to the *Codex Guidelines on Nutrition Labelling: General Principles for Establishing NRVs of Vitamins and Minerals for the general population* is ready to advance to Step 5.

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<sup>1</sup> "Nutrient intake value" is used as the generic term to encompass average nutrient requirement (ANR), individual nutrient level (INLx) or acceptable range of intake as proposed by FAO/WHO/UNU/UNICEF Expert meeting in 2005. For more details, see King and Garza, "International harmonization of approaches for developing nutrient-based dietary standards", Food and Nutrition Bulletin vol. 28, no. 1 (supplement), 2007

<sup>2</sup> "General population" is defined as children older than 36 months through the adult age groups.

## Appendix

**PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN *CODEX GUIDELINES ON NUTRITION LABELLING* AT STEP 3****1. INTRODUCTION**

1. The Codex Alimentarius Commission (CAC) adopted the *Codex Guidelines on Nutrition Labelling* at its 16<sup>th</sup> Session in 1985. The guidelines provided that numerical information on certain nutrients might be expressed as a proportion of Reference Recommended Daily Allowances (RDAs). The Reference RDAs were described as being based primarily on a single group of consumers.
2. In 1988, following the deliberations of the Commission and with the support of the government of Finland, a Joint FAO/WHO Expert Consultation was held in Helsinki to advise on RDAs for labelling purposes and on other nutritional matters of interest to the Commission. The Consultation recommended that the Codex Reference RDAs be replaced by “Nutrient Reference Values (NRVs)” to clearly indicate that the references served only as a standard for comparison of nutrient content of foods and did not relate to individual nutrient needs. The Consultation reviewed all available data at national and international levels as well as the Codex Reference RDAs and recommended NRVs for nutrients to include 9 vitamins (A, D, C, thiamin, riboflavin, niacin, B<sub>6</sub>, folic acid, and B<sub>12</sub>), 5 minerals (Calcium, Magnesium, Iron, Zinc, Iodine) and protein.
3. Following the recommendations of Helsinki Expert Consultation, Section 3.3.4 of the *Codex Guidelines on Nutrition Labelling* was amended in 1993 with the understanding that it was subject to revision in accordance with new scientific data. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was requested to develop general principles to guide the choice and amendment of NRVs.
4. Current NRVs are also included in the *Codex Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55-2005) and the *Codex Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997, Rev. 1-2004) as a basis for criteria for nutrition and health claims.

**2. SCOPES AND PROCESS OF THE CURRENT WORK**

5. The essentiality of vitamin and minerals is well established and there is likely to be a greater body of evidence to define the recommendations for most vitamins and minerals than for other food components. Therefore the Committee agreed that the scope of the current work should be limited to vitamins and minerals.
6. The Committee also agreed to the importance of elaborating 2 sets of NRVs for (1) the general population 36 months of age and older and (2) the infants and young children 6 months to 36 months of age. For simplicity, this work would involve a process to develop the general principles for establishing NRVs for the general population as a first step. This step would include a process to review all available nutrient intake values and their scientific basis by the general principles agreed upon and, if appropriate, update and extend the current list of vitamin and mineral NRVs in the *Guidelines on Nutrition Labelling*. Then the Committee would next develop the principles that would apply to NRVs for infants and young children 6 months to 36 months of age, using the principles identified for NRVs for the general population as a basis and modifying them as appropriate.
7. Prior to starting this proposed work, the Committee needs to determine if it may be appropriate to update and extend the current NRVs in these guidelines as opposed to identifying only general principles for governments to derive their own set of food labeling values, considering the increased complexity in establishing the specific international food labeling values since the Helsinki consultation.
8. If the Committee determines to proceed in revising and expanding the NRVs despite the complexity of the work, there may be merit in providing guidance on the development of tables to review nutrient intake values available from all scientific data sources that meet agreed upon criteria for the discussion

at the 31th Committee Session. Alternatively, if the Committee determines to identify only general principles for governments, it needs to be noted in the preamble of the draft Annex that governments may consider the suitability of these general principles and additional factors specific to a country or region, such as the bioavailability of food sources for nutrients and the upper levels of intake based on their derivation, in establishing their own reference values for labeling purposes. The current introductory text to the NRVs should also be revised to provide this clarification. It now states in Sec. 3.4.4 that the "...Nutrient Reference Values should be used for labeling purposes in the interests of international standardization and harmonization"—thus implying that all food label reference values should be uniform.

