codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8 **CX/NFSDU 06/28/8**
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CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

TWENTY-EIGHTH SESSION

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DISCUSSION PAPER ON THE PROPOSALS FOR ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR FOOD LABELLING PURPOSES

Prepared by South Africa

1. Background

At the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, the Committee decided that there was a need to update the Nutrient Reference Values (NRVs) that had been established following the Helsinki Consultation (September 1988). It was agreed that a circular letter would seek proposals for the addition or revision of the NRVs for labelling purposes. The proposals were to be submitted for consideration by an electronic working group coordinated by South Africa.

At the 26th session the Committee agreed that the purpose of revising NRVs was to establish reference values for the purpose of labelling that would apply to all foods. It was agreed that the discussion paper should address the following points:

- the development of principles for the establishment of NRVs, taking into account the guidelines developed by member countries in this area
- the need to establish NRVs for different population groups
- the revision of the current list of nutrients

The Committee also noted at the 26th Session that it did not appear feasible to convene a specific expert consultation on the revision of NRVs in the near future and welcomed the offer of the FAO and WHO to address the establishment of NRVs in the framework of expert consultations that would be convened in the future, including NRVs for carbohydrates and fats and oils.

At the 27th Session of the Committee the FAO indicated that the United Nations University will convene a technical workshop in collaboration with the FAO and WHO to look at the process and concepts of harmonization of nutrient requirement recommendations and that the report is expected in 2006.

At the 27th session the revised paper, based on comments received, was discussed. The paper covered:

- criteria for the establishment of NRVs
- proposals for four different population groups
- criteria for the selection of nutrients

The Delegate from South Africa outlined the different means of establishing NRVs in several countries, including the USA, Australia/New Zealand, the EC and South Africa. The Committee agreed that the Electronic Working Group should continue development of the discussion paper with a focus on:

- principles for the establishment of NRVs for labelling purposes
- the need to establish NRVs for different population groups, taking into account discussions and comments made at this Session.

2. MANDATE OF THE WORKING GROUP

At the 26th Session in November 2004 it was agreed that an electronic Working Group coordinated by South Africa should address the following points:

- development of principles for the establishment of NRVs, taking into account the guidelines developed by member countries in this area;
- the need to establish NRVs for different population groups; and
- the revision of the current list of nutrients.

Following discussions at the 27th session, the Committee agreed that the electronic Working Group coordinated by the Delegation of South Africa would revise the discussion paper with a focus on:

- principles for the establishment of NRVs for labeling purposes; and
- the need to establish NRVs for different population groups

3. Method of working

In March 2005 South Africa distributed a questionnaire to the members of the electronic working groups seeking views on criteria for NRV's, the selection of population groups for NRVs and the selection of nutrients. The discussion paper was prepared based on comments from the following countries and organisations: Australia, the European Community, South Africa, the United States of America, Council of Responsible Nutrition and the National Health Federation.

In March 2006 South Africa prepared a draft discussion paper inviting comments on principles for the establishment of NRVs for labelling purposes and the need to establish NRVs for different population groups. There was an opportunity to add new comments or to make suggestions on how to improve the format and lay-out of the document that was presented in the March 2006 draft discussion paper. Additional background information, such as the principles for the establishment of NRVs as taken from the IOM report, the Opinion of the European Community's Scientific Committee on Food (March 2003) and the Report of the Joint FAO/WHO Expert Consultation on Recommended Allowances of Nutrients for Food labelling purposes (Helsinki, 1988), that may be helpful and relevant, are included in this

updated report (Annexure 1). Annexures 1 and 2 explain the different terminology used by various countries and organisations across the world.

The comments received from the EWG since 2004 and the discussions as reflected in Alinorm 05/28/26 and Alinorm 06/29/26 are incorporated in this discussion document. Comments received in 2006 by the EWG will be made available in a separate Conference Room Document (CRD) as well as the updated version of the draft discussion document, which was circulated in March 2006 to EWG members.

4. Overview of existing situation - current practice in member countries

4.1 USA:

In 2005 the USA indicated that the Food and Drug Administration (FDA) identified in its regulations food label reference values for specific vitamins and minerals for the following populations groups:1) the general population over 4 years, 2) children under 4 years, 3) infants and 4) pregnant and lactating women. The food label reference values for the general population were generally derived by selecting the highest Recommended Dietary Allowance from among those established for adults and children 4 or more years of age (excluding pregnant and lactating women) by the National Academy of Sciences. In 2003, the Institute of Medicine of the National Academy of Sciences published a report, which, among other things, proposed guiding principles for the establishment of food label reference values for nutrients. In terms of the future, the FDA plans to consider the recommendations of this NRV EWG and to solicit comments from the public on whether the agency should update its label reference values, and if so, how. The USA anticipates that the agency will ask questions about individual nutrients in addition to more general questions about the populations for which label reference values are intended and the approach for establishing label reference values.

4.2 Australia/New Zealand

Comments provided by Australia in 2005:

Australia, jointly with New Zealand, is revising the official Nutrient Reference Values. This revision is based mainly on the United States/Canadian review of Dietary Reference Intakes, however consideration was also given to recommendations from the United Kingdom, Germany and the European Union. Other sources of relevant data were also considered. The revision retains the traditional concept of adequate physiological or metabolic function and/or avoidance of deficiency states as the prime reference point for establishing nutrient reference values, and deals with chronic disease prevention separately.

