

CODEX ALIMENTARIUS COMMISSION



**Food and Agriculture
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Agenda Item 4

**CX/NFSDU 10/32/4 -Add.3
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING

- Comments at Step 3 of the Procedure -

Comments from:

EU

NHF

European Union

The European Union (EU) has the following comments on the Proposed Draft Additional or revised Nutrient Reference Values for labelling purposes in the Codex Guidelines on Nutrition Labelling (ALINORM 10/33/26).

The EU notes that for the proposed Nutrient Reference Values for labelling purposes (NRVs) under 3.4.4. there are issues that require further consideration. It is stated in the General principles that relevant and recent daily nutrient intake values provided by FAO/WHO should be taken into consideration as primary source, however, that also recent values that reflect independent review of science from other recognized authoritative scientific bodies could be taken into consideration.

For some of the nutrients there might be more recent data available than that considered by the FAO/WHO report which is basing the values on an expert consultation in 1998. Therefore, the Committee may wish to consider for certain nutrients, such as vitamin A, vitamin C and folate where there is a major difference in the current Codex values and the proposed new values, the need for further consideration of the proposed values. The EU suggests consideration be given to referring the question to the newly established Joint FAO/WHO Expert Meetings on Nutrition (JEMNU).

The EU notes that the figures proposed for Phosphorus, Chloride, Copper, Fluoride, Manganese, Chromium, Molybdenum are based on the Dietary Reference Intake values from the Institute of Medicine (IOM) reports. The inclusion of these figures should be considered without prejudice to recommendations from other authoritative bodies. In particular, in the case of chloride the EU notes from the IOM 2005 Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate report that the recommendations are related to those for sodium. In the European Union the recommended daily allowance for nutrition labelling for chloride is based on the minimum level of intake, which seems to reflect the approach for the other nutrients in the table. Given the potential differences in approach, again the EU suggests that consideration be given to whether the advice of JEMNU should be sought for the nutrients for which there are no figures in the report of the FAO/WHO.

The EU notes that potassium has not been included in the list and would appreciate clarification of the reason for its omission.

Another question is the approach to rounding the figures. For example, consideration could be given to whether the figures for vitamin E, iron and zinc should be rounded to a whole integer. Another example is the case of thiamin where the average representative adult value has been rounded up to 1.2mg. As one of the reasons for following the option 2 is to have lower values it could equally have been rounded down to 1.1mg.

The EU notes that the terminology of “folic acid” has changed to “folate”. While the EU agrees to the value being expressed as “µg DFE”, it should be possible to label not only “folate” but also “folic acid” as this term may be best understood by a population in a country or region. It is possible that similar situations may arise for other nutrients such as the B vitamins. Therefore, there should be flexibility around the terminology used for the nutrients themselves. The EC wonders if there is a need for this to be explicitly included in the Guidelines.

Footnote 5, which comes from the existing Guidelines, indicates that the NRVs for vitamin D and iodine may not be applicable in certain circumstances. It is not clear on which basis these nutrients have been identified and the impact that the footnote has on the use of the NRVs. Therefore, the EC would ask whether this footnote is still applicable given the development of the general principles on the establishment of NRVs.

The EU notes that the NRV for protein is no longer in the list of nutrients in paragraph 3.4.4. The EU understands that the review is of the figures concerns the vitamins and minerals, however, the figure for protein should still be included in the list to ensure that at the end of the review process it is not deleted from the provisions in the Guidelines on Nutrition Labelling.

The National Health Federation

The National Health Federation (NHF), a non-profit consumer organization, respectfully submits the following comments:

General Overview.

As NHF argued at the last session of CCNFSDU, the proposed draft Nutrient Reference Values (NRVs) are already too low. For example, an NRV for Vitamin C at 60 milligrams is astoundingly low, especially considering, among many other things, that: (1) cigarette smokers alone destroy, on average, 60 milligrams of Vitamin C with each cigarette smoked; and (2) that this 60-mg level was never established for optimal health in the first place but instead simply as the level that would prevent death from scurvy caused by Vitamin-C deficiency. NRVs should and must be set for optimal health levels, not subsistence levels.

Therefore, it is extremely embarrassing to see this Committee actually moving away from optimal levels. Instead, some delegations have mistakenly proposed that lower NRVs be adopted for certain important vitamins and minerals, including Vitamin C. For example, the Proposed Draft Additional or Revised NRVs for Labelling Purposes in the Codex Guidelines on Nutrition Labelling suggests reducing the Vitamin A NRV from 800 micrograms down to 550 micrograms, Vitamin C down from an already-too-low 60 milligrams to 45 milligrams, Thiamin down from 1.4 milligrams to 1.2 milligrams, Niacin from 18 milligrams down to 15 milligrams, Magnesium down from 300 milligrams to 240 milligrams, and so forth.

While the suggestion to reduce these NRVs may be well-intended, the effect will be disastrous. Many consumers rely upon NRVs (or rather its national equivalent, RDAs and RDIs) to know whether or not they are obtaining enough of a necessary vitamin or mineral in their diets. They lack the training or general nutritional knowledge about optimal intake of specific amounts of these nutrients to be able to determine whether their diet is supplying a sufficient quantity or not of a particular vitamin or mineral. In other words, for them, if they see an NRV of 100% of a nutrient on a label, they will assume that they have consumed an adequate amount of that nutrient for the day, regardless of what the “hard” milligram or microgram numbers say on a label and regardless of whether or not that NRV is even true for them.

That is why establishing correct and health-optimal NRVs is important and not a task to be taken lightly or through the use of bad science.

Bad Science Is Behind the Current Effort to Downgrade NRVs.

Unfortunately, in setting these NRVs, this Committee is relying upon flawed science.

In its written comments (CX/NFSDU 10/32/4), the delegation of Costa Rica very correctly pointed out that the FAO/WHO expert consultation relied upon by CCNFSDU1 for these NRVs used 22-year-old data for Vitamin A. NHF has also noted that the data found for other nutrients is similarly out-dated and behind current nutritional knowledge.

Again, Costa Rica correctly posits that “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 future.” NHF concurs with this statement, except that we would not just say “could be increased in the future” but “should be increased in the future.”

NHF holds that published data sources from nutritional surveys used by the expert consultation 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. Yet, this incomplete expertise is exactly what this Committee is being asked to rely upon in downgrading its NRVs!

¹ *Vitamin and Mineral Requirements in Human Nutrition*, 2nd edition, FAO/WHO, 2004, at <http://whqlibdoc.who.int/publications/2004/9241546123.pdf>.

Again, we strongly recommend that an expert panel with relevant and broad clinical expertise be established to allow a meaningful review of proposed values and to then make proper recommendations to this Committee.

The NRV Levels Should be Increased.

The NHF strongly objects to the lowering of any of the vitamin and mineral NRVs (with the exception of fluoride and iron) as recent science has demonstrated repeatedly that these nutrients are needed in the daily diet at levels far higher than those provided by NRV amounts.

