

CODEX ALIMENTARIUS COMMISSION



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.org

Agenda Item 4

CX/NFSDU 15/37/4 Add.2
Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

37th Session
Bad Soden a.T. - Germany
23 – 27 November 2015

PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE GUIDELINES ON NUTRITION LABELLING (VITAMIN A, D, E, MAGNESIUM, PHOSPHOROUS, CHROMIUM, COPPER, CHLORIDE AND IRON)

Comments of Egypt, Malaysia, Mali and FoodDrinkEurope

EGYPT

Recommendation 1- NRV-R for Vitamin A

Egypt agrees with the proposed NRV-R for vitamin A of 800 µg based on IOM.

Recommendation 2 - NRV-R for Vitamin D

Egypt agrees with the proposed NRV-R for vitamin D of selecting either 10 µg or 15 µg based on relevant RASB.

Recommendation 3 – Footnote to NRV-R for Vitamin D

Egypt agrees with this footnote

Recommendation 4 - NRV-R for Vitamin E

Egypt agrees with the proposed NRV-R for vitamin E of 9 mg based on Nordic Council and average of EFSA, NHRMC/MOH, NIH, WHO/FAO (all AIs).

Recommendation 5 - NRV-R for Iron

Egypt agrees with modifying the NRV-R for Iron to refer to % dietary absorption and revising the NRV-R from 14 mg to 14 mg (15% dietary absorption) and 22mg (10% dietary absorption) and based on WHO/FAO.

Recommendation 6 – Dietary Description for Iron:

Egypt supports the dietary descriptions for iron adapted from WHO/FAO (2006) that correspond to the selected NRVs-R.

Recommendation 7 – Footnote to NRV-R for Iron

Egypt supports attaching to iron the ** footnote indicator currently attached to zinc.

Recommendation 8 - NRV-R for Magnesium

Egypt agrees with revising the NRV-R for magnesium to 310mg, based on the average of IOM, NIH, WHO/FAO ± Nordic Council (INL₉₈ ± RI)

Recommendation 9 - NRV-R for Phosphorus

Egypt supports the establishment of a NRV-R of 700 mg for Phosphorus based on the IOM.

Recommendation 10 - NRV-R for Copper

Egypt supports the establishment of NRV-R of 900 µg for copper and based on IOM.

Recommendation 11 - NRV-R for Chromium

Egypt supports the establishment of NRV-R of 30 µg for Chromium and based on IOM.

Recommendation 12 - NRV-R for Chloride

Egypt supports the establishment of NRV-R for chloride and selecting either 2300 mg or 3000 mg based on relevant rationale or RASB.

Recommendation 13 – Vitamin A Dietary Equivalents and Conversion Factors

Egypt agrees with all recommendations for vitamin A dietary equivalents and conversion factors.

Recommendation 14 – Vitamin E Dietary Equivalents and Conversion Factors

Egypt agrees with all recommendations for vitamin E dietary equivalents and conversion factors.

Recommendation 15 – Second Table Heading and Footnote

Egypt supports proposed revisions in section 4.5 above.

Recommendation 16 – RASB Definition in *Guidelines on Nutrition Labeling*

Egypt agrees with the insertion of the definition of RASB in the Annex to *Guidelines on Nutrition Labeling* at new paragraph 2.5

Recommendation 17 – Record of NRV-R Decisions

Egypt agrees with the decision to record the details of all NRVs-R from this revision in the Annex to the *Guidelines on Nutrition Labeling* and insert the table in section 6 into the Annex at new section 4 updated to include decisions from this session of CCNFSDU.

Recommendation 18 – Draft General Principles for NRVs-R for Older infants and Young Children

Egypt supports the drafting of General Principles for NRVs-R for Older Infants and Young Children.

Recommendation 19 – Consequential amendments to age of general population in Nutrition Labeling Guidelines

Egypt agrees with revising 'older than 36 months' to '36 months and older' in paragraph 3.4.4, the Annex Preamble and GP 3.2.1.2 in the *Guidelines on Nutrition Labeling*.

MALAYSIA**Recommendation 1 – NRV-R for Vitamin A**

Malaysia supports to retain current NRV-R for vitamin A (800 µg).

Recommendation 2 – NRV-R for Vitamin D

Malaysia supports NRV-R for vitamin D based on average levels from IOM (15 µg) and Nordic Council (10 µg) be used which is close to 13 µg.