In the draft revisions of the Nutrient Reference Values for Australia and New Zealand. The following rationale is stated for their establishment:

"These recommendations are for healthy people and may not meet the specific nutritional requirements of individuals with various diseases or conditions, for pre-term infants, or for people with specific genetic profiles. They are designed for nutrition and health professionals to use as a reference for the dietary assessment of individuals and groups. They may also be used by public health nutritionists, food legislators and the food industry, in relation to dietary modelling and/or food labelling and food formulations."

Australia currently has 3 sets of Nutrient Reference Values for labelling purposes, namely:

- The general population
- Children aged 1-3 years; and
- Infants under the age of 12 months

The two categories for children in Australian regulations were selected because

- Products are specifically manufactured for infants and supplementary foods for young children; and

- There is a requirement that added vitamins and minerals, if claimed, should be declared in nutrition labelling including expressed as a percentage of the Australian recommended Dietary Intake per serving.

Codex currently has reference daily requirements for older infants and children listed in codex Guideline CAC/GL 08-1991 as a guide to the appropriate composition of products.

The rationale for selection of the number of age categories should be:

- the number of available products categories that are targeted to discrete age groups for which declaration of essential nutrients as a proportion of the Nutrient Reference Value are considered appropriate.

Australia considers that such declarations are appropriate for all foods except infant formula and follow-up formula, i.e., for infant foods and foods for young children as well as for people beyond that life stage more generally.

4.3 European Community

The existing EC legislation on NRVs for adults are based on the figures in the Codex Alimentarius Guidelines on nutrition labelling. In the EC legislation there are two sets of labelling reference values, one for foods intended for the population in general and one for foods intended to satisfy the particular nutritional requirements of infants and young children when appropriate complementary feeding is introduced. The upper age limit of young children in the EC legislation is "up to 36 months of age" which is in line with the definition in the Codex Standards on foods for special dietary uses intended for infants and young children, such as the standard on processed cereal-based foods. The NRVs for foods intended for infants and young children included in the EC legislation are based on the opinion expressed in 1992 of the Scientific Committee for Food[1]. These values are based on population reference intakes of children aged between 6 months and 3 years.

In 2003 the Scientific Committee on Food proposed that the "labelling reference values" should be based on the population reference intakes that are sufficient to satisfy the needs of the majority of the population.

4.4 South Africa

South Africa is in the process of revising NRV levels for the different population groups. South Africa intends to base the revised reference values on the RDA values from the US National Academy of Sciences (2000), using these values as the minimum requirement recommended to maintain health. South Africa will consider the role of NRVs in international trade. However, the health and well being of the consumer will remain a priority and South Africa is committed to provide optimum nutrition to the people of South Africa, including through new NRVs and by implementing the WHO Global Strategy on Diet, Physical Exercise and Health.

5. Criteria for establishing NRV's for food labelling purposes

[1] Nutrient and energy intakes of the European Community. Reports of the Scientific Committee for Food 31st series, Office for Official Publications of the European Communities, Luxembourg 1993

The following criteria were identified from the comments received from the EWG members and from additional information sources such as the Helsinki Expert Consultation report, the IOM report and the Opinion of the EC's Scientific Committee on Food.

5.1 Applications of Food Nutrients Reference Values

5.1.1 Consumers

Generally, consumers use nutrition labelling for the following purposes:

- to use the information about the nutrient content of food products to compare different products with one another.

- to assess a food product's contribution to an individual consumer's nutritional needs and preferences, in other words to assess the information about the nutritional value of certain foods so that they can choose foods to contribute to a healthy diet

- to use the information about the nutrient content of the food item to estimate its usefulness in an overall healthful diet in terms of its percentage contribution to the recommended nutrient intakes

Some members of the EWG indicated that they believed that the typical consumer is likely to assume that if a specific food contains a specific percentage of the NRVs for a nutrient, consumption of the reference quantity of the food is likely to provide specified percentages of his/her daily needs for the nutrient. Although NRVs are not intended to reflect nutrient needs of individual consumers or to serve as prescriptive endpoints but rather as general guidelines for consumers in making food choices, they should be easier to harmonize. The fact remains that all over the world consumers do use the NRVs to determine the adequacy of their daily nutrient intake, notwithstanding a Government's intention.

5.1.2 Use of NRVs by Regulatory Authorities

- A government may select to use the Codex Nutrient Reference Values (NRVs), or alternatively, establish reference values that take into account additional factors specific to a country or region. For example, at the national level, values for the general population may be based on population-based averages of science-based reference values for daily intakes of the different age-gender groups. In addition, the bioavailability of food sources for a nutrient such as iron in a country may influence recommended intakes of that nutrient and consequently, a country's food label reference values.

- Another application of NRVs by regulatory authorities is in nutrition labelling guidelines. They are used as a basis for the declaration of the content of a nutrient in a food in relation to a recommended intake. The recommended intake should be sufficiently adequate to meet the needs of the population using either RDA (97-98%) or EAR (50%). Some delegations believe that since NRVs are used as an indication of recommended intake, the levels used should be sufficiently adequate to provide for optimum nutrient intake to meet the needs of the highest percentage of the population.