1. Vitamin A

For example, expanding upon the comments of Costa Rica, we note that the Helsinki Consultation in 1988 set an NRV for Vitamin A of 800 micrograms of retinol equivalent. In setting this figure, the Consultation took into consideration the relation between carotene and the prevention of cancer, and stated that although this subject had not yet been resolved from the scientific point of view, it considered that this aspect might lead to an increase in the international recommended daily intakes in the future when new scientific data was available. Since 1988, however, a large body of scientific evidence has clearly demonstrated that higher intakes of carotenes and/or pre-formed Vitamin A are protective against the development of a number of cancers.²

Although some research exists to suggest that large doses of beta-carotene may possibly be capable of increasing the risk of lung cancer in smokers, we consider that in view of the many important health benefits to be obtained from higher intakes of carotenes it would be irresponsible for the CCNFSDU to recommend

² Cancer Epidemiol Biomarkers Prev. 2003 Aug;12(8):713-20, "Premenopausal intakes of vitamins A, C, and E, folate, and carotenoids, and risk of breast cancer," Cho E, Spiegelman D, Hunter DJ, Chen WY, Zhang SM, Colditz GA, Willett WC; Br J Cancer. 2003 May 6;88(9):1381-7, "Dietary intakes of vitamins A, C, and E and risk of melanoma in two cohorts of women," Feskanich D, Willett WC, Hunter DJ, Colditz GA; J Biol Regul Homeost Agents. 2003 Jan-Mar;17(1):92-7, "Retinoids in chemoprevention of cancer," Verma AK; Plant Foods Hum Nutr. 2002 Fall;57(3-4):319-41, "Palm oil: biochemical, physiological, nutritional, hematological, and toxicological aspects: a review," Edem DO.; Asian Pac J Cancer Prev. 2001 Jul-Sep;2(3):215-224, "A Study of Various Sociodemographic Factors and Plasma Vitamin Levels in Oral and Pharyngeal Cancer in Gujarat, India," Patel PS, Raval GN, Patel DD, Sainger RN, Shah MH, Shah JS, Patel MM, Dutta SJ, Patel BP; Cancer Sci. 2003 Jan;94(1):57-63, "Serum carotenoids and mortality from lung cancer: a case-control study nested in the Japan Collaborative Cohort (JACC) study," Ito Y, Wakai K, Suzuki K, Tamakoshi A, Seki N, Ando M, Nishino Y, Kondo T, Watanabe Y, Ozasa K, Ohno Y; JACC Study Group; Curr Drug Metab. 2003 Feb;4(1):1-10, "Retinoic acid metabolism and mechanism of action: a review," Marill J, Idres N, Capron CC, Nguyen E, Chabot GG; J Am Coll Nutr. 1995 Oct;14(5):419-27, "Epidemiologic studies of antioxidants and cancer in humans," Flagg EW, Coates RJ, Greenberg RS; Bibl Nutr Dieta. 1995;(52):75-91, "Cardiovascular disease and vitamins. Concurrent correction of 'suboptimal' plasma antioxidant levels may, as important part of 'optimal' nutrition, help to prevent early stages of cardiovascular disease and cancer, respectively," Gey KF; Cancer Causes Control. 2001 Feb;12(2):163-72, "Dietary patterns, nutrient intake and gastric cancer in a high-risk area of Italy," Palli D, Russo A, Decarli A; Soz Praventivmed. 1989;34(2):75-7, "Vitamins and cancer: results of a Basel study," Stahelin HB; Am J Epidemiol. 1991 Apr 15;133(8):766-75, "Plasma antioxidant vitamins and subsequent cancer mortality in the 12-year follow-up of the prospective Basel Study," Stahelin HB, Gey KF, Eichholzer M, Ludin E, Bernasconi F, Thurneysen J, Brubacher G; Ital J Gastroenterol. 1991 Sep-Oct;23(7):429-35, "Gastric cancer in Italy," Cipriani F, Buiatti E, Palli D; EXS. 1992;62:398-410, "Inverse correlation between essential antioxidants in plasma and subsequent risk to develop cancer, ischemic heart disease and stroke respectively: 12-year follow-up of the Prospective Basel Study," Eichholzer M, Stahelin HB, Gey KF; Int J Cancer. 1994 Mar 1;56(5):650-4, "Serum micronutrients in relation to pre-cancerous gastric lesions," Zhang L, Blot WJ, You WC, Chang YS, Liu XQ, Kneller RW, Zhao L, Liu WD, Li JY, Jin ML, et al.; Am J Epidemiol. 1994 Mar 1;139(5):466-73, "Nutritional factors and gastric cancer in Spain," Gonzalez CA, Riboli E, Badosa J, Batiste E, Cardona T, Pita S, Sanz JM, Torrent M, Agudo A; Int J Cancer. 1994 Jun 1;57(5):638-44. Nutrients and gastric cancer risk, "A population-based case-control study in Sweden," Hansson LE, Nyren O, Bergstrom R, Wolk A, Lindgren A, Baron J, Adami HO; Int J Cancer. 1995 Mar 16;60(6):748-52, "Attributable risks for stomach cancer in northern Italy," La Vecchia C, D'Avanzo B, Negri E, Decarli A, Benichou J; Zhonghua Yu Fang Yi Xue Za Zhi. 1995 Jul;29(4):198-201, "Relationship between serum micronutrients and precancerous gastric lesions," Zhang L, Zhao L, Ma J; Int J Cancer. 1996 Apr 10;66(2):145-50, "Prediction of male cancer mortality by plasma levels of interacting vitamins: 17-year follow-up of the prospective Basel study," Eichholzer M, Stahelin HB, Gey KF, Ludin E, Bernasconi F; Cancer Lett. 1999 Feb 8;136(1):89-93, "Serum antioxidative vitamin levels and lipid peroxidation in gastric carcinoma patients," Choi MA, Kim BS, Yu R; Int J Cancer. 1998 Nov 9;78(4):415-20, "Nutrient intake patterns and gastric cancer risk: a case-control study in Belgium," Kaaks R, Tuyns AJ, Haelterman M, Riboli E; J Nutr. 2002 Apr;132(4):756-61, "A dietary oxidative balance score of vitamin C, beta-carotene and iron intakes and mortality risk in male smoking Belgians," Van Hoydonck PG, Temme EH, Schouten EG.

lower intakes for the entire population, as a means of protecting smokers, when official WHO policy is to substantially reduce the incidence of tobacco use. Tobacco, not carotene, is the main cause of lung cancer in smokers.

We also consider that the case for Vitamin A being linked to birth defects has been overstated in most cases. In one study, for example, no birth defects were reported among 120 infants exposed to maternal intakes of Vitamin A greater than 50,000 IU per day.³ In addition, compared to the infants that were not exposed to high maternal doses of Vitamin A the infants in this study who were exposed to high doses actually experienced a 50% decreased risk for birth defects. In fact, excessive dietary intake of Vitamin A has been associated with birth defects in humans in fewer than 20 reported cases over the past 30 years.⁴ Other data suggests that 30,000 IU of Vitamin A per day should be considered safe for pregnant women.⁵

In short, the most-recent and up-to-date data indicate that **the NRV for Vitamin A should actually be set substantially higher – at a range of 1000 to 1400 micrograms.**

2. Vitamin C

Similarly, it is unthinkable to consider lowering the NRV for Vitamin C when the current level of 60 milligrams is not even sufficient to keep the population in optimal health. Anyone suggesting *lowering* the NRV for Vitamin C is completely out of touch with the latest science on nutrition and is relying on old and flawed data.