### **3. DEVELOPMENT OF GENERAL PRINCIPLES FOR ESTABLISHING VITAMIN AND MINERAL NRVs FOR THE GENERAL POPULATION**

#### **3.1 Selection of the appropriate basis**

9. If the purpose of NRVs were limited to helping consumers compare the nutrient content of different products, any reference value would suffice as a basis. However if another main purpose of NRVs is to estimate the relative contributions of individual products to the overall dietary intake, then the reference values chosen should be scientifically based and related to requirements.
10. Given that now many member nations and authoritative bodies have established multiple categories of nutrient intake values, it must be determined which basis of these nutrient intake values is the most appropriate for use consistently throughout the labelling process to provide consumers a simple, coherent, understandable, and meaningful reference point.
11. Two nutrient intake values have been proposed as follows:
  - (1) Average Nutrient Requirement (ANR)<sup>3</sup> is the nutrient intake value that is estimated to meet the requirement for a nutrient in 50 percent of the apparently healthy individuals in a specific life stage and gender group (e.g., considering the subgroup's sex and lifestage such as age and pregnancy/lactation). It is based on a specific chosen criterion of adequacy or of optimal health;
  - (2) Individual Nutrient Level (INLx)<sup>4</sup> is the nutrient intake value that is estimated to meet the nutrient requirements of most of (98 percent) the apparently healthy individuals in a specific life stage and gender group (e.g., considering the subgroup's sex and lifestage such as age and pregnancy/lactation). It is generally based on the ANR plus 2-Standard Deviations (SD) of the ANR if the distribution of requirements is a normal distribution.
12. For a vitamin or a mineral which is considered essential but for which there is insufficient scientific evidence to establish an ANR, no INLx is set. In this case, it is appropriate to consider the use of the acceptable range of daily intake<sup>5</sup>. It may be based on insufficient scientific evidence or on median intakes of the nutrient in an apparently healthy population where there is no evidence of a deficiency. Therefore it may be necessary to review how these values are derived on a case-by-case basis to establish the NRVs.

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<sup>3</sup> "Average Nutrient Requirement (ANR)" is used as the generic term. Different countries may use other terminology for this concept, for example, Estimated Average Requirement (EAR), Average Requirement (AR) or promedio de los requerimientos nutrimentales (RN)

<sup>4</sup> "Individual Nutrient Level (INLx)" is used as the generic term. Different countries may use other terminologies for this concept, for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), Population Reference Intake (PRI), or ingestión diaria recomendada (IDR)

<sup>5</sup> "Acceptable range of daily intake" is used as a generic term to express the observed intake that is considered adequate to satisfy the requirements of the majority of the population. Different countries may use other terminology for this concept, for example Adequate Intake (AI), lower end of the range of safe intakes or Ingestión diaria sugerida (IDS) .

13. Current NRVs have been established based on the INLx to cover the needs of as much of the population as possible, but not necessarily all. It has been argued that this could lead to an upward trend in the level of nutrients added to foods due to the demand of consumers who expect higher levels of nutrients as well as manufacturers' efforts to enhance nutritive value of their food products.
14. By definition, ANRs represent the best statistical estimate of the average nutrient requirement for individuals within a specific age and sex group. Therefore, in view of the potential use of nutrition labelling, it might or might not be acceptable to use this value for NRVs. If consumers use the NRV on the labels for the sole purpose of comparing foods, the ANRs are one appropriate basis. If consumers use the NRVs as surrogates for their INLx values, the ANRs are not the appropriate basis for NRVs. However this approach creates a set of values for some nutrients, for which NRs are available, that is substantially different (lower) compared to the existing NRVs, which would lead to more confusion instead of giving a uniform and simple system. For other nutrients, for which no ANR is available, the range of intake would be needed. Therefore some would advocate continuing to use the basis of INLx for NRVs.

### *3.2 Consideration of different age-sex specific values*

15. Once the most appropriate basis of nutrient intake values is selected, either average requirements or recommended intakes, the nutrient intake values for different age-sex groups in the general population should be considered.
16. Four approaches have been proposed as follows:
  - (1) Considering the highest values from the different age-sex groups;
  - (2) Considering the population-weighted values using census data from one country or region and proportions of each age-sex group;
  - (3) Considering the population-weighted values using a hypothetical age-sex distribution;
  - (4) Considering the specific sub-group population weighted means, such as means of adult males and females values.
17. Current NRVs have been established based on the highest INLx of all different age and sex groups. For most nutrients, this has meant the INLx of adult males, except for iron for which INLx for women of childbearing age were selected.
18. With the selection of the highest values, the needs of almost all of the population would be covered. Advocates of this approach believe that use of it would help improve food quality through better processing or nutrient restoration and fortification. However, arguments have been made that this approach overestimates the actual needs of some age and gender groups, particularly younger children. In some cases, use of the highest INLx may result in a reference nutrient intake value that is close to or above the upper nutrient level (UNL)<sup>6</sup> established for younger and potentially vulnerable subgroups of the population who do not require such high intakes. However it may be important to develop a separate principle that addresses how to consider the UNL, because the UNL has uncertainty factor already built in. Some have argued that this approach would also underestimate the nutritional value of the some traditional foods.
19. The population-weighted approach for all different age and gender groups in the population would be used, using census data or a hypothetical age-sex distribution. For example, the different age-sex specific nutrient intake value is multiplied by the number of persons in each group. Then the resulting