- Ideally, NRVs should also facilitate international trade in food by reducing national regulatory barriers in terms of food labelling practices.

- In guidelines on nutrition claims the NRVs can be used as the basis for criteria for nutrition claims such as "sources of …", or "high in…" or comparative claims and certain health claims. In fact NRVs is an essential tool in the substantiation process for when a nutrition or health claim on a label is made.

- NRVs used in nutrition labelling could support actions by governments or private initiatives in the area of nutrition education, which targets the general public. Knowledge of the basic principles of nutrition and appropriate nutrition labelling contribute towards enabling consumers to make food choices appropriate to their individual needs.

5.1.3 Food manufacturers:

- NRVs could serve as an encouragement to food manufacturers to formulate more nutrient-dense foods, which could compensate for the decline in micronutrients in agricultural produce as a result of the depletion of trace nutrients in soil by commercial agricultural practices.

- Nutrition labelling expressed as a percentage of the NRVs provide a means for food manufacturers and retailers to become more aware of the nutritional properties of their products and to encourage them to emphasize these properties to consumers.

5.2 The basis of NRV's

5.2.1 The basis of the values in relation to the nutrient requirements of a population

Science-based reference values for daily intake of vitamins and minerals that are established by authoritative scientific bodies and that reflect independent reviews of the science shall be used as the basis for the NRVs. Higher priority may be given, as appropriate, to more recent references from authoritative scientific bodies.

There are two options for the basis of the values in relation to the nutrient requirements of a population, although in cases where estimated average requirements have not been established for certain vitamins and minerals or for populations groups such as infants, another reference values for nutrient requirements (e.g. Adequate Intake) may be established as an intake goal and used to establish NRVs. If the consumer is using the nutrition labelling information to compare the nutrient content of different products the basis of the selection for the NRVs will not affect such comparisons. However, the basis becomes important for the expression of the vitamin/mineral content of a food as a percentage of a reference value. The NRVs could be based on one of the following type of science-based reference value for daily intake:

Option 1:

[values that meet the requirements of 50 percent of an apparently healthy population]

Option 2:

[values that meet the requirements of majority (97 to 98 percent) of an apparent healthy population]

The advantages and disadvantages of each option could be:

Option 1

Advantages

Provides information about the usefulness of the food items in relation to the overall diet since it reflects the average nutritional needs and not the extreme needs of a few in the population.

Disadvantages

NRV based on the average requirement would indicate that consumptions of 100 percent of this amount would have only (approximately) a 50 percent probability of being adequate for the typical consumer.

Option 2

Advantages

Cover the needs of the majority of the population thus an individual can reasonably be confident that their own needs will be fulfilled if they consume the recommended intake. Whilst this approach results in NRVs of higher values than are recommended for certain groups, in general they would be well below what is generally considered upper safe levels. This option ensures coverage for the maximum percentage of the population. Annexure 4 shows a comparison of upper safe levels recommended by different scientific bodies.

Disadvantages

Could lead to an upward trend in the level of vitamins and minerals in foods due to the expected demands of the consumer for higher levels of nutrients as well as manufacturers' efforts to enhance nutrient value. However, this is not necessarily a disadvantage when one considers the safety margin between RDA and UL and even beyond UL to NOAEL. In some cases the safety extends as far as the LOAEL (Figure 1, Annexure 3).

5.2.2 The basis of the values of the NRVs in terms of age-gender groups

After the basis of the NRV is selected, either the recommended intake or the average requirement, the next consideration is the basis of the values selected. The two options most often considered are:

Option 1

The highest values from the different age-gender groups (such as pre-menopausal adult females for iron)

Option 2

A population- weighted average of the values – usually adult males and females equally weighted

If the purpose of the NRV used on the label is only to compare foods, any basis will serve this purpose, as long as it is consistently applied. However, if there are other purposes than the advantages and disadvantages of the two options, they need to be considered.

Option 1

Advantages

Use of the highest age-gender group value as the basis of the NRV would assure adequate nutrition to most consumers who read the label.

Disadvantages

Potential tendency to increasing levels of intakes of nutrients with the possible risk that certain population groups or individuals could have excessive intakes. There would need to be an

assessment as to whether any population groups could be at risk of exceeding the tolerable upper intake level for individual nutrients.

Option 2

Advantages

Less risk of individuals or population groups having increasing levels of intakes with the possible risk that they could have intakes that approach or exceed the tolerable upper intake level.

Disadvantages

If consuming the NRV quantity of a nutrient is taken as an indication of adequately meeting individual needs by a substantial fraction of the population, the population-weighted average would not be a benchmark of the nutrient requirements of about half the population.

5.2.3 The basis of NRVs in terms of different population groups

When developing tables that list science-based reference values for daily intakes that are applicable to the NRV population group(s), the following criteria should be used to select suitable sources for these values:

a. The sources should reflect independent reviews of the science by authoritative scientific bodies.

b. Higher priority may be given, as appropriate, to more recent references from authoritative scientific bodies.

In addition, the following criteria should be used in presenting science-based reference values for daily intakes from suitable sources:

a. The form of the nutrient upon which the science-based reference value is based should be identified.

b. The specific population group upon which the science-based reference value is based should be identified.