Fortunately, both the delegations of Costa Rica and China point the proper way forward, that is, to increase the NRV. Costa Rica's position on Vitamin C has already been discussed above, and the NHF agrees with Costa Rica's written comments.

In addition, the delegation of China correctly suggested in its written submission to the 31st session of CCNFSU (CRD 19) that the NRV for Vitamin C be – not decreased – but increased to 100 milligrams. This kind of foresight is clearly a step in the right direction and an example to follow.

The NHF holds, however, that a strong argument exists for increasing the NRV for Vitamin C even more dramatically. (See NHF's written comments to CCNSFUDU, submitted as early as June 2004.)

Studies have shown that several population groups have an inadequate intake of Vitamin C, and that deficiencies of ascorbic acid are far more prevalent than is commonly believed.⁶ Moreover, patients suffering from dementia,⁷ epilepsy,⁸ preeclampsia,⁹ gallbladder disease,¹⁰ schizophrenia,¹¹ coronary artery

³ Mastroiacovo P, Mazzone T, Addis A, Elephant E, Carlier P, Vial T, Garbis H, Robert E, Bonati M, Ornoy A, Finardi A, Schaffer C, Caramelli L, Rodriguez-Pinilla E, Clementi M, "High vitamin A intake in early pregnancy and major malformations: a multicenter prospective controlled study," *Teratology*. 1999 Jan;59(1):7-11.

⁴ Biesalski HK, "Comparative assessment of the toxicology of vitamin A and retinoids in man," *Toxicology* 1989;57:117-61).

⁵ Wiegand UW, Hartmann S, Hummler H, "Safety of vitamin A: recent results," *Int J Vitam Nutr Res* 1998;68:411-6 [review].

⁶ Chapman KM, Ham JO, Pearlman RA, "Longitudinal assessment of the nutritional status of elderly veterans," *J Gerontol A Biol Sci Med Sci*. 1996 Jul;51(4):B261-9; Yin S, Su Y, Liu Q, Zhang M, "Dietary status of preschool children from day-care kindergartens in six cities of China," *Wei Sheng Yan Jiu*. 2002 Oct;31(5):375-8; Weinstein M, Babyn P, Zlotkin S, "An orange a day keeps the doctor away: scurvy in the year 2000," *Pediatrics*. 2001 Sep;108(3):E55; Hampl JS, Taylor CA, Johnston CS, "Intakes of vitamin C, vegetables and fruits: which schoolchildren are at risk?" *J Am Coll Nutr*. 1999 Dec;18(6):582-90; Vannucchi H, da Cunha DF, Bernardes MM, Unamuno MR. Brasil, "Serum levels of vitamin A, E, C and B2, carotenoid and zinc in hospitalized elderly patients," *Rev Saude Publica*. 1994 Apr;28(2):121-6; Boulinguez S, Bouyssou-Gauthier M, De Vencay P, Bedane C, Bonnetblanc J, "Scurvy presenting with ecchymotic purpura and hemorrhagic ulcers of the lower limbs," *Ann Dermatol Venereol*. 2000 May;127(5):510-2; Werbach MR, "Nutritional strategies for treating chronic fatigue syndrome," *Altern Med Rev*. 2000 Apr;5(2):93-108; Dejmeck J, Ginter E, Solansky I, Podrazilova K, Stavkova Z, Benes I, Sram RJ, "Vitamin C, E and A levels in maternal and fetal blood for Czech and Gypsy ethnic groups in the Czech Republic," *Int J Vitam Nutr Res*. 2002 May;72(3):183-90; Clow CL, Laberge C, Sriver CR, "Neonatal hypertyrosinemia and evidence for deficiency of ascorbic acid in Arctic and subarctic peoples," *Can Med Assoc J*. 1975 Oct 4;113(7):624-6; Sauberlich HE, "Human requirements and needs. Vitamin C status: methods and findings," *Ann N Y Acad Sci*. 1975 Sep 30;258:438-50; Dawson KP, Richardson WW, Orsborn CE, "The leucocyte ascorbic acid levels of children in hospital," *N Z Med J*. 1977 Feb 23;85(582):141-3. 4; Stephen R, Utecht T, "Scurvy identified in the emergency department: a case report," *J Emerg Med*. 2001;21(3):235-237.

⁷ Tabet N, Mantle D, Walker Z, Orrell M, "Endogenous antioxidant activities in relation to concurrent vitamins A, C, and E intake in dementia," *Int Psychogeriatr*. 2002 Mar;14(1):7-15.

disease,¹² cerebral vascular disease,¹³ esophageal, stomach and colorectal cancers¹⁴ and gastric cancer,¹⁵ have all been found to have significantly lower levels of Vitamin C than are found in normal healthy people. This suggests that their Vitamin-C needs are greater and that an NRV of 45-60 milligrams would be insufficient.

- Similarly, the risk of stroke has been shown to increase significantly with a decreased intake of Vitamin C,¹⁶ and low levels of ascorbic acid are implicated in the development of gastric cancer,¹⁷ periodontal disease,¹⁸ and cardiovascular disease.¹⁹ A high intake of ascorbic acid, on the other

⁸ Sudha K, Rao AV, Rao A, "Oxidative stress and antioxidants in epilepsy," *Clin Chim Acta*. 2001 Jan;303(1-2):19-24.

⁹ Kharb S, "Vitamin E and C in preeclampsia," *Eur J Obstet Gynecol Reprod Biol*. 2000 Nov;93(1):37-9; Panburana P, Phuapradit W, Puchaiwatananon O, "Antioxidant nutrients and lipid peroxide levels in Thai preeclamptic pregnant women," *J Obstet Gynaecol Res*. 2000 Oct;26(5):377-81.

¹⁰ Simon JA, Hudes ES, "Serum ascorbic acid and gallbladder disease prevalence among US adults: the Third National Health and Nutrition Examination Survey (NHANES III)," *Arch Intern Med*. 2000 Apr 10;160(7):931-6.

¹¹ Suboticanec K, Folnegovic-Smalc V, Turcin R, Mestrovic B, Buzina R, "Plasma levels and urinary vitamin C excretion in schizophrenic patients," *Hum Nutr Clin Nutr*. 1986 Nov;40(6):421-8; Suboticanec K, Folnegovic-Smalc V, Korbar M, Mestrovic B, Buzina R, "Vitamin C status in chronic schizophrenia," *Biol Psychiatry*. 1990 Dec 1;28(11):959-66.

