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FOOD AND AGRICULTURE
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PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING AT STEP 3

(Prepared by the Republic of Korea and Australia with the assistance of Brazil, Canada, Costa Rica, Egypt, European Community, Japan and United States of America and the observers from IADSA and IDF)

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Principles at Step 3 (see Appendix 1 and Appendix 2) 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: 1) 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 with a copy to: 2) Dr Hye-Kyung Park, Korea Food and Drug Administration, Nutrition Policy Division, 194 Tongil-ro, Eunpyung-gu, Seoul, Korea, Fax: +82-2-382-6380, e-mail: codexkorea@korea.kr and 3) Secretary, 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 by **15th October 2009**.

BACKGROUND

1. At the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), the Committee decided that there was a need to update the Nutrient Reference Values (NRVs) for labelling purposes in the *Guidelines on Nutrition Labelling (CAC/GL 2-1985)*.
2. At the 29th Session of the CCNFSDU in 2007, the Committee agreed that the scope of this 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 (CAC/GL 2-1985)*. 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).

3. The 31th Session of the Commission approved new work on the revision of Vitamin and Mineral Nutrient Reference Values (NRVs) for Food Labelling Purposes and agreed to the Committee's proposal (ALINORM 08/31/REP, Appendix X).

PROGRESS MADE AT THE LAST SESSION OF THE COMMITTEE¹

4. A proposed Draft Annex to the *Guidelines on Nutrition Labelling: General Principles for Establishing NRVs for the General Population* was prepared by the delegation of the Republic of Korea with assistance from other interested parties (CX/NFSDU 08/30/7). Also a physical working group was held prior to the session in order to review comments received and prepare proposals on how to revise the document for consideration by the Plenary (ALINORM 09/32/26, para 103).
5. During the 30th Session of the CCNFSDU in 2008, the Committee agreed to use the terminology proposed by the United Nations University/FAO/WHO/UNICEF workshop on harmonization of approaches for developing nutrient-based dietary standards² (ALINORM 09/32/26, paras 104-106). It was also agreed that it would be useful to add a new section on definitions (ALINORM 09/32/26, para 117).
6. The Committee agreed to editorial amendments proposed in the Preamble, pointing out the importance of the second paragraph to clarify that a country should be able to select its own values based on scientific justification, including consideration of country- and region-specific factors (ALINORM 09/32/26, para 107).
7. The discussion on the process to develop the general principles for establishment of NRVs for the general population is summarized as follows (ALINORM 09/32/26, paras 108-119):
 - Many delegations preferred Individual Nutrient Level (INL₉₈) to Average Nutrient Requirements (ANR) as the basis of NRVs. The definition of INL₉₈ was amended to read: the estimated nutrient intake value that meets the requirements of most (98 percent) of an apparently healthy specific subgroup of the population. In cases where INLs are not available, other reference values established by authoritative scientific bodies could be used on a case-by-case basis after reviewing how these values were derived.
 - The Committee agreed to use the following two options for considering the different age-sex specific values: Option 1 (the highest values from different age-sex groups) and Option 2 (the average mean value for a chosen reference population group such as means of adult male and female values). However, the Committee noted that practical implications of choosing one approach were not clear and that it was difficult to decide on how either option could work in practice. Therefore, the Committee decided to put these two options in square brackets for further consideration.
 - The Committee agreed that recent and relevant FAO/WHO values would be the most appropriate data source for NRVs. However if such FAO/WHO values are not available, alternatively, relevant and recent values from recognized authoritative scientific bodies other than FAO/WHO could be used.

¹ Alinorm 09/32/26, paras 103-122; CX/NFSDU 08/30/7; CX/NFSDU 08/0/7-Add. 1 (comments from United States of America and South Africa); CRD 1 (Report of the Physical Working Group); CRD 7 (comments from the European Community, Indonesia, Kenya, Philippines); CRD 12 (WHO/UNICEF/WFP/UNHCR Information on Informal Consultation on management of moderate malnutrition in under-5 children); CRD 13 (Summaries of the comments from E-WG members (Australia, Brazil, China, Costa Rica, European Community, Malaysia, New Zealand, Switzerland, CRN, IADSA and NHF) and recommendations); CRD 18 (Results of the Physical Working Group on NRVs)

² International Harmonization of Approaches for Developing Nutrient-Based Dietary Standards, Janet King and Cutberto Garza, Guest editors, Food and Nutrition Bulletin, Vol 28, No1, 2007.