The following two tables summarizes:

- the current situation in member countries
- the recommendations of EWG members and the 3 Authoritative reports previously referred to:

Summary of the current situation in member countries

	0 to 12 months	6 to 12 months	6 months to 3 years	1 to 3 years	1 through 3 years	General population	Pregnant and lactating women	Other age groups
Australia/New Zealand	√			√		√		
EC			√			√		
SA				√		√		√
USA	√				√	√	√	

Summary of recommendations from various Authoritative Scientific Reports and EWG members

	0 to 12 months	6 to 12 months	1 to 3 years	1 through 3 years	6 months to 3 years	6 months to 4 years	Birth up to 3 years	Birth through 3 years	General population	Pregnant and lactating women	Other age groups	Other age groups
EC SCI Com						√			√			
Helsinki Report[6]									√			
IOM report[7]									√			√[7]
Australia/New Zealand		√	√						√[1]			
EC					√				√			
SA		√		√					√	√[3]		
USA[2]				√					√			
CRN[5]								√	√			√[5]
NHF							√		√	√		√[4]

1 Australia/NZ comments 2005: General population values based on a combination of other age groups achieved by either selecting the higher of the two midlife adults male or female values, or an average of the two

2. USA 2006: Taking into consideration the attached draft principles for selecting NRV population groups, we propose that at a minimum, the Committee consider updating the general population in the *Codex Guidelines for Nutrition Labelling.* In updating the general population , the Committee will likely consider the age range for which these values are intended (e.g., persons 3 years and older or persons 4 years and

older). In support of the former age range, it was pointed out at the 26th CCNFSDU session that certain Codex texts define "young children" as persons age 12 to 36 months. On the other hand, the Committee will want to also consider that some reference values for recommended intakes and/or upper levels of intake have been established for the age range 1 *through* 3 years[2]. While consideration of the frequently lower recommended intakes for the 1 through 3 year age range would not impact on a general population NRV if based on adult recommended intakes, the frequently lower upper intake levels could have implications for establishing a general population NRV in cases where the adult recommended intake value(s) exceed the upper level of intake value(s) for children 1 through 3 years of age.

We further note that since the establishment of the current , the list of nutrients with science-based reference values for daily intakes has not only increased, but the level of complexity in identifying values for individual nutrients has also increased. For example, the 1998 joint FAO/WHO expert consultation on human vitamin and mineral requirements identifies iron recommended nutrient intake values at four levels of bioavailability for 17 different life stage groupings (i.e, age, gender, pregnancy and lactation) for a total of 68 values. In addition, any updates to the current will need to also take into account recent science-based values for upper levels of intake. Thus, the Committee may wish to consider this increased complexity in decisions about the process for updating the general population and about whether to establish values for additional NRV population groups.

3. SA 2006: Only when a food product is marketed specifically for this particular group

4. NHF 2004/5: NHF would prefer to see NRVs set for the comprehensive range of age groups. If, however, the consensus in the EWG is to have only two sets of NRVs for labelling purposes, then we would recommend that the cut-off age for the group for infants and young children should be set at birth up to three years, on the grounds that birth through three years is an overly wide range for which to formulate a single NRV for this section of the population.

5. CRN 2005: CRN believes that the accuracy of nutrition advice provided through the label would be improved by having three groups of numbers: a) persons 13 years and older, b) children 4 through 12 years; and c) infants and children through 3 years. If CCNFSDU decides to develop only 2 sets of values CRN recommends a) persons 4 or more years and b) infants and children through 3 years, The latter groups should apply only to products specifically labelled and promoted for young children.

6. The Helsinki Consultation recognised that the current NRVs in the Codex Guidelines were based primarily on a single group of consumers, and considered the possibility of recommending different labelling requirements for specific consumers groups, for example, infants, young children, pregnant and lactating women and the elderly. It was recognised the labelling provisions for individual foods for special dietary uses were specified in standards for these products, and that therefore such provisions were beyond the scope of the present discussion. These included foods for infants and children up to the age of 3 years. Although the Consultation recognised that individual requirements for the intake of various nutrients were a function of age, sex, weight and physiological condition, it also recognised that, for most part, the same foods were eaten by all members of the population above three years of age. There it concluded that only a single Codex NRV should be established for individual nutrients, but that this should not represent the specific requirements of individuals in the population.

7. The IOM report stated under GUIDING PRINCIPLE 2: "…a single reference value is most appropriate for the Nutrition Facts box, but this value must be designed to be meaningful for a base population that is 4 years of age and older." " Because it is not practical to provide a DV for nutrition labelling for each of the 13 life stages groups, it is necessary to combine DRI's for the groups to produce a single DV for the general population." However, GUIDING PRINCIPLE 8 identifies 4 distinctive life stage groups namely (< 1 year based on EAR's or AI's of older infants [7 to 12 months], 1 to 3 years, pregnancy and lactation and recommends separate DVs for food for these four life stage groups.

In selecting population groups for NRVs, the following factors should be considered:

a. the main purpose of food label reference values for nutrients;
b. the anticipated use of the NRVs, given that some governments may establish country or region-specific food label reference values, and the resources required for the Committee to develop one versus multiple sets of science-based NRV values from complex data sources.
c. how food products are marketed (i.e., the extent to which products are marketed to the general public versus specific population groups) and practical considerations such as the amount of food label space; and
d. the lifestage (i.e., age, pregnancy and lactation) and gender that correspond to science based reference values for both: 1) recommended intakes and 2) upper levels of intake.

