

CODEX ALIMENTARIUS COMMISSION



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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Agenda Item 3

**CX/NFSDU 10/32/3
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

**CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
32nd Session**

**Santiago, Chile
1 – 6 November 2010**

**PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT
REFERENCE VALUES OF VITAMINS AND MINERALS FOR THE GENERAL
POPULATION**

- Comments at Step 6 of the Procedure -

Comments from:

ARGENTINA

AUSTRALIA

COSTA RICA

MEXICO

NEW ZEALAND

PARAGUAY

UNITED STATES OF AMERICA

IDF - International Dairy Federation

IFT - Institute of Food Technologists

ARGENTINA

Argentina welcomes the opportunity to make the following comments:

References

Text in bold: text observed in the document

Text in italics: justification

2. DEFINITIONS

2.1. **The individual nutrient level**₉₈ (INL₉₈) is the daily nutrient intake value that is estimated to meet the nutrient requirements of 98 percent of apparently healthy individuals in a specific life stage and gender group.

*With respect to this point, Argentina considers that it ought to be part of the definition of the term "**intake**" considering the phrase "individual nutrient intake level" does not seem to be the most adequate because it tends towards confusion in relation to the definition, which refers to the needs of 98 % of the population. Section 2.1 would be the following:*

2.1. **The individual nutrient level**₉₈ (INI₉₈)¹ is the daily nutrient intake value that is estimated to meet the nutrient requirements of 98 percent of apparently healthy individuals in a specific life stage and gender group.

2.2. The maximum intake (UL) is the **habitual** maximum intake level originating from all sources of a nutrient whose probabilities of causing harmful effects for the health of humans are considered to be reduced.

With respect to this point, Argentina is of the opinion that the term "habitual" is confusing. It is necessary to handle this definition with care and to take into account that it is not the habitual intake, but the intake that is proven to produce adverse effects.

Note 1 (footnote)

1 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), to name a few examples.

2 Other countries may use different terms for this concept: Tolerable Upper Nutrient Intake Level (UL).

Argentina states that it would be advisable to produce a translation to Spanish of the various English abbreviations with the aim of standardising language among the various Spanish-speaking countries and in texts published in Spanish.

Argentina is in agreement with the rest of the document and concurs with the provisions set out, taking into account the provisions in its applicable standards.

AUSTRALIA

Australia wishes to make the following further comments on the draft General Principles.

General Comments

Australia notes the separate work being undertaken on the development of principles for establishing nutrient reference values for nutrients associated with risk of diet-related noncommunicable diseases

(NRVs-NCD), and that this work is seeking to retain where applicable consistency with the text and organisation of the General Principles for NRVs for vitamins and minerals.

We also note that these General Principles are not applicable to the younger age population group of 6 – 36 months and that it is intended that further work be undertaken, as a separate second step, to consider principles for this age group. We understand that this is expected to involve using the draft General Principles as a basis and modifying where appropriate for the younger age group.

Specific Comments

Preamble

Australia proposes changes to the 2nd paragraph of the Preamble to make clear that there are two circumstances in which governments may choose to establish their own NRVs, these being either for nutrients with NRVs as listed in the *Codex Guidelines on Nutrition Labelling*, or for any additional nutrients. In addition we have also suggested a word change (deletion shown as ~~strike through~~ and additions as **bolded text**) to better reflect meaning as follows:

‘A government may ~~select~~ **choose** 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 nutrient reference values for labelling purposes **both for nutrients with NRVs and for any additional nutrients.**’

Section 3A Selection of suitable data sources to establish NRVs

We note concurrent work now underway on establishing draft Additional or Revised NRVs using these General Principles as well as work developing draft principles for establishing nutrient reference values for nutrients associated with risk of diet-related noncommunicable diseases (NRVs-NCD). As this work progresses, this may raise issues that warrant refinement of the General Principles for NRVs for vitamins and minerals. In particular Australia would support inclusion in the General Principles of additional criteria for selection of suitable data sources as has been proposed in the draft principles for establishing

NRVs-NCD (CX/NFSDU 10/32/7). We suggest replacement of the second sentence in this section with the following:

‘Relevant and recent values ~~that reflect independent review of the science~~, from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration.