8. The Committee also discussed the next step, to develop a process to update and extend the current NRVs in the *Guidelines on Nutrition Labelling*.
 - The Committee considered whether the actual NRVs should be elaborated by FAO/WHO or by the CCNFSDU. It was noted that human requirements for vitamins and minerals were recently published in the report, *FAO/WHO Vitamin and Mineral Requirements in Human Nutrition*³. Therefore, the Committee agreed that elaboration of NRVs for labelling purposes was the responsibility of CCNFSDU (ALINORM 09/32/26, para 120).
9. Given that questions remained, the Committee agreed to return the *General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population* to step 2/3 for redrafting. Special elaboration on the options for the consideration of different age-sex groups was required. The electronic working group led by the delegation of the Republic of Korea was re-established with the understanding that the Delegation of Australia would help in calculating NRVs for labelling purposes based on option 1 and 2 using data from *FAO/WHO Vitamin and Mineral Requirements in Human Nutrition* (ALINORM 09/32/26, paras 121-122).

PROCEEDINGS OF THE ELECTRONIC WORKING GROUP

10. In April 2009, the Republic of Korea invited all members of CCNFSDU interested in participating in the E-WG to provide contact information by May 15, 2009. The expressions of interest in participating were received from 24 members (Argentina, Australia, Brazil, Belgium, Canada, Costa Rica, European Community, Egypt, Germany, Japan, Kenya, New Zealand, Norway, United States of America, CIAA (Confédération des industries Agro-Alimentaires), CRN (Council for Responsible Nutrition), EuSalt (the European Salt Producers' Association), IADSA (International Alliance of Dietary/Food Supplement Associations), ICBA (International Council of Beverages Associations), ICGMA (International Council of Grocery Manufacturers Association), IDF (the International Dairy Federation), ILCA (International Lactation consultants association), Laboratorio Tecnológico del Uruguay and WHO (World Health Organization)).
11. E-WG members were invited to provide comments on the potential Nutrient Reference Values (*p*NRVs) prepared by Australia (see *Table 1*) and some questions for consideration by June 15. The invitation for comments was accepted by 7 member countries (Australia, Brazil, Canada, Costa Rica, Egypt, Japan and United States of America), 1 member organization (European Community) and 2 non-government organizations (IADSA and IDF).
12. Codex standards define “young children” as persons aged 12 to 36 months. However, the age groups in some data sources of daily intake reference values, including the FAO/WHO publication, do not exactly coincide with this. In this respect, E-WG members were invited to reconsider the age range of the general population. Based on the comments submitted, the description of general population on the 1st Section (1. Preamble) has been amended as individuals older than 36 months to be consistent with the definitions in all other Codex standards.
13. The 2nd Section (2. Definitions) has been reconstructed according to the recommendation at the 30th Session and the comments of E-WG.
14. For consideration of the options on the 3rd Section (3. General Principles for Establishing Vitamin and Mineral NRVs), the Delegation of Australia kindly calculated 2 sets of the potential Nutrient Reference Values (*p*NRVs) of 6 minerals and 13 vitamins, using data from *FAO/WHO Vitamin and Mineral Requirements in Human Nutrition (2004)*, and compared these *p*NRVs with Tolerable Upper Intake Levels (ULs) for the most relevant young age group (4-8 years) from *FAO/WHO Guidelines on Food Fortification with Micronutrients (2006)* respectively (*Table 1*). E-WG has largely agreed that the most

³ Vitamin and Mineral Requirements in Human Nutrition, 2nd edition, FAO/WHO, 2004

appropriate option for considering different age-sex specific values is option 2. The values of option 2 are generally lower and less likely to exceed ULs for the most relevant young age group.