¹² Delport R, Ubbink JB, Human JA, Becker PJ, Myburgh DP, Vermaak WJ, "Antioxidant vitamins and coronary artery disease risk in South African males," *Clin Chim Acta*. 1998 Nov;278(1):55-60; Singh RB, Ghosh S, Niaz MA, Singh R, Beegum R, Chibo H, Shoumin Z, Postiglione A, "Dietary intake, plasma levels of antioxidant vitamins, and oxidative stress in relation to coronary artery disease in elderly subjects," *Am J Cardiol*. 1995 Dec 15;76(17):1233-8; Singh RB, Niaz MA, Bishnoi I, Sharma JP, Gupta S, Rastogi SS, Singh R, Begum R, Chibo H, Shoumin Z, "Diet, antioxidant vitamins, oxidative stress and risk of coronary artery disease: the Peerzada Prospective Study," *Acta Cardiol*. 1994;49(5):453-67; Gey KF, "Vitamins E plus C and interacting conutrients required for optimal health. A critical and constructive review of epidemiology and supplementation data regarding cardiovascular disease and cancer," *Biofactors*. 1998;7(1-2):113-74; Akkus I, Saglam NI, Caglayan O, Vural H, Kalak S, Saglam M, "Investigation of erythrocyte membrane lipid peroxidation and antioxidant defense systems of patients with coronary artery disease (CAD) documented by angiography," *Clin Chim Acta*. 1996 Jan 31;244(2):173-80.

¹³ Chen JH, Liu XJ, Wang QC, Zeng H, Jiang XP, "Study on the changes in endogenous oxidation agents and levels of anti-oxidation agents in patients with cerebral vascular disease," *Zhongguo Wei Zhong Bing Ji Jiu Yi Xue*. 2003 Apr;15(4):232-4.

¹⁴ Skrzydlewska E, Kozusko B, Sulkowska M, Bogdan Z, Kozlowski M, Snarska J, Puchalski Z, Sulkowski S, Skrzydlewski Z, "Antioxidant potential in esophageal, stomach and colorectal cancers," *Hepatogastroenterology*. 2003 Jan-Feb;50(49):126-31; Beno I, Ondreicka R, Magalova T, Brtkova A, Grancicova E, "Precancerous conditions and carcinomas of the stomach and colorectum – blood levels of selected micronutrients," *Bratisl Lek Listy*. 1997 Dec;98(12):674-7.

¹⁵ Choi MA, Kim BS, Yu R, "Serum antioxidative vitamin levels and lipid peroxidation in gastric carcinoma patients," *Cancer Lett*. 1999 Feb 8;136(1):89-93.

¹⁶ Yokoyama T, Date C, Kokubo Y, Yoshiike N, Matsumura Y, Tanaka H, "Serum vitamin C concentration was inversely associated with subsequent 20-year incidence of stroke in a Japanese rural community," *The Shibata study*. *Stroke*. 2000 Oct;31(10):2287-94.

¹⁷ You WC, Zhang L, Gail MH, Chang YS, Liu WD, Ma JL, Li JY, Jin ML, Hu YR, Yang CS, Blaser MJ, Correa P, Blot WJ, Fraumeni JF Jr, Xu GW, "Gastric dysplasia and gastric cancer: *Helicobacter pylori*, serum vitamin C, and other risk factors," *J Natl Cancer Inst*. 2000 Oct 4;92(19):1607-12; Kodama M, Kodama T, "In search of the cause of gastric cancer," *In Vivo*. 2000 Jan-Feb;14(1):125-38; Dabrowska-Ufniaz E, Dzieniszewski J, Jarosz M, Wartanowicz M, "Vitamin C concentration in gastric juice in patients with precancerous lesions of the stomach and gastric cancer," *Med Sci Monit*. 2002 Feb;8(2):CR96-103.

¹⁸ Nishida M, Grossi SG, Dunford RG, Ho AW, Trevisan M, Genco RJ, "Dietary vitamin C and the risk for periodontal disease," *J Periodontol*. 2000 Aug;71(8):1215-23.

¹⁹ Rath M, Pauling L, "Solution to the puzzle of human cardiovascular disease: Its primary cause is ascorbate deficiency, leading to the deposition of lipoprotein (a) and fibrinogen/fibrin in the vascular wall," *Journal of Orthomolecular Medicine*. 1991; 6:125-134.

hand, has been found to be protective against the development of gastric cancer,²⁰ as well as cancers of the esophagus,²¹ uterus,²² oral cavity, stomach, pancreas, cervix, rectum, lung,²³ breast,²⁴ ovaries,²⁵ and others.²⁶ In this respect it is B Vitamins, Vitamin C, Vitamin D, Magnesium, Zinc, and Selenium.

interesting to note that megadoses of Vitamin C and other nutrients have been shown to significantly reduce the recurrence of tumors in patients with bladder cancer,²⁷ and that male smokers with a high intake of Vitamin C have been shown to have a lower risk of cancer than male smokers with a lower intake of Vitamin C.²⁸

Deaths from stomach cancer and cardiovascular disease and cerebrovascular disease are all associated with low levels of Vitamin C;²⁹ in fact, it has been demonstrated that mortality for all causes of death decreases strongly with an increased intake of Vitamin C.³⁰ A study of 8,453 Americans' serum ascorbic acid (SAA) levels and mortality rates from disease, for example, found that those with a normal to high level of SAA had a 21%-25% lower risk of dying from cardiovascular disease, and that they had a 25%-29% decrease in risk of mortality from all causes compared to those with low levels of SAA.³¹

²⁰ De Stefani E, Boffetta P, Brennan P, Deneo-Pellegrini H, Carzoglio JC, Ronco A, Mendilaharsu M, "Dietary carotenoids and risk of gastric cancer: a case-control study in Uruguay," *Eur J Cancer Prev.* 2000 Oct;9(5):329-34; La Vecchia C, D'Avanzo B, Negri E, Decarli A, Benichou J, "Attributable risks for stomach cancer in northern Italy," *Int J Cancer.* 1995 Mar 16;60(6):748-52; Ekstrom AM, Serafini M, Nyren O, Hansson LE, Ye W, Wolk A, "Dietary antioxidant intake and the risk of cardia cancer and noncardia cancer of the intestinal and diffuse types: a population-based case-control study in Sweden," *Int J Cancer.* 2000 Jul 1;87(1):133-40; Feiz HR, Mobarhan S, "Does vitamin C intake slow the progression of gastric cancer in *Helicobacter pylori*-infected populations?" *Nutr Rev.* 2002 Jan;60(1):34-6; Valle J, Gisbert JP, "Helicobacter pylori infection and precancerous lesions of the stomach," *Hepatogastroenterology.* 2001 Nov-Dec;48(42):1548-51; Zhang L, Blot WJ, You WC, Chang YS, Liu XQ, Kneller RW, Zhao L, Liu WD, Li JY, Jin ML, et al., "Serum micronutrients in relation to pre-cancerous gastric lesions," *Int J Cancer.* 1994 Mar 1;56(5):650-4; Kikuchi S. Epidemiology of *Helicobacter pylori* and gastric cancer. *Gastric Cancer.* 2002;5(1):6-15; Mayne ST, Risch HA, Dubrow R, Chow WH, Gammon MD, Vaughan TL, Farrow DC, Schoenberg JB, Stanford JL, Ahsan H, West AB, Rotterdam H, Blot WJ, Fraumeni JF Jr., "Nutrient intake and risk of subtypes of esophageal and gastric cancer," *Cancer Epidemiol Biomarkers Prev.* 2001 Oct;10(10):1055-62; Hansson LE, Nyren O, Bergstrom R, Wolk A, Lindgren A, Baron J, Adami HO, "Nutrients and gastric cancer risk. A population-based case-control study in Sweden," *Int J Cancer.* 1994 Jun 1;57(5):638-44; Cohen M, "Ascorbic acid and gastrointestinal cancer," *J Am Coll Nutr.* 1995 Dec;14(6):565-78; Zhang L, Zhao L, Ma J, "Relationship between serum micronutrients and precancerous gastric lesions," *Zhonghua Yu Fang Yi Xue Za Zhi.* 1995 Jul;29(4):198-201.

