



**NATIONAL
HEALTH
FEDERATION**

A NOT-FOR-PROFIT HEALTH-FREEDOM ORGANIZATION

***National Health Federation Comments
on Discussion Paper Prepared by the United
States and Thailand re Nutrient Reference Values
(NRVs) for Nutrients Associated with Risk of
Noncommunicable Diseases***

15 September 2009

GENERAL COMMENTS

Background

The draft should make clear that, although it has been decided to limit the present scope of work to vitamins and minerals (an approach that was contrary to the NHF's written recommendations made to the CCNFSDU in June 2004, March 2007, and June 2008), there are a wide range of other important micronutrients which are required by consumers, these including essential fiber, fatty acids, amino acids, nucleotides, phytonutrients, enzymes, probiotics, and prebiotics. Failure to make clear the importance of micronutrients other than vitamins and minerals – as well as recommendations for particular categories and sub-categories of macronutrients – would be both misleading and a disservice to consumers. It would also be contrary to the general principles laid out in the WHO's Global Strategy on Diet, Physical Activity, and Health.

The range of factors that contribute to a variation in micronutritional requirement between individuals should also be made clearer. Factors that should be expanded upon include, but are not limited to: variations in dietary intake; genetic make-up; ethnicity; gender; life stage; lifestyle; body weight; health status; physiological/immunological stress; and mobility/exercise regimen.

COMMENTS ON SPECIFIC QUESTIONS

Question A1. For establishing principles and criteria for NRVs-NCD, do you support a similar organization as for the vitamin and mineral NRVs with separate sections for a Preamble, Definition(s), and General Principles at a minimum?

Response: Yes, because this will track better the format and organization of other Codex documents.

Question A2. Do you support the above topics under general principles or have other suggestions?

Response: In the past, NRVs, usually expressed as RDAs, have been a vehicle for merely attempting to ensure the minimal necessary health to avoid death (such as in the case of preventing scurvy through small amounts of Vitamin C) or extreme ill-health (such as arguably in the case of the small amounts of Vitamin D). This is an outmoded and narrow-minded way of thought. A far better approach would be to take this opportunity to consider NRVs as a vehicle for optimizing health, particularly in strengthening the body so as to prevent noncommunicable diseases. Therefore, we

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propose that the topic “Consideration of values that would optimize human health” be added to the list of general principles.

Question B1. How would you describe the population(s) for which NRVs-NCD would be applicable? For example, do you support their applicability to the “general population”?

Response: NHF believes that there are population groups to which NRVs-NCD would be applicable. In that sense, the second question is vaguely worded since the NRVs-NCD would of course be applied to the “general population” but with further explanation. That is, various differences within the general population should be considered. An NRV-NCD that might be appropriate for an adult female may very well not be for an adult male, and vice versa. It would be inappropriate and remiss on our part to not take into account such important biological and physiological differences within the general population group.

Question B2. If the answer to the second question above is “yes”, is there a need to further define an age range for the “general population”? If so, what criteria should be used for defining this age range?

Response: Yes, as mentioned above, there is most definitely a need for further definition. Given the above, the NHF does not think it is appropriate to issue a single value for each NRV for a given population group.

As stated by the NHF during the CCNFSDU’s 29th Session (see page 21, paragraph 131 of Report), the NHF had proposed the idea of providing an NRV for the population group with the greatest requirement. Given that this was not accepted by the Committee, the NHF, having consulted with medical doctors working in the field of clinical and functional medicine, wishes to propose an alternative approach. This would involve the publication of a **Nutrient Reference Range (NRR)**, in addition to an NRV. Ranges are already widely used in the medical profession for such markers as cholesterol, triglycerides, and hormones and are well understood by the consumer. An average value is scientifically weak compared with a range of values, given that the average represents nothing more than a mathematical approximation of a given range (each with variable statistical distributions) and does not necessarily indicate a requirement for an individual. The range could be comprised of the 10th centile requirement for the lowest value in the range and the 90th centile for the highest value.

The NHF proposes that a nutrient range is an extremely useful indicator, but for it to have scientific value, as well as value to the consumer, it must be based upon

the most recent scientific evidence, that includes an assessment of all available, and the most recent, observational and clinical evidence, as well that derived from qualified experts with the greatest experience and knowledge of the effects of micronutritional intake and supplementation, namely medical doctors practicing clinical nutritional or functional medicine. The range should also take into account the requirement for optimum health, rather than provide the minimum value for the prevention of certain well-known vitamin or mineral deficiency-related diseases (e.g. scurvy, beri-beri, rickets, pellagra, anemia, etc.).

Age-specific Reference Values. Given that the Committee has agreed to develop NRVs for infants by 2012 (that is, by the 34th Session of the CCNFSDU), it is important that current NRVs, and any subsequent modifications to NRVs, are expressly indicated to exclude infants. To ensure that the risk of young persons being exposed to excess nutrients – a concern of some Codex delegations such that they are inclined to support an Average Requirement/Estimated Average Requirement (AR/EAR) approach rather than a highest-level approach – the NHF recommends that a clear indication is made that the values apply to adults only, with further indications of any additional exemptions (e.g., pregnant or lactating women). This could be by way of a footnote describing the meaning of the value or range of values.