Recommendation 3 – Footnote to NRV-R for vitamin D

Malaysia supports the NRV-R is based on minimal sunlight exposure throughout the year with average levels of 15 µg and 10 µg be used which is close to 13 µg.

Recommendation 4 – NRV-R for Vitamin E

Malaysia prefers to adopt average values based on INL₉₈ from IOM (15 mg) and Nordic Council (9 mg) be used which is 12mg.

Recommendation 5 – NRV-R for Iron

Malaysia prefers WHO/FAO DIRV (14 mg), based on 15% of absorption.

Malaysia is of the opinion that it is more practical to have only one international DIRV for the purpose of labelling. If CCNFSDU decides to adopt two DIRVs according to % absorption, Malaysia proposes that there should be a footnote to allow countries to select either one of the DIRVs based on the needs of the country.

Recommendation 6 – Dietary Description for Iron

Malaysia has no objection to the dietary descriptions for iron adapted from WHO/FAO (2006) as specified in Table 3.3. However, Malaysia would like to suggest the dietary descriptions as follows:

"Diversified diet containing greater amounts of meat, fish, poultry and/or greater amounts of fruits and vegetables" (15% absorption).

"Diet of cereals, roots or tubers, with some foods of animal origin (meat, fish or poultry) and/or containing some fruits and vegetables" (10% absorption).

Recommendation 7 – Footnote to NRV-R for Iron

Malaysia agrees to the proposed footnote.

Recommendation 8 – NRV-R for Magnesium

Malaysia prefers to adopt average values based on INL₉₈ from IOM (365 mg), NIHN (320 mg) and WHO/FAO (240 mg) be used which is closed to 310 mg.

Recommendation 9 – NRV-R for Phosphorus

Malaysia prefers to adopt average values based on INL₉₈.

Therefore, Malaysia proposes the average levels from IOM (700 mg), NHMRC/MOH (1000 mg) and Nordic Countries (600 mg) be used which is 770 mg.

Recommendation 10 – NRV-R for Copper

Malaysia prefers to adopt average values based on INL₉₈. Therefore, Malaysia proposes the average levels from IOM (900 µg) and NIHN (800 µg) be used which is 850 µg.

Recommendation 11 – NRV-R for Chromium

Malaysia prefers to adopt value based on INL₉₈. Therefore, Malaysia proposes the levels from NIHN be used which is 35 µg.

Recommendation 12 – NRV-R for Chloride

Malaysia prefers to adopt value based on Equimolar with NRV-NCD for sodium which is 3100 mg.

Recommendation 13 – Vitamin A Dietary Equivalents and Conversion Factors

- A. Malaysia has no objection to insert a dietary equivalents and conversion factors to paragraph 3.4.4.1.
- B. Malaysia supports the term Retinol Equivalents (RE) and its conversion factors for natural isomers of vitamin A listed in WHO/FAO 2004 publication and not Retinol Activity Equivalents (RAE).
- C. Malaysia objects to the exclusion of 2 µg all-trans-β-carotene in oil as a supplement from section 4.2. This is because this form is also a form of commercially available vitamin A added to food and contributes to retinol activity. In addition, Malaysia would like to highlight the fact that the activity of beta carotene in oil is contrastingly higher than that found in many vegetables and other foods. Malaysia is therefore of the opinion that this factor should be retained and not be excluded.
- D. Malaysia agrees with the proposed deletion

Recommendation 14 – Vitamin E Dietary Equivalents and Conversion Factors

- A. Malaysia has no objection to insert an entry for vitamin E in the second table to paragraph 3.4.4.1 of the *Guidelines on Nutrition Labelling*.
- B. Malaysia objects to the inclusion of only α-tocopherol as the active form of vitamin E occurring naturally in food as shown in section 4.3.

Malaysia strongly recommends the inclusion of the conversion factors listed by FAO/WHO (2004) publication which includes other isomers of vitamin E.

The majority of science in the past has looked at vitamin E in the α-tocopherol form in the context of elucidating an effect that relates to certain activities¹. However, on the basis of more recent evidence, other forms of vitamin E including α-, γ-, and δ-tocotrienols have been shown to be present in the plasma and vital organs^{2,3,4,5}. There is growing evidence on the important biological activities of the tocotrienol forms of vitamin E, which are different from that of α-tocopherol^{2,6,7}, independent of the alpha-tocopherol transfer proteins^{8,9}.

It is therefore crucial to assess the current evidence on the role of all forms of vitamin E in human health and to recommend a suitable level of daily intake for all these forms.