²¹ Terry P, Lagergren J, Ye W, Nyren O, Wolk A, "Antioxidants and cancers of the esophagus and gastric cardia," *Int J Cancer.* 2000 Sep 1;87(5):750-4.

²² Flagg EW, Coates RJ, Greenberg RS, "Epidemiologic studies of antioxidants and cancer in humans," *J Am Coll Nutr.* 1995 Oct;14(5):419-27.

²³ Block G, "Epidemiologic evidence regarding vitamin C and cancer," *Am J Clin Nutr.* 1991 Dec;54(6 Suppl):1310S-1314S.

²⁴ Ibid.; Do MH, Lee SS, Jung PJ, Lee MH, "Intake of dietary fat and vitamin in relation to breast cancer risk in Korean women: a case-control study," *J Korean Med Sci.* 2003 Aug;18(4):534-40; Zhang S, Hunter DJ, Forman MR, Rosner BA, Speizer FE, Colditz GA, Manson JE, Hankinson SE, Willett WC, "Dietary carotenoids and vitamins A, C, and E and risk of breast cancer," *J Natl Cancer Inst.* 1999 Mar 17;91(6):547-56.

²⁵ Fleischauer AT, Olson SH, Mignone L, Simonsen N, Caputo TA, Harlap S, "Dietary antioxidants, supplements, and risk of epithelial ovarian cancer," *Nutr Cancer.* 2001;40(2):92-8.

²⁶ Mirvish SS, "Experimental evidence for inhibition of N-nitroso compound formation as a factor in the negative correlation between vitamin C consumption and the incidence of certain cancers," *Cancer Res.* 1994 Apr 1;54(7 Suppl):1948s-1951s.

²⁷ Lamm DL, Riggs DR, Shriver JS, van Gilder PF, Rach JF, DeHaven JI, "Megadose vitamins in bladder cancer: a double-blind clinical trial," *J Urol.* 1994 Jan;151(1):21-6.

²⁸ Van Hoydonck PG, Temme EH, Schouten EG, "A dietary oxidative balance score of vitamin c, beta-carotene and iron intakes and mortality risk in male smoking Belgians," *J Nutr.* 2002 Apr;132(4):756-61.

²⁹ Eichholzer M, Stahelin HB, Gey KF, "Inverse correlation between essential antioxidants in plasma and subsequent risk to develop cancer, ischemic heart disease and stroke respectively: 12-year follow-up of the Prospective Basel Study," *EXS.* 1992;62:398-410.

³⁰ Enstrom JE, Kanim LE, Klein MA, "Vitamin C intake and mortality among a sample of the United States population," *Epidemiology.* 1992 May;3(3):194-202.

³¹ Simon JA, Hudes ES, Tice JA, "Relation of serum ascorbic acid to mortality among US adults," *J Am Coll Nutr.* 2001 Jun;20(3):255-63.

Vitamin C supplements have also been shown to improve the body's ability to metabolize glucose and lipids and as such are seen as being beneficial to those with Type II diabetes.³² Similarly, people with higher levels of Vitamin C have been found to have a lower incidence and risk of hyperglycemia.³³

Critically-ill surgery patients have been shown to be significantly less likely to experience organ failure, spend less time using mechanical ventilation, and have shorter times in intensive care units when they are given supplements of Vitamin C and Vitamin E.³⁴

Adequate amounts of Vitamin C (i.e., more than 60 milligrams) have been shown to be an effective treatment for hypertension, both in non-diabetics,³⁵ and in diabetics,³⁶ and have been found to reduce muscle soreness and improve muscle function after exercise.³⁷

Research has also demonstrated the ability of higher doses of Vitamin C to delay bone loss,³⁸ and to increase bone density.³⁹ Similarly, an increased intake of Vitamins C and E has been shown to reduce the risk of hip fractures.⁴⁰

Researchers also recommend that people who are smokers, diabetics, pregnant, users of antibiotics, people who ingest alcohol, and users of contraceptives all need to consume higher-than-normal amounts of Vitamin C.⁴¹ Indeed, Vitamin C is depleted in women who use oral contraceptives, which may result in cardiac problems and thrombosis.⁴² Since vitamin supplements are routine for pregnancy, they should also be routine for the pseudo-pregnancy of oral contraception.

The list of recent research proving the nutritional benefits of levels of Vitamin C higher than 60 milligrams per day could fill books. They should not need to be repeated here. However, what evidently does need to be repeated here is that any lowering of the NRV for Vitamin C from 60 mg to 45 mg will only ensure *more* sickness and ill-health – the exact opposite of what Codex is supposed to accomplish. Relying on outdated and clearly-flawed science simply because it comes from a cherished institution is nothing less than dereliction of our duty owed to our fellow citizens.

3. Vitamin D

The science supporting the human need for *significantly* higher levels of Vitamin D is increasing by leaps

³² Paolisso G, Balbi V, Volpe C, Varricchio G, Gambardella A, Saccomanno F, Ammendola S, Varricchio M, D'Onofrio F, "Metabolic benefits deriving from chronic vitamin c supplementation in aged non-insulin dependent diabetics," J Am Coll Nutr. 1995 Aug;14(4):387-92.

³³ Sargeant LA, Wareham NJ, Bingham S, Day NE, Luben RN, Oakes S, Welch A, Khaw KT, "Vitamin C and hyperglycemia in the European Prospective Investigation into Cancer--Norfolk (EPIC-Norfolk) study: a population-based study," Diabetes Care. 2000 Jun;23(6):726-32.

³⁴ Nathens AB, Neff MJ, Jurkovich GJ, Klotz P, Farver K, Ruzinski JT, Radella F, Garcia I, Maier RV, "Randomized, prospective trial of antioxidant supplementation in critically ill surgical patients," Ann Surg. 2002 Dec;236(6):814-22.

³⁵ Hajjar IM, George V, Sasse EA, Kocher MS, "A randomized, double-blind, controlled trial of vitamin C in the management of hypertension and lipids," Am J Ther. 2002 Jul-Aug;9(4):289-93; Brody S, Preut R, Schommer K, Schurmeyer TH, "A randomized controlled trial of high dose ascorbic acid for reduction of blood pressure, cortisol, and subjective responses to psychological stress," Psychopharmacology (Berl). 2002 Jan;159(3):319-24. Epub 2001 Nov 20; Sherman DL, Keaney JF Jr, Biegelsen ES, Duffy SJ, Coffman JD, Vita JA, "Pharmacological concentrations of ascorbic acid are required for the beneficial effect on endothelial vasomotor function in hypertension," Hypertension. 2000 Apr;35(4):936-41; Fotherby MD, Williams JC, Forster LA, Craner P, Ferns GA, "Effect of vitamin C on ambulatory blood pressure and plasma lipids in older persons," J Hypertens. 2000 Apr;18(4):411-5.