It is important to remember, though, that the Estimated Average Requirement is defined as the usual intake level that is required to meet the requirement of *half* the *healthy* individuals in a life stage and gender group. At this level of intake, the other half of the healthy individuals would not have their needs met. Therefore, the NHF in no way condones or suggests use of an AR/EAR approach or application.

A *highest* RDA/PRI approach, while more valid than any approach utilizing either weighted RDA/PRI or highest ARs, is only scientifically valid if it takes into account the following factors:

- a) dietary intake
- b) genetic make-up
- c) ethnicity
- d) gender
- e) life stage
- f) lifestyle
- g) body weight
- h) health status

- i) physiological/immunological stress
- j) mobility/exercise regimen.
- k) The most recent clinical and published evidence (from observational and clinical studies)

Based upon the above, NRV-NCD values could be established for multiple life stages, as previously suggested by the NHF. These would provide a more nuanced approach and would include the following:

- Infants 0-6 months
- Infants 7-12 months
- Children 1-3 years
- Children 4-8 years
- Males 9-13 years
- Males 14-18 years
- Males 19-70 years
- Males > 70 years
- Females 9-13 years
- Females 14-18 years
- Females 19-70 years
- Females > 70 years
- Pregnancy
- Lactation

An assessment of the existing proposed *highest* RDA/PRI values, though, demonstrates very clearly that the levels for adults are still well beneath those that would be typically considered, by medical doctors practicing clinical nutrition or functional medicine, both safe and beneficial (particularly in terms of reducing the risk of chronic, degenerative diseases) for the majority of individuals.

Question C1: Do you agree that the purpose and use of the NRVs-NCD should be addressed in a preamble in the development of general principles for these NRVs?

Response: Yes.

Question C2: If so, do you have comments on the above possible adaptation of text in the vitamin and mineral NRV preamble or other suggestions for text to describe the purpose and use of NRVs-NCD?

Response: The NHF suggests that the words “one way” be used in preference to “a means” since the wording “one way” is more vivid and absorbable by the human mind when reading the text. In addition, NHF supports the deletion of the first struck-through sentence (“*For example, at the national level, population weighted values for the general population may be established by weighting science-based reference values for daily intakes for age sex groups using census data for a country and proportions of each age sex group.*”) because it merely amplifies the problem NHF mentioned above whereby an average requirement leaves at least half of the population at a huge nutritional disadvantage.

NHF supports retention, however, of the second struck-through sentence because there could exist nutrient absorption or utilization factors specific to a country or region that could also impact these nutrient values. The Working Group and the Committee need to be careful to avoid adopting a “one size fits all” approach out of sheer convenience or even laziness. Consumer health is too important for that approach.

Most importantly, though, we propose the addition of the words “and optimize health” be added to the end of the first sentence reading, “*These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as (one way/a means) to compare the nutrient content between products.*”

Question D1: Is there a need for a definition section in the general principles, and if so what term(s) should be defined?

Response: We have generally found a need for definitions in Codex texts, with this document being no exception. All major terms of art used in this text should be defined, but especially NRVs-NCD and, if adopted, NRRs.

Question D2: In the Annex to this paper, do you support option 1 or 2 or another option?

Response: Of the two choices, Option 1 may be the better wording. However, NHF suggests that a blend of the two, or an Option 3, could be better overall. The suggested wording would be as follows: “**Nutrient Reference Values – Noncommunicable Disease (NRVs-NCD)** refer to Codex nutrient reference values for food labeling purposes for nutrients, the lack or less-than-optimal amounts of which are associated with risk of noncommunicable diseases, including diet-related chronic diseases.”

Question E1: Do you agree that the Committee should consider CCFL proposals for expanding the list in section 3.2 but also consider additional factors and criteria in proposing nutrients for NRVs-NCD?

Response: Yes, sodium should be included. Additionally, it is inappropriate, and indeed even irresponsible, to publish revised values, if a range of other key essential nutrients are missing from these determinations. Very obvious omissions are currently: Vitamin E; Vitamin K; pantothenic acid; biotin; inositol; potassium; sulfur; chromium; and phosphorus. Omissions may give the consumer the impression that these nutrients are of lesser value than those for which values are published, or, worse still, are of no nutritional significance.

Question E2: Do you support including sodium and saturated fat in the scope of nutrients to be considered for NRVs-NCD?

Response: The NHF supports including sodium (as well as the other additional, above-named nutrients) for consideration for NRVs-NCD. The NHF has mixed opinions on the inclusion of saturated fats, but generally notes that given an adequately-nutritional-dense diet, saturated fats are not typically a health problem in that cholesterol is not a major cause of heart disease, rather it is calcification of the arteries. Establishing an NRV-NCD for saturated fat would mislead the consumer away from the true cause of heart disease. Moreover, there are other sources of saturated fat than from meat; and consumers could be misled by high vegetable sources of saturated fats that are not necessarily harmful, given the above facts.