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[2] Human Vitamin and Mineral Requirements. Report of a Joint FAO/WHO Expert Consultation. Bangkok, Thailand. 2002; and Dietary Reference Intakes Tables-The Complete Set. Institute of Medicine, National Academy of Sciences. http://www.iom.edu/subpage.asp?id=7292

5.3 Regional differences

A government may select to use the Codex, or alternatively, establish other food label reference values that take into account additional factors specific to a country or region. For example, at the national level, values for the general population may be based on population-weighted averages of science-based reference values for daily intakes of the different age-gender groups. In addition, the bioavailability of food sources for a nutrient such as iron in a country may influence recommended intakes of that nutrient and consequently, a country's food label reference values. Similarly, genetic differences in a specific population could have an influence, e.g., a high incidence of haemochromatosis in a population will affect the determination of the NRV for iron in that region.

5.4 Practical considerations

Space available on packaging and other non-scientific factors should take into account the non-scientific factors that contribute to diverse needs, demands and expectations among the various users and stakeholders of NRVs. These include considerations related to pragmatism (simplicity, available label space, comprehensibility and avoidance of confusion by the consumer, consistency over time), maintaining economic fairness across products and producers, supporting economic innovation in the marketplace, supporting and protecting consumer values and interests and minimizing confusion in the marketplace. The fact is these values and interests can be informed by science, but, by definition cannot be resolved by science alone. Many of the major conflicts and controversies surrounding the guidelines arise from this basic fact and therefore suggest a need to consider whether and how the contributions of scientific experts might be strengthened and complemented by more explicit stakeholder-based deliberations.

6. Conclusions and Recommendations for consideration by CCNSDFU

6.1 CCNFSDU should consider, reach consensus and expand where necessary on the validity of the criteria identified above;

6.2 CCNFSDU should consider and reach consensus on the number of NRV population groups;

6.3 Consensus on 6.1 and 6.2 are essential in order to proceed to the next step, which is consideration of how to develop tables that identify the science-based reference values from suitable references according to agreed upon principles;

6.4 CCNFSDU should come to final decision on how the protein NRV would be updated. Currently the Codex Guidelines for Nutrition Labelling (CAC/GL 2-1985) (Rev.1-1993) includes protein in addition to vitamins and minerals. While the report of the 26th CCNFSDU session indicated that the Committee welcomed the offer of the FAO and WHO to address the establishment of NRVs in the framework of expert consultations that would be convened in the future, including for carbohydrates (2006) and fats and oils (date to be determined) the report did not specifically address how the protein NRVs would be updated (ALINORM 05/28/26, para 38-40);

6.5 The Committee should consider and reach consensus on which nutrients will be focussed on at first. Although the Committee at the 26th Session had an exchange of views on the substances that should be included in the list of NRVs, and one member country (EC) indicated that the list should focus on vitamins and minerals and should not include other substances such as fatty acids, lutein, choline and lycopene, the discussion did not conclude final consensus on the issue. The question is should the revision NRVs focus first on vitamins and minerals only to get the process going and continue with the other substances such as protein, fatty acids, lutein, choline, lycopene and other substances later?; and

6.6 It is the opinion of most EWG members as reflected in their comments since 2004, as well as the opinions expressed in the reports of the Joint FAO/WHO Expert Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes (Helsinki,) and the European Community 's Scientific Committee on Food (March 2003) that ***consumers use the information about the nutrient content of the food item to estimate its usefulness in the overall diet in terms of its percentage contribution to the recommended nutrient intakes in order to select a diet based on the individual preferences and nutritional needs.*** It thus appears that consumers will trust their governments to protect their health and well-being. This should be strong motivation to use recommended levels for optimum nutrient intake which would be in line with the proposed action recommended for CCNFSDU in paragraph 25 of CX 2/7.2 CL 2006/44-CAC (September 2006) regarding the REQUEST FOR COMMENTS ON DRAFT ACTION PLAN FOR IMPLEMENTATION OF THE GLOBAL STRATEGY ON DIET, PHYSICAL ACTIVITY AND HEALTH, namely that, Nutrient Reference Values be developed for nutrients that are associated with both increased and decreased risk of non-communicable diseases.

At the 27th Session of the Committee the FAO indicated that the United Nations University will convene a technical workshop in collaboration with the FAO and WHO to look at the process and concepts of harmonization of nutrient requirement recommendation and that the report is expected in 2006. Since recommended nutrient requirements for consumers are such an important principle, it may therefore be prudent to hold back on further work on the revision of NRV's until such time that the report of the above-mentioned technical workshop regarding nutrient requirement recommendations to provide at least the basis for harmonized nutrient requirement recommendations on which NRVs can be based upon, is available.

ANNEX 1

TERMINOLOGY

USA AND CANADIAN TERMINOLOGY:

- **DRI (Dietary Reference Intakes)**

  This term was developed in the USA and Canada and is a more complete set of reference values, including the RDA, AI (Adequate Intake), UL (Tolerable Upper Intake level) and EAR (Estimated Average Requirement). DRIs are expressed as intakes per day, but are meant to represent intakes averaged over time. As will be seen below, each DRI expression (RDA, AI, UL and EAR) has specific use.