In Appendix 1:

- The Committee may wish to determine whether to delete option 1 and the square bracket.
- The Committee may wish to consider the age group that should reasonably represent the general population.

Table 1. The potential Nutrient Reference Values (pNRVs) derived according to Options 1 and 2, and ULs for 4-8 year age group

Nutrient		Option 1 Highest value (4 years and older)	Option 2 Mean Adult value (19-50 years ⁴)	UL (4-8 years)
MINERALS				
Calcium (mg/day)		1300	1000	2500
Selenium (µg/day)		34	30	150
Magnesium (mg/day)		260	240	N/D ⁵
Zinc (mg/day)	High bioavailability	5.1	3.6	12
	Moderate bioavailability	8.6	6.0	
	Low Bioavailability	17.1	11.9	
Iron (mg/day)	15% bioavailability	21.8	14.3	40
	12% bioavailability	27.7	18.0	
	10% bioavailability	32.7	21.6	
	5% bioavailability	65.4	43.1	
Iodine (µg/day)		150	150	300
VITAMINS				
Vitamin C (mg/day)		45	45	650
Thiamine (mg/day)		1.2	1.2	N/D
Riboflavin (mg/day)		1.3	1.2	N/D
Niacin (mg NE/day)		16	15	15 (niacin only)⁶
Vitamin B ₆ (mg/day)		1.7	1.3	40
Pantothenate (mg/day)		5	5	N/D
Biotin (µg/day)		30	30	N/D
Vitamin B ₁₂ (µg/day)		2.4	2.4	N/D
Folate (µg DFE/day)		400	400	400 (folic acid only)⁷
Vitamin A (µg RE/day)		600	550	900
Vitamin D (µg/day)		15	5	50
Vitamin E (mg α-TE/day)		10	8.8	300
Vitamin K (µg/day)		65	60	N/D

⁴ The most likely age groups were 19-50 or 19-65 years because they had the greatest span of years of any single age group. The RNIs for males aged 19-65 and for females aged 19-50 were averaged to determine the pNRVs. (Note that RNIs for males aged 19-50 years were able to be used for vitamin B₆ and vitamin D.)

⁵ Not determined

15. Additional *p*NRVs of 7 minerals were calculated, using data from the United States Institute of Medicine (IOM) of the National Academy of Sciences (Table 2). The process for compilation of these *p*NRVs was consistent with Australia's procedure as Table 1.

Table 2. The additional potential Nutrient Reference Values (*p*NRVs) calculated using the Dietary Reference Intake values from IOM

Nutrient	Option 1 Highest value (4 years and older)	Option 2 Mean Adult value (19-50 years)	UL (4-8 years)
Chloride (g/day)	2.3*	2.3*	2.9
Chromium (µg/day)	35*	30*	ND
Copper (µg/day)	900	900	3000
Fluoride (mg/day)	4*	3.5*	2.2
Manganese (mg/day)	2.3*	2.1*	3
Molybdenum (µg/day)	45	45	600
Phosphorus (mg/day)	1250	700	3000

*: Chloride, Chromium, Fluoride and Manganese are AIs (Adequate Intakes) Adequate Intake (AI) is a recommended average daily nutrient intake value based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate - used when an RDA(Recommended Dietary Allowance) cannot be determined-.

16. According to the discussion at the 30th Session and the comments of E-WG, the draft list of revised or additional *p*NRVs of 13 minerals and 13 vitamins in Paragraph 3.4.4 of the Codex Guidelines on Nutrition Labelling has been constructed in Appendix 2.

In Appendix 2 :

- Committee may wish to consider and provide comments on the proposed list of *p*NRVs and the following issues (1) and (2).

- (1) For the nutrients with multiple bioavailabilities (e.g., iron, zinc), there may be three options for values representing different bioavailabilities. Committee may wish to discuss to choose the best one.

Option 1: Select the NRV for which the bioavailability of the mineral best represents the bioavailability of the mineral in the global diet (and include a footnote that describes quantitatively or qualitatively the assumption regarding bioavailability), and **DO NOT** include provisions to permit countries to determine their own NRV that most reflects the likely bioavailability of their national diet.