Question F1: What are your views about the use of the above criteria for the development of NRVs-NCD?

Response: These three criteria are a good start, but, as written, the criteria are not comprehensive enough.

Question F2: Are there other criteria that are applicable?

Response: Other criteria for the establishment of NRVs-NCD are that they should be based upon those amounts necessary to prevent disease, promote optimum health, and prolong lifespan in the majority of the general population.

Question F3: What are your views about the use of the above principles and criteria for selection of suitable data sources in the development of NRVs-NCD?

Response: The referenced principles and criteria for suitable data sources appears to be very limited in that they call only for consideration of sources outside of FAO/WHO in establishing NRVs only when FAO/WHO has not set such values! **That is an incredible and unbelievable limitation**, especially when many respected scientific bodies throughout the World would be ignored as possible sources of information. Does this Codex Committee really think that FAO/WHO holds a monopoly on such scientific thought? With all due respect to FAO/WHO, they do not. Why unnecessarily limit ourselves? The Committee can still select and choose amongst many other reputable sources in establishing NRVs-NCD.

Therefore, the introductory language should preferably read:

“Relevant and recent values provided by FAO/WHO and other recognized and authoritative scientific bodies should be taken into consideration in establishing NRVs.” [delete the second, following sentence as unnecessary]

Question F4: Are there other principles and criteria that are applicable?

Response: Please see our response immediately above. In addition, the NHF holds that published data sources from nutritional surveys are presently insufficient to allow scientifically meaningful values for global application. Data relating to trace and ultra-trace elements, for example, are particularly inadequate. In the absence of adequate data, there can be no alternative but to gain interim input from a panel of experts, derived from leading medical doctors practicing in the fields of clinical nutrition and functional medicine.

It would be quite irresponsible to continue such work if the appropriateness and benefits of any values were not considered by a panel of experts with the greatest expertise in this field. **A great concern is that most of the expertise presently being deployed in the development of NRVs is derived from experts in the field of risk assessment, who utilize primarily published data, based upon highly precautionary models.** At no time has clinical expertise been sought, nor has there been adequate input from experts deeply familiar with the beneficial effects of nutrients and micronutrients, their ability to promote optimum health and minimize risk of disease. Again, we strongly recommend that an expert panel with relevant clinical expertise be established to allow a meaningful review of proposed values.

Question F5: Do you have suggestions for specific references that the Committee

should consider based on the above criteria?

Response: Please see our response to Question F3 above.

Question F6: Based on your responses to F1 through 5 above and consideration of any other relevant information, are there particular nutrients that should receive the highest priority for the development of NRVs-NCD?

Response: Vitamin C, Vitamin D, Folic Acid, Magnesium, and Selenium.

Question G1: With regard to daily intake reference values from recognized authoritative scientific bodies that are expressed as a percentage of caloric intake, do you support establishing a Codex NRV-NCD based on a reference diet of 2000 calories or another calorie level?

Response: Yes, if any Codex NRV-NCD is to be established, then it should be based upon a 2000-calorie diet.

Question G2: Do you agree that any single daily reference caloric intake selected for the Codex NRVs-NCD may not be applicable to all countries? If so, do you support: 1) indicating this in the general principles, and 2) including in any proposed table on NRVs-NCD not only the NRVs-NCD based on the single reference caloric intake (in milligrams or grams), but also daily intake reference values for the selected nutrients (as a percentage of calories) for governments to derive their own values based on another reference caloric intake?

Response: Yes, the NHF agrees. This is exactly why the suggested Nutrient Reference Ranges (NRRs) would accommodate this variability. NRRs should be acceptable to all Codex members and INGOs as a viable compromise that makes sense given this variability.

Summary of Specific Recommendations

1. A range of daily intakes (NRRs) is much preferable to a single value, as indicated above. These ranges should not only be based on experimental data, as these data are often too limited to be applicable to all key sub-population groups. It is critical that observational studies as well as clinical evidence are taken into account. An expert panel comprising leading medical experts in the field of clinical nutrition and functional medicine should be assigned to assist with this work. The Institute of Functional Medicine (www.functionalmedicine.org) is probably the World's largest repository of such international expertise and the IFM should be contacted to assist in gathering an international panel of experts for this purpose, for evaluation by the Committee.

2. A highest RDA/PRI approach is preferred over the weighted RDA/PRI or highest AR approach, but it is essential that all factors and the most recent scientific evidence is taken into account in determination of any values. These determinations should consider evidence from observational and clinical studies, as well as input from medical doctors practicing in the field of clinical nutrition and functional medicine. A panel of such experts should be consulted in the determination of these levels.

3. Data for "missing nutrients" should be included as a matter of priority, and revised values should not be published until such time as agreed upon.

4. The NHF considers that, in the absence of adequate international sources of data, it is of utmost importance to establish a panel of medical experts with extensive clinical experience in the fields of clinical nutrition and functional medicine. Input from this panel will be invaluable in dealing with deficiencies in the quality or applicability of existing sources of data from existing international and national authorities

5. We propose that the re-evaluation and development of NRVs cannot be continued without bringing to bear a new expert panel with extensive clinical