³⁶ Mullan BA, Young IS, Fee H, McCance DR, "Ascorbic acid reduces blood pressure and arterial stiffness in type 2 diabetes," Hypertension. 2002 Dec;40(6):804-9.

³⁷ Thompson D, Williams C, McGregor SJ, Nicholas CW, McArdle F, Jackson MJ, Powell JR, "Prolonged vitamin C supplementation and recovery from demanding exercise," Int J Sport Nutr Exerc Metab. 2001 Dec;11(4):466-81; Nieman DC, Peters EM, Henson DA, Nevines EI, Thompson MM, "Influence of vitamin C supplementation on cytokine changes following an ultramarathon," J Interferon Cytokine Res. 2000 Nov;20(11):1029-35.

³⁸ Schaafsma A, de Vries PJ, Saris WH, "Delay of natural bone loss by higher intakes of specific minerals and vitamins," Crit Rev Food Sci Nutr. 2001 May;41(4):225-49.

³⁹ Morton DJ, Barrett-Connor EL, Schneider DL, "Vitamin C supplement use and bone mineral density in postmenopausal women," J Bone Miner Res. 2001 Jan;16(1):135-40.

⁴⁰ Melhus H, Michaelsson K, Holmberg L, Wolk A, Ljunghall S, "Smoking, antioxidant vitamins, and the risk of hip fracture," J Bone Miner Res. 1999 Jan;14(1):129-35.

⁴¹ J Dryburgh DR, "Vitamin C and chiropractic," Manipulative Physiol Ther. 1985 Jun;8(2):95-103.

⁴² Henley S, "Women on the pill are opening up a small case of side effects every morning," Body Forum. 1977 Jan 30;2(7):20.

and bounds. In particular, the old and out-dated concept that humans can get by on a daily intake of just 5 micrograms of Vitamin D is dead.

Instead, **adequate** levels of Vitamin D (i.e., from 25 micrograms up) are recognized as being necessary by such agencies as Health Canada and others. The scientific evidence supporting this position is extremely well-documented, but NHF will only footnote a small portion of such research here.⁴³ To ignore this science by establishing below-minimum nutritional requirements for Vitamin D (such as an NRV of only 5 micrograms) borders on negligence, if not worse.

4. B Vitamins

As with Vitamins A, C, and D above, NHF could submit to this Committee substantial and extensive scientific research in support of its position that the NRVs for Thiamin, Riboflavin, Niacin, B6, Folate, Pantothenic Acid, Biotin, and B12 should all be increased so as to be in line with the most-recent research showing the need for higher consumption levels of these important nutrients.⁴⁴ That the Working Group for this Committee would suggest that the levels for Thiamin, Riboflavin, Niacin, and B6 should be lowered instead of raised indicates that the latest research and science has been overlooked.

The latest scientific research supports the following NRVs for B vitamins: Thiamin (23 to 40 mg); Riboflavin (23 to 40 mg); Niacin (190-200 mg); Pantothenic Acid (200 mg); B6 (50 mg); B12 (100 mcg); Folate (800 mcg); and Biotin (800 mcg).

5. Minerals

The same arguments also apply to the mineral NRVs, particularly magnesium and excepting iron. In the case of **iron**, the NRVs have been set for growing children and menstruating females, both of which groups require higher iron intake than males and menopausal women. The typical male at age 45 has four times the iron levels in his body as a woman of the same age and this is a significant factor in increased heart attacks and cancer rates in males versus females. So, in this case, establishing young-female-friendly NRVs for iron actually harms males and mature females.

⁴³ Mezquita Raya P, Munoz Torres M, Lopez Rodriguez F, Martinez Martin N, Conde Valero A, Ortego Centeno N, Gonzalez Calvin J, Raya Alvarez E, Luna Jd Jde D, Escobar Jimenez F, "Prevalence of vitamin D deficiency in populations at risk for osteoporosis: impact on bone integrity," *Med Clin (Barc)*. 2002 Jun 22;119(3):85-9; Rodriguez-Martinez MA, Garcia-Cohen EC, "Role of Ca(2+) and vitamin D in the prevention and treatment of osteoporosis," *Pharmacol Ther*. 2002 Jan;93(1):37-49; Lilliu H, Pamphile R, Chapuy MC, Schulten J, Arlot M, Meunier PJ, "Calcium-vitamin D3 supplementation is cost-effective in hip fractures prevention," *Maturitas*. 2003 Apr 25;44(4):299-305; Pfeiffer, J *Bone Min Res*. 2000, 15:1113-6; Trivedi DP, Doll R, Khaw KT, "Effect of four monthly oral vitamin D3 (cholecalciferol) supplementation on fractures and mortality in men and women living in the community: randomised double blind controlled trial," *BMJ* 2003;326:469-72; Chapuy MC, Arlot ME, Duboeuf F, Brun J, Crouzet B, Arnaud S, Delmas PD, Meunier PJ, "Vitamin D3 and calcium to prevent hip fractures in the elderly women," *N Engl J Med*. 1992; 327:1637-1642; Dawson-Hughes B., Harris S. S., Krall E. A., Dallal G. E., "Effect of Calcium and Vitamin D Supplementation on Bone Density in Men and Women 65 Years of Age or Older," *N Engl J Med* 1997; 337:670-676; Fardellone P, Sebert JL, Garabedian M, Bellony R, Maamer M, Agbomson F, Brazie rM, "Prevalence and biological consequences of vitamin D deficiency in elderly institutionalized subjects," *Rev Rhum Engl Ed*. 1995 Oct;62(9):576-81; Markestad T, "Effect of season and vitamin D supplementation on plasma concentrations of 25-hydroxyvitamin D in Norwegian infants," *Acta Paediatr Scand*. 1983 Nov;72(6):817-21; Zamora SA, Rizzoli R, Belli DC, Slosman DO, Bonjour JP, "Vitamin D supplementation during infancy is associated with higher bone mineral mass in prepubertal girls," *J Clin Endocrinol Metab*. 1999 Dec;84(12):4541-4; Garland CF, Garland FC, Gorham ED, "Calcium and vitamin D. Their potential roles in colon and breast cancer prevention," *Ann N Y Acad Sci*. 1999;889:107-19; Peehl DM, "Vitamin D and prostate cancer risk," *Eur Urol*. 1999;35(5-6):392-4; Hypponen E, Laara E, Reunanen A, Jarvelin MR, Virtanen SM, "Intake of vitamin D and risk of type 1 diabetes: a birth-cohort study," *Lancet*. 2001 Nov 3;358(9292):1500-3; Munger KL, Zhang SM, O'Reilly E, Hernan MA, Olek MJ, Willet WC, Ascherio A, "Vitamin D intake and incidence of multiple sclerosis," *Neurology*. 2004 Jan 13;62(1):60-65; Goldberg P, Fleming MC, Picard EH, "Multiple sclerosis: decreased relapse rate through dietary supplementation with calcium, magnesium and vitamin D," *Med Hypotheses*. 1986 Oct;21(2):193-200; Sasidharan PK, Rajeev E, Vijayakumari V, "Tuberculosis and vitamin D deficiency," *J Assoc Physicians India*. 2002 Apr;50:554-8; Bicknel F, Prescott F, *The Vitamins in Medicine*, third edition. Milwaukee, WI: Lee Foundation. 1953, p.544, 584-591; Vieth, R. (1999), "Vitamin D supplementation, 25-hydroxyvitamin D concentrations, and safety," *American Journal of Clinical Nutrition*, Vol. 69, No. 5, 842-856, May 1999; Marya RK, Rathee S, Lata V, Mudgil S, "Effects of vitamin D supplementation in pregnancy," *Gynecol Obstet Invest*. 1981;12(3):155-61.