References:

1. Traber MG, Packer L. Vitamin E: beyond antioxidant function. *Am J Clin Nutr.* 1995 Dec;62(6 Suppl):1501S-1509S.
2. Fu JY et al. (2014). Bioavailability of tocotrienols: evidence in human Studies. *Nutr and Metab* 11:5.
3. Meganathan et al. (2015). A new formulation of Gamma-Delta Tocotrienol has superior bioavailability compared to existing Tocotrienol-Rich Fraction in healthy human subjects. *Scientific Reports*, 13550;doi:10.1038/srep13550.
4. Yap et al. (2001). Pharmacokinetics and bioavailability of alpha-, gamma- and delta-tocotrienols under different food status. *J*

Pharm Pharmacol, 53(1):67–71.

5. Yap et al. (2004). Influence of lipolysis and droplet size on tocotrienol absorption from self-emulsifying formulations. Int J Pharm 2004, 281(1–2):67–78.
6. Watson, R.R., and Preedy, V.R., Eds. Tocotrienols: vitamin E beyond tocopherols (2009). First Edition. CRC Press Taylor & Group, AOCS Press, Boca Raton.
7. Tan, B., Watson, R.R., and Preedy, V.R., Eds. Tocotrienols: vitamin E beyond tocopherols (2013). Second Edition. CRC Taylor & Francis Group, AOCS Press, Boca Raton.
8. Khanna S, Patel V, Rink C, Roy S, Sen CK. Delivery of orally supplemented alpha-tocotrienol to vital organs of rats and tocopherol-transport protein deficient mice. Free Radic Biol Med. 2005 Nov 15;39(10):1310-9.
9. Patel, V et al. (2012). Oral Tocotrienols Are Transported to Human Tissues and Delay the Progression of the Model for End-Stage Liver Disease Score in Patients. J Nutr 142: 513–519.

C. Malaysia has no objections to include the three common forms of vitamin E that are added to food as shown in section 4.4.

Recommendation 15 – Second Table Heading and Footnote

Malaysia supports the proposed heading and footnote.

Recommendation 16 – RASB Definition in Guidelines on Nutrition Labelling

Malaysia supports the proposed RASB definition in Guidelines on Nutrition.

Recommendation 17 – Record of NRV-R Decisions

Malaysia has no objection to record the details of NRVs-R and to insert into the Annex at new section 4.

19 – Consequential amendments to age of general population in Nutrition Labelling Guidelines

Malaysia agrees to the revision of 'older than 36 months' to '36 months and older' in paragraph 3.4.4, the Annex Preamble and GP 3.2.1.2. in the Guidelines on Nutrition Labelling.

MALI

Observations d'ordre général :

Le Mali félicite le groupe de travail électronique présidé par l'Australie pour la préparation du document de travail. Il approuve globalement l'avant-projet et est favorable à sa progression à l'étape suivante de la procédure.

Observations spécifiques

Recommandation 1: VNR-R pour la vitamine A

Position: Le Mali soutient l'adoption de la recommandation.

Justification: Le Mali considère que le niveau proposé est sans danger pour la population et qu'un tel niveau viendra compléter les efforts de gestion de la carence en vitamine A dans la région. La vitamine A est physiologiquement importante, surtout en ce qui concerne l'immunité du corps et la vision. La vitamine A contribue à la réduction de la mortalité chez les enfants âgés de moins de cinq ans.

Recommandation 2 et 3: VNR-R pour la vitamine D

Position: le Mali propose le maintien à 5 µg. En outre, une note en bas de page devrait être introduite pour permettre aux autorités nationales de régler les niveaux jusqu'à 15 µg.

Justification: La carence en vitamine D est surtout liée à l'exposition à la lumière du soleil. Les pays situés dans les tropiques ont idéalement une exposition fiable qui permettrait aux gens de ces régions les synthèses de suffisamment de vitamine D. Cependant, d'autres pays qui ne bénéficient pas d'une telle exposition peuvent avoir besoin de ce que la vitamine D soit fournie à travers l'alimentation, d'où le besoin de donner aux autorités nationales la latitude de prendre une décision sur cet aspect.

Recommandation 4: VNR-R pour la vitamine E

Position : Le Mali appuie l'adoption de la recommandation.

Justification: La vitamine E est un antioxydant important dans le corps et les niveaux proposés sont physiologiquement appropriés pour sa fonction.