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

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

Section C Consideration of upper level of intake

Australia is unclear on how this principle is expected to be applied to consideration of suitable NRVs beyond a simple comparison.

Australia does not support this principle as a risk management strategy because it is not very targeted and assumes the unlikely event that the nutrient content of a food expressed as % [adult] NRV/serve or /100g would drive sustained behaviour change to increase the intake of that food or other sources of that nutrient (aiming for 100% [adult] NRV) which could then inadvertently exceed the UL of a young child. We prefer that the principle be deleted (and that it also not apply to consideration of NRV-NCDs).

Given that CCNFSDU is considering expanding the list of NRVs to include NRVs-NCDs, this Committee could refer a request to CCFL to consider an appropriate risk management strategy that

directly informs the consumer, such as a statement close to the Nutrition Declaration to the effect that % NRVs are based on adult requirement and these may be higher or lower for other population groups.

This could be done at the time that all NRVs are finalised.

COSTA RICA

In cases of vitamins A and C, they are particularly worrying because the values proposed are around 30% less than those of the Directives. While reviewing the Consultation of FAO/WHO experts for the vitamin and mineral requirements in human nutrition, we note that they used 1988 data for vitamin A and, consequently, we are not sure of the reason why the NRV was fixed at 550 µg RE/day for option 2 instead of the current value of 800 µg RE/day.

The same consultation of experts mentions that there is even a high prevalence of vitamin A deficiency in the region of the Americas, which would also support the need to establish a higher NRV for this nutrient.

Equally, for vitamin C, the consultation establishes a value of 45 mg/day instead of the current value of 60 mg/day, and we do not understand the change because literature reviews indicate that this value could be increased in the near future.

As a developing country, we believe that the new NRVs must be harmonised as far as possible with the aim of saving costs for local industries that have to use different labels to comply with the requirements of the target markets for their exports. For this reason, regarding the NRV for zinc and iron, we are inclined to select Option 1, which refers to the NRV with mineral bioavailability representing the bioavailability of the mineral better in the world dietary regimen, without including regulations permitting countries to calculate their own NRV to then be able to represent the probable bioavailability in the national dietary regimen better.

MEXICO

SUGGESTED AMENDMENTS	JUSTIFICATION
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 defined as individuals 36 months and older. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake total recommended intake and 2) as one way to compare the nutrient content between products.	It is suggested that the words dietary and healthful be eliminated due to the fact that the daily dietary intakes of a population cannot be classified.
In addition, governments may establish food label reference values that take into account country or region specific factors that affect nutrient absorption or utilization. Governments may also consider whether to establish separate nutrient label reference values for specific segments of the general population such as pregnant and lactating in the lactating period .	The translation of the words "lactancy women" to Spanish does not conform to the terms used in that language.
2. DEFINITIONS	
2.3. Reference nutrition values.- set of figures that serve as a guideline for evaluating and planning intake of nutrients by healthy and well-fed populations, which includes the	Mexico suggests including a definition for reference nutrition values in the document.

Recommended Daily Intake (RDI) and Suggested Daily Intake (SDI).	
3. GENERAL PRINCIPLES FOR ESTABLISHING VITAMIN AND MINERAL NRVs	
<p>A. Selection of suitable data sources to establish NRVs</p> <p>When establishing NRVs, relevant and recent daily intake reference values provided by FAO/WHO should be taken into consideration.</p> <p>Relevant and recent values that reflect independent evaluations of the scientific data and which originate from governmental and non-governmental scientific bodies that are competent, recognised and are different from FAO/WHO could also be taken into consideration.</p>	<p>Mexico believes that each country possesses governmental educational and research institutions that have experience relevant to the subject.</p>
<p>The NRVs for the general population must be determined by calculating the average value or values of a chosen reference population group 36 months and older. The nutrient reference values obtained by CCNFSDU are based on values for adult men (19 to 65 years old) and adult women (19 to 50 years old).]</p> <p>For the purpose of establishing these NRVs, the values for pregnant and lactating women in the lactancy period are excluded.</p>	<p>The translation of the words lactancy women to Spanish does not conform to the terms used in that language.</p>
FOOT OF PAGE	
<p>1 Other countries may use different terms for this concept: 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), NRV (Nutrient Reference Value), to name a few examples.</p> <p>2 Other countries may use different terms for this concept: Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range, to name a few examples.</p>	<p>It is suggested that the term NRV be added, in compliance with the proposal suggested in the definitions.</p>