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<sup>6</sup> "Upper nutrient level (UNL)" is used as the generic term. Different countries may use other terminology for this concept, for example Upper Tolerable Nutrient Intake Level (UL), upper end of safe intake range or limite superior de consumo (LSC).

sum of requirements is divided by the respective total population size and rounded off if necessary to the nearest whole value. This approach would lead to a figure that is not significantly higher than the need of certain population groups but would still be approaching the reference nutrient intake value that would satisfy the needs of the majority of the population. However there is an argument that this approach will add complexity because NRVs have been set by making assumptions about both body weight factor and age factor. Also this approach will add difficulty in global harmonization because each country has a different mix of children to adults. The alternative more simple approach would be weighted means of the ANR or INLx values for males and females in the chosen population sub-group.

20. In cases, the nutrient intake values for pregnant and lactating women should be excluded, because these are most likely to exceed the recommended maximum intakes of some of the target group.

\* An example how the values change depending on the basis and the integration approach taken is provided below.

Nutrient	Highest INLx	Weighted INLx	Highest ANR(AI)	Weighted ANR(AI)	UNL 4~8 yrs
Vitamin A( $\mu$ gRE)	900	754	630	531	900
Vitamin D( $\mu$ g)			(15)	(7)	50
Vitamin C(mg)	90	74	75	61	650
Thiamin(mg)	1.2	1.1	1.0	0.9	-
Riboflavin(mg)	1.3	1.1	1.1	0.9	-
Niacin(mg)	16	14	12	11	15
Vitamin B <sub>6</sub> (mg)	1.7	1.3	1.4	1.1	40
Folic acid( $\mu$ g) <sup>7</sup>	400	378	330	304	400
Vitamin B <sub>12</sub> ( $\mu$ g)	2.4	2.3	2.0	1.9	-
Calcium(mg)			(1300)	(1091)	2500
Magnesium(mg) <sup>8</sup>	420	341	350	283	110
Iron(mg)	18	11	8	6	40
Zinc(mg)	11	9.1	9.4	7.7	12
Iodine( $\mu$ g)	150	144	95	91	300
Copper(mg)	0.9	0.8	0.7	0.7	3
Selenium( $\mu$ g)	55	52	45	43	150

(Source: Federal Register (2007). 72 FR 62149-62175)

* An example of gender averaged reference values is provided below. Nutrients	Highest male INLx	Highest female INLx	Proposed NRVs
Iron (mg) *10% bioavailability	13.7	29.4	21.6
Zinc (mg) *moderate bioavailability	7.0	4.9	6.0
Vitamin A ( $\mu$ gRE)	500	600	550
Vitamin C (mg)	45	45	45

(Source: Australian response to e-working group, June 2008 )

<sup>7</sup> Folic acid is used in fortified foods and supplements, but does not occur naturally in significant quantities in foods. Naturally occurring food folates are pteroyl poly glutamates. UNL applies to folic acid, but does not apply to naturally occurring food folates.

<sup>8</sup> UNL for magnesium were established for magnesium from non-food sources. In contrast, the INLx for magnesium were established for total magnesium intake from all sources, especially the intake from conventional foods.

### 3.3 Selection of a suitable data sources

21. The *Codex Guidelines on Nutrition Labelling* recommended that NRVs should as far as possible be based on nutrient intake values recommended by FAO/WHO. However the first reference values for labelling did not come from the reports of FAO/WHO. With three exceptions (vitamin B<sub>6</sub>, magnesium, and iron), these values are from the 1980 RDAs of the United States National Research Council (9<sup>th</sup> edition).
- 22.
23. The guidelines revised in 1993 no longer required that these should be based, if possible, on the nutrient intake values recommended by FAO/WHO. They merely state that the list of nutrients and reference values for labelling should be kept up-to-date in line with scientific progress, future recommendations of joint FAO/WHO and other committees and all relevant information (footnote #2 and section 5.1 in the *Codex Guidelines on Nutrition Labelling*), acknowledging that “the definition and review of these values was ongoing process, subject to revision in accordance with new scientific data” (ALINORM 93/40, para 182).
24. Taken together, where relevant advice has been provided by FAO/WHO, this should be taken into consideration in establishing NRVs. If recent FAO/WHO resources are not available, recent nutrient intake values from authoritative scientific bodies other than FAO/WHO should be used as a basis.
25. In evaluating the existing list of science-based nutrient intake values that are applicable to establishing NRVs for the general population, the following criteria shall be used:
- The sources should reflect independent review of the science by authoritative scientific bodies;
  - Higher priority may be given, as appropriate, to more recent nutrient intake values from authoritative scientific bodies.