Recommandation 5: VNR-R pour le fer

Position: le Mali soutient l'adoption de la recommandation.

Recommandation 6: Caractéristiques de l'alimentation pour le fer

Position: Le Mali appuie l'adoption de la recommandation.

Recommandation 7: Note en bas de page pour la VNR-R pour le fer

Position: Le Mali est favorable à l'adoption de la recommandation.

Justification des recommandations liées au fer: La qualité d'absorption du fer et du zinc dépend de la source (les sources animales sont mieux absorbées par rapport aux sources végétales, par exemple l'hème et le fer non hémique).

Recommandation 8: VNR-R pour le magnésium

Position: Le Mali appuie l'adoption de la recommandation.

Justification: Le magnésium est un minéral important dans le fonctionnement normal des muscles, y compris le cœur, et donc le niveau proposé appuiera cette fonction surtout avec l'accroissement des complications cardio-vasculaires.

Recommandation 9: VNR-R pour le phosphore

Position: Le Mali recommande l'adoption d'une VNR-R de 550 mg au lieu de 700 mg.

Justification: Pour une bonne absorption du phosphore, un ratio Ca:P de 2:1 est optimale et veillera à ce que le calcium et le phosphore soient bien absorbés par le corps. 550 mg assureront un ratio de 1,8 qui est tout à fait dans la fourchette de l'absorption optimale.

Recommandation 10: VNR-R pour le cuivre

Position: Le Mali appuie l'adoption de la recommandation.

Justification: Le cuivre est un élément important dans les coenzymes du corps, ce niveau est à la fois non toxique et efficace.

Recommandation 11: VNR-R pour le chrome

Position: Le Mali appuie l'adoption de la recommandation.

Justification: Il y'a peu d'information en ce qui concerne le chrome, même s'il est en général admis qu'il joue un rôle important dans le métabolisme du corps. Les autres OSCR devraient être encouragés à effectuer des examens plus approfondis sur cet élément, soit pour confirmer le niveau ci-dessus, soit pour former la base de sa révision à l'avenir.

Recommandation 12: VNR-R pour le chlorure

Position: Le Mali est favorable à l'adoption de la recommandation.

Justification: 3 000 mg est basé sur le rapport molaire du sodium au chlorure, qui est la principale source de chlorure dans le corps. Etant donné que le comité a déjà adopté une VNR de 2 000 mg de Na et que l'OMS recommande une consommation de 5 g (5 000 mg) de sel (principalement sous forme NaCl), donc 3 000 mg sera une VNR adéquate pour Cl.

Recommandation 13: Équivalents alimentaires de la vitamine A et facteurs de conversion

Position: Le Mali appui l'adoption de la recommandation.

Justification: Cela va permettre de faire la comparaison entre les différentes formes de la vitamine A et même d'interpréter les résultats.

Recommandation 14: Équivalents alimentaires de la vitamine E et facteurs de conversion

Position: Le Mali est favorable à l'adoption de la recommandation.

Justification: Cela va permettre de faire la comparaison entre les différentes formes de la vitamine A et même d'interpréter les résultats.

Recommandation 15: Titre et note en bas de page du deuxième tableau

Position: Le Mali appuie l'adoption de la recommandation.

Justification: Telle que modifiée, la note en bas de page ajoutera de la clarté au tableau et permettra d'assurer la cohérence dans les directives.

Recommandation 16: Définition des OSCR dans les Directives concernant l'étiquetage nutritionnel

Position: Le Mali est favorables à l'adoption de la recommandation.

Justification: Cela permettra d'améliorer la compréhension commune de la terminologie.

Recommandation 17: Compte-rendu des décisions sur les VNR-R

Position: Le Mali soutient l'adoption de la recommandation.

Recommandations 18 et 19: Approche en vue d'établir des VNR-R pour les nourrissons du deuxième âge et les enfants en bas âge

Position: Le Mali est favorable à l'adoption des deux recommandations.