NEW ZEALAND

- New Zealand is aware of parallel work items on nutrient reference values (NRVs) for labelling that are currently under critical review at different steps via the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU):
 - *‘Proposed Draft General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population’* (at Step 6) and,
 - *‘Principles and Criteria for the Development of NRVs for Labelling Purposes for Nutrients Associated with Risk of Diet-Related Noncommunicable Diseases.’* (at Step 3).
- To support a unified approach in the area of standards development, New Zealand would strongly encourage these two work items being brought together as soon as possible.
- Once these items are coordinated under one work item by CCNFSDU, the Committee will have to consider issues that are likely to arise where nutrient reference values for labelling purposes differ depending on whether they are based on the need to prevent deficiency or reduce the risk of diet related noncommunicable chronic diseases

PARAGUAY

PARAGUAY has studied this document at meetings chaired by the national coordinators of the sub-committee of the Codex Committee on Nutrition and Foods for Special Dietary Uses and the aforementioned sub-committee is in agreement with this document, wishing to point out that the tables of FAO and WHO are the common reference for our country and that it is important to avail of these updated values.

UNITED STATES OF AMERICA

The United States thanks the Delegation of the Republic of Korea for facilitating progress on this agenda item. We offer the following preliminary comments on the draft Codex provisions in Appendix III of ALINORM 10/33/26.

I. GENERAL COMMENTS

Coordination of work. The United States continues to support close coordination of the development of these principles and criteria with those for the separate but related agenda item on NRVs for nutrients associated with risk of diet-related noncommunicable diseases (NRVs-NCD). Accordingly, our comments aim to retain, wherever applicable, the same or similar text and organization for these two sets of principles, based on consideration of the text in Appendix III and the revised proposal of the draft principles for NRVs-NCD in the report of the electronic working group.

Numbering of Provisions. In the next revision of these principles, the Committee may wish to consider if the provisions in Section 3 should be numbered as follows:

3. GENERAL PRINCIPLES FOR ESTABLISHING VITAMIN AND MINERAL NRVs

3.1 Selection of suitable data sources to establish NRVs

3.1.1 Relevant and recent daily nutrient intake values provided by FAO/WHORelevant and recent values that reflect independent review of the science....

3.1.2 *(new proposed text below)*

3.2 Selection of the appropriate basis

3.3 Consideration of upper level of intake

II. SPECIFIC COMMENTS

1. PREAMBLE

2nd paragraph, 1st sentence

We propose adding the following bolded text to the end of this sentence:

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 nutrient reference values for labeling purposes, **both for these nutrients and for additional nutrients.**

Rationale: The added text helps to clarify the two circumstances in which it may be appropriate for governments to establish their own NRVs based on additional factors specific to a country or region.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVS

Selection of Suitable Data Sources to Establish NRVs

In addition, the United States supports adding the following text in new 3.1.2 which is proposed in the electronic working group report on draft general principles for NRVs-NCD:

(new 3.1.2) “Higher priority should be given, as appropriate, to values from recognized authoritative scientific bodies in which the evidence has been evaluated through a systematic review.”

Selection of the Appropriate Basis

2nd paragraph

The United States has the understanding that these general principles are intended to be applicable to the establishment of NRVs both now in the future. With that in mind, the Committee may wish to consider whether the following sentence with additional proposed edits shown would be more appropriate as a footnote providing specific information about the updated NRV values in 3.4.4 of the Codex Guidelines on Nutrition Labelling than as a general principle:

“**These** Nutrient Reference Values derived by the CCNFSDU are based on values for adult males (19 to 65 years) **(except that the B₆ and Vitamin D values are based on 19-50 years)** and females (19 to 50 years).”

With the above edits, the first sentence in this paragraph could then be slightly revised to read:

“The general population NRVs should be determined by calculating the mean values for a chosen reference population group older than 36 months **(e.g., adult males and females)**.”