Option 2: Select the NRV for which the bioavailability of the mineral best represents the bioavailability of the mineral in the global diet (and include a footnote that describes quantitatively or qualitatively the assumption regarding bioavailability), and **DO** include provisions to permit countries to determine their own NRVs based on alternative assumptions.

⁶ Based on the flushing effects of nicotinic acid. If niacinamide is used as the fortificant, the UL would be much higher. A UL for 4-6yrs olds of 220 mg niacinamide/day has been recommended by the European Commission(SCF, 2006) .

⁷ Refers to folic acid derived from fortified foods, or supplemental folic acid.

Option 3: Provide multiple NRVs for varying bioavailability in the Codex listing of NRVs (and include a footnote that describes quantitatively or qualitatively the assumption regarding bioavailability).

(2) For the unit of Niacin

The current unit for niacin in the Guidelines on Nutrition Labelling reads as ‘mg niacin’ rather than ‘mg NE’ i.e. niacin equivalents. Given that the FAO/WHO requirement values are expressed as mg NE, the committee may wish to determine which unit and corresponding niacin value is appropriate.

The NRV for niacin applies to nutrient declaration and it forms the basis of the minimum criterion for content claims. The choice of units is relevant to the niacin content claim criterion as it might apply to niacin fortification. The amount of niacin added to a low tryptophan food would be greater if the NRV and therefore the content claim criterion were expressed as a minimum percentage of mg NE rather than mg niacin. The greater amount of niacin added, the greater the potential to reach or exceed the UL.

However, expressing the NRV for this vitamin as Niacin Equivalents is consistent with the units used in the 2004 FAO/WHO reference, and takes into account the contribution of tryptophan in meeting recommended intakes.

RECOMMENDATIONS TO THE COMMITTEE

17. The revised proposed draft of “General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population” is presented in Appendix 1. This is intended as an annex to the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985)
18. The proposed list of Nutrient Reference Values of Vitamins and Minerals for the General Population is presented in Appendix 2. This is intended to be included in Section 3.4.4 of the Codex *Guideline on Nutrition Labelling* (CAC/GL 2-1985)
19. E-WG recommends that further discussion will focus on determination of actual NRVs at the 31th Session of the CCNFSDU.
20. The Committee may wish to consider the content of Appendix 1 and Appendix 2, with the view of forwarding them for adoption at Step 5 to the Codex Alimentarius Commission.

APPENDIX 1

**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 ⁸**
(At step 3 of the Procedure)

1. 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 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, 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.

2. DEFINITIONS

2.1. Individual Nutrient Level 98 (INL₉₈) is the daily nutrient intake 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.

Different countries may use other terms for this concept, for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), Population Reference Intake (PRI), or Ingesa Diaria Recomendada (IDR)

2.2. Upper Nutrient Level (UNL) is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals in a specific lifestage and sex group.

Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL), upper end of safe intake range or Límite Superior de Consumo (LSC).

3. GENERAL PRINCIPLES FOR ESTABLISHING VITAMIN AND MINERAL NRVs

A. Selection of a suitable data sources to establish NRVs

Relevant and recent **daily intake reference** values provided by FAO/WHO should be taken into consideration in establishing NRVs. If such values are not available, then relevant and recent values from recognized authoritative scientific bodies other than FAO/WHO could be used.

⁸ Note: This document is intended as an annex to the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985, Rev. 1-1993)

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 may be given, as appropriate, to more recent values from recognized authoritative scientific bodies

B. Selection of the appropriate basis

The NRVs shall be based on Individual Nutrient Level **98** (INL₉₈), the estimated nutrient intake values that meet the requirements of ~~most~~ (98 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 an established INL₉₈ for a nutrient for a specific sub-group, it may be appropriate to consider the use of other reference values or ranges that have been established by **recognized** authoritative scientific bodies. It is necessary to review how these values were derived on a case-by-case basis.

C. 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 the average mean value for chosen reference population group that reasonably represents the general population above 3 years of age, 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.