- **Estimated Average Requirement (EAR):** the average daily nutrient intake level estimated to meet the requirement of half the healthy individuals in a particular life stage and gender group.

- **Recommended Dietary Allowance (RDA):** the average daily nutrient intake level sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group.

- **Adequate Intake (AI):** a recommended average daily nutrient intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of healthy people that are assumed to adequate—used when an RDA cannot be determined.

- **Tolerable Upper Intake Level (UL):** the highest average daily nutrient intake level likely to pose no risk of adverse health effects to almost all individuals in a particular life stage and gender group. As intake increases above the UL, the potential risk of adverse health effects increases.

BRITISH TERMINOLOGY

- **DRV (Dietary Reference Values)**

  This term was adopted and introduced in the UK in 1991 and reflects safe and adequate intakes. The term applies to the range of intakes based on an assessment of the distribution of requirements for each nutrient [10-11]. DRVs apply to groups of healthy people and are not appropriate for those with disease or metabolic abnormalities. As in the case of the USA/Canadian RDAs, the DRV for one nutrient presuppose that requirements for energy and all other nutrients are met. While the USA/Canadian DRIs give two values for most nutrients (an EAR and RDA), the British DRVs give three values for most nutrients: the LRNI, EAR and RNI. For some nutrients, the DRVs give a “safe intake”, and for carbohydrate and fat, individual minimum, maximum and population averages are specified.

- **LRNI (Lower Reference Nutrient Intake)**

  This term is part of the British DRVs and describes the mean or average intake (EAR) minus a notional two standard deviations. Intakes below this level will be inadequate for nearly all of the population.

- **EAR (Estimated Average Requirement)**

As in the case of the USA and Canada, the British EAR reflects the intake that meets the estimated nutrient need of half the individuals in a group, assuming normal distribution of variety.

- **RNI (Reference Nutrient Intake)**

  This British term reflects the RDA of the USA and Canada and the PRI of the European Union. It is, therefore, two standard deviations above the EAR. If only one value is given in summary tables, this is usually the value chosen.

- **Safe intakes**

  For nutrients where there is insufficient data to set a DRV, a safe intake is judged to be *a level* or *range of intakes* above which there is no risk of deficiency and below a level where there is a risk of undesirable effects. The upper level when a range of intakes is given will correspond to the USA and Canadian UL, while the lower level is similar to the AI.

- **Individual minimum, maximum and population averages**

  These terms are used by the British for specific carbohydrate and fat needs.

EUROPEAN COMMUNITIES TERMINOLOGY:

- **PRI (Population Reference Intake)**

  This term was introduced by the European Union in 1993 and reflects acceptable range of intakes. It is set at the mean requirement plus two standard deviations and is therefore similar to the USA/Canadian RDA and British RNI.

- **LTI (Lowest Threshold Intake)**

  This European Union term is similar to the British LRNI and describes the mean intake minus two standard deviations. Intakes below this level will be inadequate for nearly all of the individuals in a group.

- **ARI (Average Requirement Intake)**

  This term reflects the average requirement (Estimated nutrient need of half the individuals in a group) and is similar to the USA and British EAR.

- **Acceptable range**

  A range of safe values given where insufficient information is available. It is similar to the British safe intakes and AI of the USA/Canada.

EC: Opinion of the Scientific Committee on Food on the revision of reference values for nutrition labelling (March 2003)

RLV (Reference Labelling Values). The RLVs correspond with the Codex's Nutrient Reference Values (NRVs).

WHO (WORLD HEALTH ORGANIZATION) TERMINOLOGY:

The WHO, together with the FAO (Food and Agriculture Organization) and the UNU (United Nations University) published a number of recommendations (reference values) for different groups of nutrients over time and use the following terms for some nutrients:

- **Basal requirement**

  This term refers to the mean requirement to prevent clinically detectable signs of impaired function attributable to inadequacy of the nutrient.

- **Normative requirement**

  This term is used for the mean requirement to maintain a level of tissue storage that is judged to be desirable.

  Population-level intake recommendations were also suggested for trace elements in (1996). These recommendations consider both the variability of intakes and the variability of requirements to establish a safe range of population mean intakes.

- **Upper limit of the population mean intake**

  This is the upper limit of safe ranges of population mean intakes. It is set so that only 2-3% of individuals would have mean intakes above the average threshold of toxicity for a nutrient.

- **Lower limit of the population mean intake**

  This is the lower limit of safe ranges of population mean intakes. It is set so that only 2-3% of individuals would have usual intakes below the average requirement.

  It should be mentioned that the WHO goals for macronutrients are markedly different from the DRIs. The latter refer to limits for usual intakes of individuals, while the WHO goals refer to populations or large group mean intakes.

OTHER IMPORTANT TERMINOLOGY

No Observed Adverse Effect Level (NOAEL)

The highest level of intake at which no chronic, long-term adverse effect has occurred.

Lowest Observed Adverse Effect Level (LOAEL)

The lowest level of intake at which a chronic, long-term adverse effect has occurred.