The United States appreciates the opportunity to share these preliminary comments, and looks forward to progress on this agenda item this year

IDF - International Dairy Federation

The IDF respectfully requests that the following comments to be considered:

Preamble

IDF agrees with the statement that 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 nutrient reference values for labelling purposes.

The aim of setting NRVs for labelling purposes is to provide consumers with relevant information to enable them to make informed decisions as regards getting sufficient bioavailable vitamins and minerals from a healthy and balanced diet, without the need for supplements. This implies that regional food consumption patterns (and hence sources of nutrients) must be considered in setting suitable NRVs which may result in scientifically valid variations in different regions.

Following the above, IDF asks Codex to recognize and consider the importance of differences in food consumption patterns around the world (and hence sources of nutrients) to be taken into account when setting NRVs for labelling purposes.

NRV for calcium

IDF has a specific concern regarding the NRV for calcium which is proposed at 1000 mg. According to the Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Calcium (EFSA, 2006) “Foods vary widely in calcium content and bioavailability. The best sources are milk (120 mg/100 g) and milk products (up to 1100 mg/100 g), from which about 32% is absorbable, which is higher than most other natural food sources of calcium. In European diets about 45 to 70% of the dietary calcium intake is provided by dairy products.” In Japan, where dairy consumption is less than in Western countries, about 30% of the calcium intake is from milk according to the 2002 National Nutrition Survey by the Ministry of Health Labor and Welfare. Therefore, milk and milk products are a major calcium source in several parts of the world.

According to the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997), “source of calcium” may be used for solids which contain the vitamin or mineral in amounts that are at least 15% of the NRV and for liquids which contain the vitamin or mineral in amounts that are at least 7.5% of the NRV. Taking milk as a reference (120 mg calcium/100 ml), the proposed value of 1000 mg would allow to make a nutrition claim on milk as ‘source of calcium’ but not “high in” or “rich in” Calcium. As a consequence it is feared that consumers will no longer recognize the true value of milk as an excellent source of calcium which would not be in line with the purposes of the guidelines on nutrition labelling as it could be misleading for the consumer.

Reference:

EFSA. 2006. Tolerable Upper Intake Levels for Vitamins and Minerals by the Scientific Panel on Dietetic products, nutrition and allergies (NDA) and Scientific Committee on Food (SCF). Available at <http://www.efsa.europa.eu/en/scdocs/oldsc/ndaintakevitaminsminerals.htm> (access date 9 September 2010).

Protein NRV

IDF notes that the last paragraph of section 3.4. (ALINORM 10/33/26 Appendix IV) states that “.. information on protein may also be expressed as percentages of the Nutrient Reference Value”.

Although the current revision of the NRVs for labelling purposes in the Codex Guidelines on Nutrition Labelling considers NRVs for vitamins and minerals only, IDF considers that it is very important that the NRV for protein is retained in the Codex Guidelines on Nutrition Labeling in order to be able to properly label protein when applying nutrition labelling. Therefore, IDF asks that the protein reference value be cited in the proposed draft General Principles.

IDF is aware of suggestions that have been made at the 31st session of CCNFSDU to include reference to the protein NRV in the CCNFSDU ongoing work on NRVs for nutrients associated with risk of diet-related non communicable diseases (NCD). However, IDF would like to reiterate that protein is not related to increased or decreased risk of non-communicable disease (NCD) and should therefore not be encompassed in the Codex work on NRVs for nutrients associated with risk of diet-related NCD.

Vitamin K

IDF would like to ask CCNFSDU to consider a more in depth opinion on the Nutrient Reference Values (NRV) of Vitamin K, based on the differences between K1 and K2. New scientific data suggest that effects attributable to vitamin K may in fact be linked to vitamin K1, vitamin K2 or both. Recently, the European Food Safety Authority (2009) expressed an opinion on three health claims related to vitamin K and clearly differentiated between vitamin K1 and K2, and assessed their respective effects as well. In order to anticipate the future evolution of the research, IDF proposes to add “vitamin K1 + vitamin K2” in parenthesis besides the mention of “vitamin K”.

According to Schurgers et al. (2007) Vitamin K is a cofactor in the production of blood coagulation factor (in the liver) and matrix-Gla protein (cartilage and vessel wall). Accumulating evidence suggests that for optimal bone and cardio health relative high intakes of vitamin K are required. In food, the most important K vitamins are K1 notably found in green vegetables and some plant oils, and K2 composed of several longer chains of Menaquinones (MK)- MK-7 , M-8, MK-9- notably found in certain fermented foods, one example being cheese.