⁴⁴ Indeed, in June 2004, the NHF did submit extensive research supporting its position for higher NRVs for these and other nutrients.

In the case of **magnesium**, however, the suggestion to lower the NRV from 300 milligrams to 240 milligrams is absolutely not supported by the science.

Research shows that dietary magnesium consumption has progressively declined over the past century from an average intake of 475-500 mg in the period 1900-1908 to an average intake of 175-225 mg in the period 1990-2002.⁴⁵

As such it is hardly surprising that suboptimal intakes of magnesium and outright magnesium deficiencies are now commonplace in many population groups.⁴⁶ Indeed, a large segment of the U.S. population may have a chronic latent magnesium deficiency that has been linked to atherosclerosis, myocardial infarction, hypertension, cancer, kidney stones, premenstrual syndrome, and psychiatric disorders.⁴⁷ In this respect it should be noted that although serum levels are commonly used to assess magnesium deficiency, red cells and leucocytes can be still deficient despite normal serum values.⁴⁸

The value of adequate (i.e., optimal) magnesium levels cannot be overemphasized in the prevention of heart disease and other related health problems.⁴⁹ **The NRV for magnesium must, therefore, be set at no less than 400 milligrams and preferably 500 milligrams.**

For **selenium**, NHF suggests a range of **70 to 200 micrograms be established as the NRV** for this important mineral. Widely deficient from most soils, especially in Europe,⁵⁰ the importance of adequate

⁴⁵ Magnesium Trace Elements 10: 162-28, 1997.

⁴⁶ Turner RE, Langkamp-Henken B, Littell RC, Lukowski MJ, Suarez MF, "Comparing nutrient intake from food to the estimated average requirements shows middle- to upper-income pregnant women lack iron and possibly magnesium," J Am Diet Assoc. 2003 Apr;103(4):461-6; Vaquero MP, "Magnesium and trace elements in the elderly: intake, status and recommendations," J Nutr Health Aging. 2002;6(2):147-53; van der Sijs IH, Ho-Dac-Pannekeet MM, "The treatment of hypomagnesemia," Ned Tijdschr Geneesk. 2002 May 18;146(20):934-8; Milionis HJ, Alexandrides GE, Liberopoulos EN, Bairaktari ET, Goudevenos J, Elisaf MS, "Hypomagnesemia and concurrent acid-base and electrolyte abnormalities in patients with congestive heart failure," Eur J Heart Fail. 2002 Mar;4(2):167-73; Schimatschek HF, Rempis R, "Prevalence of hypomagnesemia in an unselected German population of 16,000 individuals," Magnes Res. 2001 Dec;14(4):283-90; Iannello S, Belfiore F. Hypomagnesemia, "A review of pathophysiological, clinical and therapeutical aspects," Panminerva Med. 2001 Sep;43(3):177-209; Deshmukh CT, Rane SA, Gurav MN, "Hypomagnesaemia in paediatric population in an intensive care unit," J Postgrad Med. 2000 Jul-Sep;46(3):179-80; Verive MJ, Irazuzta J, Steinhart CM, Orlowski JP, Jaimovich DG, "Evaluating the frequency rate of hypomagnesemia in critically ill pediatric patients by using multiple regression analysis and a computer-based neural network," Crit Care Med. 2000 Oct;28(10):3534-9; Fox CH, Ramsoomair D, Mahoney MC, Carter C, Young B, Graham R, "An investigation of hypomagnesemia among ambulatory urban African Americans," J Fam Pract. 1999 Aug;48(8):636-9; Faintuch JJ, Menezes MS, "Magnesium and myocardial infarction. Brazilian aspects," Rev Hosp Clin Fac Med Sao Paulo. 1997 Nov-Dec;52(6):333-6; Durlach J, Bac P, Durlach V, Rayssiguier Y, Bara M, Guet-Bara A, "Magnesium status and ageing: an update," Magnes Res. 1998 Mar;11(1):25-42; Durlach J, Bac P, Durlach V, Durlach A, Bara M, Guet-Bara A, "Are age-related neurodegenerative diseases linked with various types of magnesium depletion?" Magnes Res. 1997 Dec;10(4):339-53; Singh RB, Rastogi V, Singh R, Niaz MA, Srivastav S, Aslam M, Singh NK, Moshir M, Postiglione A, "Magnesium and antioxidant vitamin status and risk of complications of ageing in an elderly urban population," Magnes Res. 1996 Dec;9(4):299-306; Singh RB, Rastogi V, Niaz MA, Sharma JP, Raghuvanshi R, Moshira M, "Epidemiological study of magnesium status and risk of hypertension in a rural population of north India," Magnes Res. 1996 Oct;9(3):173-81; Singh RB, Niaz MA, Ghosh S, Rastogi V, Raghuvanshi RS, Moshiri M, "Epidemiological study of magnesium status and risk of coronary artery disease in elderly rural and urban populations of north India," Magnes Res. 1996 Oct;9(3):165-72; Bondarev GI, Feoktistova AI, Zemlianskaia TA, "Nutritional status of native and non-native population of Russia's Extreme North and Far East," Vopr Pitan. 1993 Mar-Apr;(2):14-8; Davydenko NV, Vasilenko IG, "Magnesium level in food rations and the prevalence of ischemic heart disease among the population," Gig Sanit. 1991 May;(5):44-6; Touitou Y, Godard JP, Ferment O, Chastang C, Proust J, Bogdan A, Auzéby A, Touitou C, "Prevalence of magnesium and potassium deficiencies in the elderly," Clin Chem. 1987 Apr;33(4):518-23.

⁴⁷ Elin RJ, "Magnesium metabolism in health and disease," Dis Mon. 1988 Apr;34(4):161-218.

⁴⁸ Landon RA, Young EA, "Role of magnesium in regulation of lung function," J Am Diet Assoc. 1993 Jun;93(6):674-7.

⁴⁹ Sjogren, A., Edvinsson, L., and Fallgren, B, "Magnesium deficiency in coronary artery disease and cardiac arrhythmias," J Int Med, 1989;226:213-22; Dubey, A., and Solomon, R, "Magnesium, Myocardial ischaemia and arrhythmias. The role of magnesium in myocardial infarction," Drugs, 1989;37:1-7; Altura B, "Magnesium in cardiovascular biology," Scientific American May/June 1995;28-35.