ANNEX 2

Table 1: Terminology : abbreviations

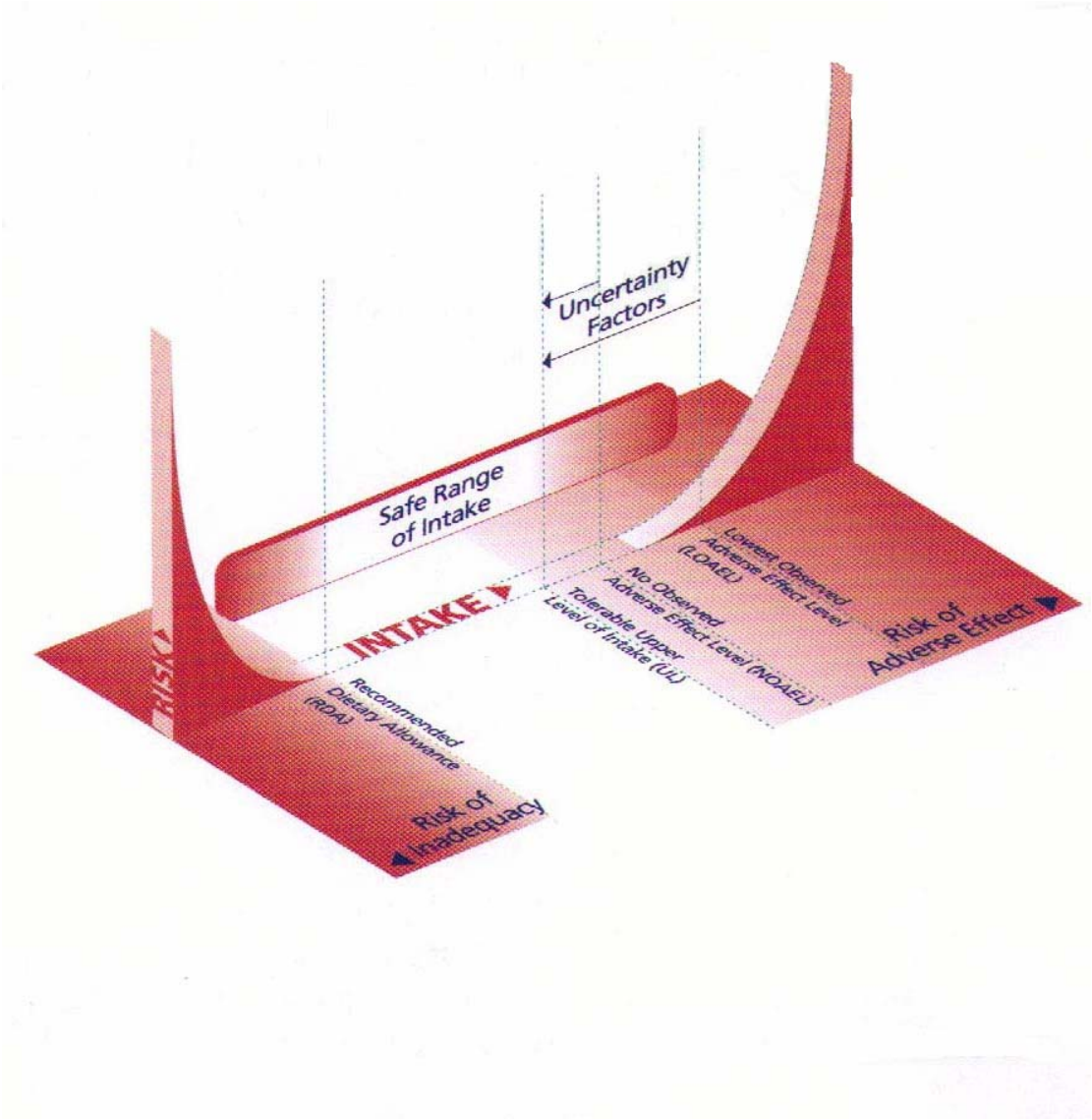
1.	***USA/Canada***	
	RDA:	Recommended Dietary Allowance
	DRI:	Dietary Reference Intake
	EAR:	Estimated Average Requirement
	AI:	Adequate Intake
	AMDR:	Adequate macronutrient distribution range
	UL:	Tolerable Upper Intake Level
2.	***UK***	
	DRV:	Dietary Reference Values
	LRNI:	Lower Reference Nutrient Intake
	EAR:	Estimated Average Requirement
	RNI:	Reference Nutrient Intake
3.	***European Community***	
	PRI:	Population Reference Intake
	LTI:	Lowest Threshold Intake
	ARI:	Average Requirement Intake
	RLV	Reference Labelling Value
4.	***WHO/FAO***	
	RNI:	Recommended Nutrient Intake
	UL:	Upper Tolerable Nutrient Intake Level
	General	
	NOAEL	No Observed Adverse Effect Level
	LOAEL	Lowest Observed Adverse Effect Level

Table 2: Summary of terminology with the same or similar application

USA/CANADA		**UK**		**EC**
DRI	=	DRV		-
RDA	=	RNI	=	PRI
EAR	=	EAR	=	ARI
-		LRNI	=	LTI
AI	=	Safe intakes	=	Acceptable range

ANNEX 3

Fig. 1: Safety of vitamins and Minerals



Source: The safety of Vitamins and MineralsAn overview of the US Institute of Medicine's risk assessment

ERNA 2002

(European Responsible Nutrition Alliance)

ANNEX 4

The U.S. Food and Nutrition Board (FNB) of the Institute off Medicine (IOM), a component of the National Academies; the European Commission Scientific Committee on Food (EC SCF); the United Kingdom Expert Group on Vitamins and Minerals (UK EVM), Japan, the Council for Responsible Nutrition (CRN) The European Responsible Nutrition Alliance (ERNA) have all reviewed and/or published comprehensive risk assessments for vitamins and minerals.