A major difference between the 2 vitamin K species is the very long half-life of MK-7 resulting in a much more stable serum level and higher accumulation during prolonged intake.

In addition, according to Hojo et al. (2007), the analysis of the different forms of Vitamin K in different cheese varieties show noticeable differences between the types contained in them, for instance one could observe in a certain cheese variety the amount of K2 ten times higher than K1.

References

European Food Safety Authority (EFSA). Scientific Opinion on the substantiation of health claims related to vitamin K and maintenance of bone (ID 123, 127, 128, and 2879), blood coagulation (ID 124 and 126), and function of the heart and blood vessels (ID 124, 125 and 2880) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2009; 7 (9): 1228

Hojo K, Watanabe R, Mori T and N Taketomo. Quantitive measurement of tetrahydromenaquinone-9 in cheese fermented by Propionibacteria. J. Dairy Sc., 2007, 90, 4078-4083.

Schurgers LJ, Teunissen KJF, Hamulyak K, Knapen, MHJ, Vik, H. and C Vermeer. Vitamin K-containing dietary supplements: comparison of synthetic vitamin K1 and natto-derived menaquinone-7. Blood, 2007, 109(8), 3279-3283.

IFT - Institute of Food Technologists

IFT believes that clarification is necessary regarding principles for establishing vitamin and mineral NRVs for healthy segments of the general adult population that exhibit increased nutritional needs due to life stage or gender. Nutrient needs increase during pregnancy and nursing, for example. Allowance for separate NRVs for certain subpopulations of the general population will help to prevent nutrient shortfalls in these groups. NRVs that recognize these increased needs, particularly for that of folic acid, can be important tools for managing public health needs. Among older adults, the increased need for vitamin B12 is well documented. However, establishing NRVs for the general population based on the increased needs of these particular subpopulations could result in needless overconsumption. Failure to recognize the increased nutrient needs of healthy subpopulations through labelling NRVs limits the usefulness of food labels as a tool that allows consumers to recognize and select foods that meet their unique nutritional needs. IFT therefore respectfully requests that guidance for the establishment of NRVs for segments of the general population be expanded in the current draft document.

Specifically, **Section 3. General Principles for Establishing Vitamin and Mineral NRVs**

Paragraph B. Selection of Appropriate basis could be modified as follows, indicated by text in *underlined italics*:

The NRVs should be based on Individual Nutrient Level 98 (INL₉₈). In cases where there is an absence of an established INL₉₈ for a nutrient for a specific sub-group(s), it may be appropriate to consider 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.

The general population NRVs should be determined by calculating the mean values for a chosen reference population group older than 36 months *excluding pregnant and lactating women and adults over 50 years.* ~~Nutrient Reference Values derived by the CCNFSDU are based on values for adult males (19 to 65 years) and females (19 to 50 years).~~

For the purpose of establishing ~~these~~ NRVs for specific segments of the general population, the daily nutrient intake value for the chosen reference population group should be used. ~~values for pregnant and lactating women should be excluded.~~

We also respectfully draw attention to the report (ALINORM 10/33/26) from the 31st CCNFSDU meeting where at several points (see paragraphs 62, 64, 69, 70 and 84) the linkage between ALINORM 10/33/26, Appendix III and the new work document CX/NFSDU 10/32/7 “*Proposed Draft Nutrient Reference Values (NRVs) for Nutrients Associated with Risk of Diet-Related Noncommunicable Disease for General Population*” was noted. We believe that the points in common between these two documents, as well as a third document ALINORM 10/22/26, Appendix IV “*Proposed Draft Revision of Codex General Principles for the Addition of Essential Nutrients to Foods*”, are important and point to the need for interdependent sets of guidance with an overarching goal of allowing Codex guidelines to make the food supply compatible with WHO’s Global Strategy on Diet, Physical Activity and Health. We recognize that it is not usual to comment on multiple documents simultaneously and so will submit coordinating remarks on these documents either in writing or verbally at the Committee session as they become available for comment.