⁵⁰ Murphy J, Hannon EM, Kiely M, Flynn A, Cashman KD, "Selenium intakes in 18-64-y-old Irish adults," Eur J Clin Nutr. 2002 May;56(5):402-8; Tutel'ian VA, Khotimchenko SA, "Selenium as an essential and deficient factor in the nutrition of Russian population," Vestn Ross Akad Med Nauk. 2001;(6):31-4; Kvicala J, Zamrazil V, Jiranek V,

levels of selenium in nutrition cannot be over-emphasized, especially pertaining to cancer prevention.⁵¹

A Range May Also be Appropriate.

The delegation of Egypt stated in its written submission to this Committee (CX/NFSDU 10/32/4) that it “recommends that the NRV values of these elements to be in a range status (Min. – Max.)” because this would provide countries with the chance to establish specific NRVs most appropriate to their general population’s requirement. NHF agrees with this range approach as the most practical and accurate fulfillment of Codex’s mission for consumer health and protection.

Where Are the Bodies?

Vitamins and minerals, even in supplement form, are amongst the safest consumer ingredients and products on the planet. Surveys and studies from Canada to the United States to Europe show significantly fewer adverse events from, for instance, vitamin and mineral food supplements than from any other consumable. In fact, statistically, a consumer is more likely to die from a lightning strike, a bee sting, or falling from a horse than he or she is from consuming vitamins and minerals.

So, a confusing question is what is the impetus for highly-restrictive limitations on NRVs of vitamins and minerals? Exactly what is Codex protecting the public from? The following chart shows that the number of adverse reports from the use of multivitamins is relatively small and the number of deaths is zero. What is the need for such restrictions? Where are the bodies that would warrant the use of so much time, energy, and money to construct “safe” levels for these already extremely safe products?

While the following chart is for the snapshot year 2002, the figures shown here are typical for other years, both before and after. Considering the enormous health benefits that would accrue from consuming optimal amounts of these natural nutrients, the path forward for this Codex Committee should be clear – adopt **higher** NRVs that promote and optimize health.

Annual report of Poison Control Centers 2002	Number of adverse reports	Number of deaths
Multivitamins	2811	0
Oral contraceptives	9948	1
Insulin	1686	8

“Characterization of selenium status of inhabitants in the region Usti nad Orlici, Czech Republic by INAA of blood serum and hair and fluorimetric analysis of urine,” Biol Trace Elem Res. 1999 Winter;71-72:31-9; Kvalica J, Zamrazil V, Cerovska J, Bednar J, Janda J, “Evaluation of selenium supply and status of inhabitants in three selected rural and urban regions of the Czech Republic,” Biol Trace Elem Res. 1995 Jan-Mar;47(1-3):365-75; Bogye G, Feher J, Georg A, Antti A, “Relationship between selenium deficiency and high mortality and morbidity of cardiovascular diseases,” Orv Hetil. 1994 Jan 16;135(3):115-8; Sluis KB, Darlow BA, George PM, Mogridge N, Dolamore BA, Winterbourn CC, “Selenium and glutathione peroxidase levels in premature infants in a low selenium community (Christchurch, New Zealand),” Pediatr Res. 1992 Aug;32(2):189-94; Maksimovic ZJ, Djubic I, Jovic V, Rsumovic M, “Selenium deficiency in Yugoslavia,” Biol Trace Elem Res. 1992 Apr-Jun;33:187-96; Kivela SL, Maenpaa P, Nissinen A, Alfthan G, Punsar S, Enlund H, Puska P, “Vitamin A, vitamin E and selenium status in an aged Finnish male population,” Int J Vitam Nutr Res. 1989;59(4):373-80; Wasowicz W, Zachara BA, “Selenium concentrations in the blood and urine of a healthy Polish sub-population,” J Clin Chem Clin Biochem. 1987 Jul;25(7):409-12.

⁵¹ Kim YS, Milner J, “Molecular targets for selenium in cancer prevention,” Nutr Cancer. 2001;40(1):50-4; Yu, Shu-Yu et al., “Regional variation of cancer mortality incidence and its relation to selenium levels in China,” Biol. Trace Elem res. 7:21-29, 1985; Burguera JL, Burguera M, Galignani M, Alarcon OM, Burguera JA, “Blood serum selenium in the province of Merida, Venezuela, related to sex, cancer incidence and soil selenium content,” J Trace Elem Electrolytes Health Dis 1990 Jun;4(2):73-7; Schrauzer GN, “Selenium and cancer: a review,” Bioinorg Chem 1976;5(3):275-81; Shamberger RJ, Frost DV, “Possible protective effect of selenium against human cancer,” Can Med Assoc J. 1969 Apr 12;100(14):682; Shamberger, R. J., and C. E. Willis, “Selenium distribution and human cancer mortality,” CRC Crit. Rev. Clin. Lab. Sci. (1971) 2:211-221; Duffield-Lillico AJ, Reid ME, Turnbull BW, Combs GF Jr, Slate EH, Fischbach LA, Marshall JR, Clark LC, “Baseline characteristics and the effect of selenium supplementation on cancer incidence in a randomized clinical trial: a summary report of the Nutritional Prevention of Cancer Trial,” Cancer Epidemiol Biomarkers Prev. 2002 Jul;11(7):630-9; Combs GF Jr, Clark LC, Turnbull BW, “Reduction of cancer mortality and incidence by selenium supplementation,” Med Klin (Munich). 1997 Sep 15;92 Suppl 3:42-5.

Diuretics	7710	10
Cough and cold remedies	97710	14
Aspirin (adult)	5249	14
Acetaminophen (Tylenol)	28991	63
Alcohol	40782	93
Antidepressants	92675	255
Source: American Journal Emergency Medicine 20: 391-452, 2002 http://www.aapcc.org/2002_poison_center_survey_results.htm		

As can be seen above, dietary supplements (the most “extreme” and concentrated way of consuming these nutrients) are far safer than aspirin tablets, other over-the-counter pain relievers, oral contraceptives, vaccines, and even table salt. In fact, dietary supplements are safer than food (there are millions of cases of food-borne infection each year and a few thousand deaths from food poisoning). The public’s unhindered access to optimally-dosed vitamin and mineral supplements is critical to maintaining public health.

If the NRVs are set too low, informed consumers will ignore them on printed food-product labels. However, the problem with too-low NRVs is that a significant portion of the population will be misled into believing that they are receiving adequate levels of nutrients, when in fact they will, at best, be receiving only the very minimal amount necessary to stave off immediate death.

Conclusion.

At the last CCNFSDU meeting (31st session), the Chairman and this Committee very wisely chose to hold back for further consideration the “Proposed Draft Additional or Revised NRVs for Labelling Purposes in the Codex Guidelines on Nutrition Labelling.” It was recognized – as well stated by the delegations of India and Iraq – that more time was necessary to ensure that the correct values were arrived at.

In setting NRVs, this Committee must –

- Use the latest and most up-to-date scientific research
- Consider *all* authoritative scientific sources of data
- Not settle for *minimal* values that are just enough to keep consumers from dying
- Raise the NRVs to *optimal* values that will maximize good health and well-being
- Remember that *these nutrients are exceedingly safe* and their benefits greatly outweigh any possible detriment
- Therefore, reject lowering any of the NRVs for Vitamin A, the B Vitamins, Vitamin C, Vitamin D, Magnesium, Zinc, and Selenium.