\* *An example of highest age-sex specific recommended daily intake for vitamin C from different country-specific values. The values range from 40-90 mg/d and would be hard to reconcile into one value for all countries.*

Country	Highest INLx for vitamin C (mg/day)
United States	90 <sup>9</sup>
New Zealand	45 <sup>10</sup>
United Kingdom	40 <sup>11</sup>
FAO/WHO	45 <sup>12</sup>

(Sources : New Zealand’s response to e-working group, June 2008 )

25. Summaries of the comments received from EWG members and recommendations will be presented in Conference Room Document (CRD) during the next session of the CCNFSDU.

<sup>9</sup> <http://www.iom.edu/Object.File/Master/7/296/webtablevitamins.pdf>

<sup>10</sup> <http://www.nrv.gov.au/Nutrients.aspx?code=43706004>

<sup>11</sup> <http://www.eatwell.gov.uk/healthydiet/nutritionessentials/vitaminsandminerals/vitamin/>

<sup>12</sup> <ftp://ftp.fao.org/es/esn/nutrition/Vitni/pdf/APPENDIX.pdf>

**PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES ON NUTRITION LABELLING :  
GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES OF  
VITAMINS AND MINERALS FOR THE GENERAL POPULATION AT STEP 3**

## **PREAMBLE**

These principles apply to the establishment of Codex Nutrient Reference Values for labelling purposes (NRVs) for vitamins and minerals for the general population identified as individuals 36 months and older. These values may be used for helping consumers 1) estimate the relative contribution of individual products to the overall dietary intake and 2) as one way to compare the nutrient content between products.

A government may select to use the NRVs, 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 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 food label reference values that take into account country or region specific factors that affect nutrient absorption or utilization (e.g., the bioavailability of nutrients such as iron in habitual diets.) 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.

## **GENERAL PRINCIPLES FOR ESTABLISHING VITAMIN AND MINERAL NRVs**

### ***A. Selection of the appropriate basis***

The NRVs shall be based on:

[Option 1]: Average nutrient requirements (ANR), the estimated nutrient intake values that meet the requirements of 50 percent of an apparently healthy specific sub-group of the population (e.g., considering the subgroup's sex and lifestage such as age and pregnancy/lactation). In cases where there is an absence of established ANRs for a nutrient for a specific sub-group, it may be appropriate to consider the use of acceptable nutrient intake values or ranges that have been established by authoritative scientific bodies. It is necessary to review how these values were derived on a case-by-case basis.

[Option 2]: Individual Nutrient Level (INLx) , the estimated nutrient intake values that meet the requirements of most of (98 percent) of an apparent healthy specific sub-group of the population (e.g., considering the subgroup's sex and lifestage such as age and pregnancy/lactation). In cases where there is an absence of established INLx for a nutrient for a specific sub-group, it may be appropriate to consider the use of acceptable nutrient intake values or ranges that have been established by authoritative scientific bodies. It is necessary to review how these values were derived on a case-by-case basis.

### ***B. Consideration of different age-sex specific values***

The general population NRVs shall be determined by :

- [Option 1]: considering the highest values from the different age-sex groups;
- [Option 2]: considering population-weighted values using census data from one country or region and proportions of each age-sex group
- [Option 3]: Considering the population-weighted values using a hypothetical age-sex distribution;
- [Option 4]: Considering the specific sub-group population weighted means, such as means of adult males and females values.

For the purpose of establishing these NRVs, the values for pregnant and lactating women are excluded.

### ***C. Consideration of upper levels of intake***

The establishment of general population NRVs may also take into account upper levels of intake established by authoritative scientific bodies.

### ***D. Selection of a suitable data sources to extract NRVs***

Where relevant and recent advice has been provided by FAO/WHO, this should be taken into consideration in establishing NRVs. If the FAO/WHO resources are not available, recent nutrient intake values from recognized authoritative scientific bodies other than FAO/WHO could be used.

In evaluating the existing list of science-based nutrient intake values that are applicable to the NRVs for the general population, the following criteria shall 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 may be given, as appropriate, to more recent nutrient intake values from recognized authoritative scientific bodies