FoodDrinkEurope

Recommendation	Comments
1. NRV-R for Vitamin A	Given the relatively low UL of vitamin A and the availability of carotenoids in most diets, it is better to keep the recommended value for vitamin A at its lower edge, i.e. 700 µg (in line with EFSA). However, the current value of 800 µg, which corresponds to IOM value could be accepted.
2. NRV-R for Vitamin D	FoodDrinkEurope supports point A and B 10 µg. This is the most recent review. It is appropriate even in countries with low sunlight exposure (Nordic countries). Moreover, the DIRV is also based on the INL ₉₈ which is a preferred selection criterion i.e. allows for a wide population group. It's important to consider also bone health as vitamin D is essential for calcium absorption. (This is also the most recent DRV from the UK SACN Draft Vitamin D and Health report). As a general comment, we note that more and more scientific evidence is available on the importance of vitamin D in multiple key functions of the body. In addition, there is a high prevalence of deficiency around the globe and across population group.
3. Footnote to NRV-R for Vitamin D	We would not recommend a footnote as it is not useful and will cause confusion. The relationship between skin exposure to UVB sunlight and the resulting serum 25(OH)D concentration is much less well defined because it is complicated by a number of factors (season, time of day, amount of skin exposed, skin pigmentation, pollution and use of SPF sunscreen). Moreover, the adoption of [in winter] for 10 µg is misleading as the winter months is for a period of 3 months, and depending on latitude vitamin D synthesis from sunlight exposure is negligible from October – March i.e. a period of 6 months.
4. NRV-R for Vitamin E	FoodDrinkEurope prefers 12 mg/day, as per the EFSA opinion.
5. NRV-R for Iron	In line with our previous remarks, FoodDrinkEurope is still of the opinion that, for the time being, iron should have only one NRV; we are concerned about the paucity of data underpinning the dietary absorption assumptions for iron. Data is not strong enough to support multiple NRVs. In addition, EFSA recently published its draft Scientific Opinion on Dietary Reference Values for Iron , which indicates that <i>"DRVs do not need to be derived for vegetarians as a separate population group because the bioavailability of iron from European vegetarian diet is not substantially different from diets containing meat."</i> This strengthens the argument for having only one single NRV. Looking at the different proposed values, most of them are close to the current value of 14 mg. In addition, the averages of all of them corresponds to a value of 13.9 mg. In this context, the current NRV for Iron could be acceptable, as a pragmatic approach for labelling purposes.
6. Dietary Description for Iron	See Recommendation 5. The dietary descriptions are not relevant if using only one single NRV.
7. Footnote to NRV-R for Iron	See recommendation 5. Footnote is not relevant.
8. NRV-R for Magnesium	FoodDrinkEurope prefers the EFSA value of 325 mg, but could accept a value between 300 and 325 mg.
9. NRV-R for Phosphorus	FoodDrinkEurope agrees with a NRV-R of 700 mg.
10. NRV-R for Copper	FoodDrinkEurope agrees with a NRV-R of 900 µg.
11. NRV-R for Chromium	FoodDrinkEurope does not support a value for Chromium, due to insufficient data. In addition, we consider that a NRV for labelling is not needed for Chromium for the general population.

12. NRV-R for Chloride	We support establishing a NRV-R for Chloride, but we would recommend waiting for the EFSA Scientific Opinion on DRV for chloride (latest systematic review of the scientific evidence) that is expected to be issued soon. However, we could support an equimolar value with sodium to simplify implementation. The amount expressed in milligrams is appropriate and we would prefer 3000 mg for now.
13. Vitamin A Dietary Equivalents and Conversion Factors	FoodDrinkEurope agrees with A and D. B: Only one unit with the corresponding factors has to be included to avoid confusion and this should be 'RE' and not 'RAE'. We support the WHO/FAO (2006) conversion factors 1:12:24, and recommend using them. C: we do not support this recommendation and the differentiation between natural and synthetic vitamin A, as it is confusing and too complex in particular from an analytical point of view.
14. Vitamin E Dietary Equivalents and Conversion Factors	FoodDrinkEurope agrees with A and B. C: we do not support this recommendation and the differentiation between natural and added vitamin E, as it is confusing and too complex in particular from an analytical point of view.
15. Second Table Heading and Footnote	FoodDrinkEurope supports this.
16. RASB Definition in Guidelines on Nutrition Labelling	FoodDrinkEurope supports this. Since, based on the collective work, we have defined the term "RASB", we think the definition should be well-understood and made clearly available. It should therefore be included in the Annex with the other definitions.
17. RECORD of NRV-R DECISIONS	FoodDrinkEurope strongly supports this.
18. Draft General Principles for NRVs-R for Older Infants and Young Children	FoodDrinkEurope supports this. However, the proposed paragraph X.2.3 in the text has to be corrected in order to align with all the age range.
19. Consequential amendments to age of general population in Nutrition Labelling Guidelines	FoodDrinkEurope supports this.