TABLE 1*: INTERNATIONAL COMPARISONS OF UPPER SAFE LEVELS FOR VITAMINS AND MINERALS IN NUTRITIONAL SUPPLEMENTS FROM CRN, US FNB, EC SCF, UK EVM AND JAPAN

* Source: John N. Hathcock, Ph.D, Vitamin and Mineral Safety, 2nd Edition, 2004. Council for Responsible Nutrition. Washington, D.C. Available at http://www.crnusa.org

	CRN ULS[1] 2004[1]	**US FNB UL[2]**	**EC SCF UL**	**UK EVM SUL[3] OR GL[4]**	**JAPAN UL[5] (1999)**
ELEMENTAL VITAMINS	***SUPPLEMENTAL INTAKE ONLY***	***TOTAL INTAKE EXCEPT AS SPECIFIED***	***TOTAL INTAKE EXCEPT AS SPECIFIED***	***TOTAL INTAKE OR SUPPLEMENTAL INTAKE AS SPECIFIED IN TEXT***	***TOTAL INTAKE***
Vitamin A (RE) (retinal and its esters)	1500 µg /5000 IU High food retinol 3000 µg /10000 IU Low food retinal	3000 µg	3000 µg (for women of childbearing age)	1500 µg total (GL) (for bone effects)	1500 µg
Vitamin D	60 µg /2400 IU	50 µg	50 µg	25 µg supplement (GL)	50 µg
Vitamin E	1000 mg/1490 IU	1000 mg	300 mg	540 mg supplement (800 IU) (SUL)	600 mg
Vitamin K	10 mg	Not established	Not established	1 mg supplement (GL)	30 mg
Thiamine (Vitamin B_1)	100 mg	Not established	Not established	100 mg supplement (GL)	Not established
Riboflavin (Vitamin B_2)	200 mg	Not established	Not established	40 mg Supplement (GL)	Not established
Niacin/ Nicotinic Acid	500 mg[7] 250 mg (slow/time release formulations)[8] 35 mg flushing	35 mg[9,10]	10 mg[10]	17 mg[10] supplement (GL)	30 mg
Nicotinamide	1500 mg	35 mg[9]	900 mg	500 mg supplement (GL)	Not established
Pyridoxine (Vitamin B_6)	100 mg	100 mg	25 mg	10 mg supplement (SUL) chronic intake	100 mg
Folic Acid	1000 µg	1000 µg	1000 µg	1000 µg	1000 µg
Cyanocobalamine (Vitamin B_{12})	3000	Not established	Not established	2000 µg supplement (GL)	Not established
Biotin	2500 µg	Not established	Not established	900 µg supplement (GL)	Not established
Pantothenic Acid	1000 mg	Not established	Not established	200 mg supplement (GL)	Not established
Vitamin C	2000 mg	2000mg	No UL (1000 mg Guidance level)[6]	1000 mg supplement (GL)	Not established

ELEMENTAL MINERALS					
Boron	6 mg	20 mg	Not reviewed	9.6 mg (SUL)	Not established
Calcium, mg	1500	2500 mg	2500 mg	1500 supplement (GL)	2500 mg
Chromium	1000 µg (any form of Cr III)	Not established	Not established	10000 µg (not picolinate) (GL)	250 µg
Copper	9 mg	10 mg	5 mg	10 mg total (SUL)	9 mg
Iodine	500 µg	1100 µg	600 µg	500 µg supplement 930 µg total (GL)	3000 µg
Iron	60 mg full stomach	45 mg empty stomach	Not reviewed	17 mg supplement (GL)	40 mg
Magnesium	400 mg	350 non-food sources	250 non-food sources	400 mg supplement (GL)	650 to 700 mg
Manganese	10 mg	11 mg	Not established	4 mg supplement 12.2 mg total (GL)	10 mg
Molybdenum	350 µg	2000 µg	600 µg	230 µg food (GL)	250 µg
Selenium	200 µg	400 µg	300 µg total	350 µg supplement total 450 µg total (SUL)	250 µg
Zinc	30 mg	40 mg	25 mg	25 mg supplement (SUL)	30 mg

1 ULS = CRN's Upper Level for Supplements
2 UL = Tolerable Upper Intake Level (applies to total intake unless specified otherwise)
3 SUL = Safe Upper Limit (may apply to either total or supplemental intake, as specified)
4 GL = Guidance Level (may apply to either total or supplemental intake, as specified)
5 Japanese Ul values in English are available only as a table and therefore not discussed in text of this publication, but have been added to this chart to extend international comparisons
6 EFSA (European Food Safety Authority) assumed this assessment function in place of EC SCF in January 2004
7 Based on liver and gastrointestinal toxicity
8 SR = slow-release (time release) formulations of nicotinic acid
9 FNB UL for Niacin is set for both nicotinic acid and nicotinamide
10 Based on vasodilative flushing reaction