D. Consideration of upper levels of intake

The establishment of general population NRVs should also take into account Upper Nutrient Levels (UNLs) of intake established by authoritative scientific bodies.

APPENDIX 2

**PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES
FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION
LABELLING⁹ AT STEP 3**

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 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 may also be expressed as percentages of the Nutrient Reference Value.³

The following Nutrient Reference Values are for the general population identified as individuals older than 36 months and should be used for labelling purposes in the interests of international standardization and harmonization.

Protein (g)	50
Vitamin A (μg RE)	800 ⁴ <u>550</u> ⁴
Vitamin D (μg)	5 ⁵
<u>Vitamin E (mg α-TE)</u>	<u>8.8</u>
<u>Vitamin K (μg)</u>	<u>60</u>
Vitamin C (mg)	60 <u>45</u>
Thiamin (mg)	1.4 <u>1.2</u>
Riboflavin (mg)	1.6 <u>1.2</u>
Niacin (mg NE)	18 ⁵ <u>15</u> ⁵
Vitamin B ₆ (mg)	2 <u>1.3</u>
Folic acid (μg)	200 <u>Folate (μg DFE) 400</u>
Vitamin B ₁₂ (μg)	1 <u>2.4</u>
<u>Pantothenate (mg)</u>	<u>5</u>
<u>Biotin (μg)</u>	<u>30</u>
Calcium (mg)	800 <u>1000</u>
<u>Phosphorus (mg)</u>	<u>700</u>
<u>Chloride (g)</u>	<u>2.3</u>
Magnesium (mg)	300 <u>240</u>

Option 1 or Option 2

Iron (mg)	14 <u>14.3, 18.0, 21.6 or 43.1</u> ⁶
Zinc (mg)	15 <u>3.6, 6.0 or 11.9</u> ⁷

Option 3

Iron (mg)	14 <u>14.3 ~ 43.1</u> ⁶
Zinc (mg)	15 <u>3.6 ~ 11.9</u> ⁷

Copper Value to be established (μg) 900

Fluoride (mg) 3.5

⁹ Note: This document is intended to be included in Section 3.4.4 of the Codex Guideline on Nutrition Labelling (CAC/GL 2-1985, Rev. 1-1993).

Manganese (mg) 2.1Iodine (µg) 150⁵Selenium ~~Value to be established~~ (µg) **30****Chromium (µg) 30****Molybdenum (µg) 45**

³ 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.

⁴ Proposed addition to Section 3.2.7 (Calculation of Nutrients) of the Codex Guidelines on Nutrition Labelling: "For the declaration of β-carotene (provitamin A) the following conversion factor should be used: 1 µg retinol = 6 µg β-carotene.

⁵ Nutrient Reference Values for Vitamin D, Niacin and Iodine may not be applicable for countries where national nutrition policies or local conditions provide sufficient allowance to ensure that individual requirements are satisfied. See also section 3.2.4.1 of the Codex Guidelines on Nutrition Labelling.

Option 1 :

⁶ **Nutrient Reference Value is based on the dietary iron bioavailability of 00%.**

⁷ **Nutrient Reference Value is based on the dietary zinc bioavailability of 00%.**

Option 2 :

⁶ **Nutrient Reference Value is based on the dietary iron bioavailability of 00%. Countries should determine the Nutrient Reference Values for iron that best represent the bioavailability of iron in national diets.**

⁷ **Nutrient Reference Value is based on the dietary zinc bioavailability of 00%. Countries should determine the Nutrient Reference Values for zinc according that best represent the bioavailability of zinc in national diets.**

Option 3 :

⁶ **The recommended NRVs with different iron bioavailability are 14.3 (15% bioavailability), 18.0 (12% bioavailability), 21.6 (10% bioavailability) and 43.1 (5% bioavailability). Countries should determine the Nutrient Reference Values for iron that best represent bioavailability of iron in national diets.**

⁷ **The recommended NRVs with different zinc bioavailability are 3.6 (high bioavailability), 6.0 (moderate bioavailability) and 11.9 (low bioavailability). Countries should determine the Nutrient Reference Values for zinc that best represent bioavailability of Zinc in national diets.**