codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 9 **CX/NFSDU 00/9**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-Second Session
Berlin, Germany, 19 – 23 June 2000

DISCUSSION PAPER ON REVIEW OF PROVISIONS FOR VITAMIN AND MINERALS IN CODEX STANDARDS: VITAMINS AND MINERALS IN FOODS FOR SPECIAL MEDICAL PURPOSES

(Prepared by Germany)

I

The 21st Session of the Committee held in Berlin from 21 to 25 September 1998 agreed that the German delegation would revise the working paper drafted for the 20th Session as CX/NFSDU 98/8[1] including the Table containing the recommendations on the vitamin and mineral levels contained in food for special medical purposes (ALINORM 99/26, para. 113). It was agreed to place this paper in square brackets and the German delegation was assigned the task of revising this discussion paper.

II

The following summarized **comments** on Discussion Paper CX/NFSDU 98/8 were submitted during the last Codex session:

1. The recommendations should be based on the following three age groups: 0-12 months, 1-11 years, and over 11 years.

2. The scope should be extended to include, for example, carbohydrates, protein and essential fatty acids.

3. Doubts were expressed as to the usefulness of proposed values based on physiological considerations and intended to ensure that nutritional needs are met and it was demanded to

[1] CX/NFSDU 98/8 was previously published in English, French and Spanish as CL 1997/11-NFSDU.

give more weight to aspects of toxicological safety instead. Some members, however, welcomed the nutritional orientation.

4. Nutritional density criteria should be expressed both in kcal and in kilojoules.

5. It was proposed to amend the reference daily energy intake from 2000 kcal to 1500 kcal.

Prior to any discussion regarding the contents of the Table we feel, however, that its status in the Codex Alimentarius should first be defined (as Standard or Guideline).

III

ad 1: With regard to the vitamin and mineral content of foods intended for patients over 1 year of age, we propose the criteria for composition given in ANNEX 1.

Products intended for infants are generally covered by the vitamin and mineral requirements of the Codex Standard for Infant Formula (CODEX STAN 72-1981), which is currently undergoing revision.

Deviations from the quantities specified are admissible where special dietary requirements call for corresponding adjustments, these deviations are explicitly stated and underlying reasons given.

ad 2: No further clarification is required since the proposals cited are not within the scope of the assigned task.

ad 3: In formulating foods for special medical purposes, vitamin and mineral content should be based on sound medical and nutritional principles. When used in accordance with manufacturers' instructions, they must be safe and beneficial in the sense that they meet the special nutritional requirements of the persons for whom they are intended as demonstrated by generally recognized scientific data.

The values originally proposed were based on the population reference intake values (PRI) of the Scientific Committee for Food of the Commission of the European Union (SCF), supplemented by US RDA data. Depending on the "therapeutic range" of each nutrient, maximum levels of approximately two, three or five times the lower values were proposed. In addition, exceptions were proposed for calcium and vitamin D for children aged 1 to 10 years. The admissibility of deviations from the specified quantities was provided for where special dietary requirements call for corresponding adjustments and these deviations are explicitly stated.

Germany adheres to the previously recommended levels (cf. CX/NFSDU 98/8), which are based on empirical scientific and nutritional data, and provides for deviations in justified cases. Specifying maximum levels based mainly or exclusively on concerns regarding toxicological safety is seen as unacceptable, particularly in light of the considerations expressed in the General Principles of CODEX STAN 180-991 for these product groups ("...should be based on sound medical and nutritional principles").

This standpoint is also supported by statements of the Institute of Medicine (USA), including the following:

"The Tolerable Upper Intake Level (UL) is the highest level of daily nutrient intake that is likely to pose no risks of adverse health effects in almost all individuals in the general population. As intake increases above the UL, the risk of adverse effects increases. The term tolerable intake was chosen to avoid implying a possible beneficial effect. Instead, the term is intended to connote a level of intake that can, with high probability, be tolerated biologically. The UL is not intended to be a recommended level of intake." (Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. Food and Nutrition Board, Institute of Medicine: DRI for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride. National Academy Press, Washington D.C., 1997)

"*The UL is not meant to apply to individuals who are treated with the nutrient or food component under medical supervision.*" (cf. Conference Room Document (CRD) 1 regarding Agenda Item 5 of the 21st Session of the CCNFSDU, Berlin 21-25 September 1998: Food and Nutrition Board, Institute of Medicine, National Academy of Sciences: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients. Abridged Version. Washington, DC, June 1998)

It should further be emphasized that these proposals are intended for complete formula foods only and that multiples of RDAs for healthy persons are normally sufficient to cover the requirements of diseased people.

ad 4: Per kilojoule (kJ) criteria were added to the table (Annex 1).

ad 5: We have compiled a provisional table with a reference daily energy intake of 1500 kcal (Annex II) in order to allow for a comparison with the heretofore proposed values based on an energy intake of 2000 kcal/day (Annex I). It is proposed that these calculations be discussed at the next session of the Committee.

ANNEX I: MINIMUM AND MAXIMUM LEVELS[2] OF VITAMINS, MINERALS AND TRACE ELEMENTS IN FOODS FOR SPECIAL MEDICAL PURPOSES (FOR PERSONS OVER 1 YEAR OF AGE)[3,4] Basis: Daily energy intake of 2000 kcal (8372 kJ) in line with CX/NFSDU 98/8 (1 kcal = 4.186 kJ)

Nutrient		At 2000 kcal (8372 kJ)/day	Per 100 kcal	Per 100 kJ
Vitamin A	µg	700-1400	(35-70)	8.36-16.72
Vitamin D	µg	5.0-10.0/ (20.0-40.0)[3]	(0.25-0.5)/ ((1-2)[3])	0.06-0.12/ (0.24-0.48)[3]
Vitamin E	mg	10.0-50.0	(0.5-2.5)	0.12-0.60
Vitamin K	µg	50.0-100.0	(2.5-5.0)	0.60-1.19
Carotinoids	µg	<3000[5]	(<150)[5]	<35.83[5]
Thiamin	mg	1.1-3.3	(0.06-0.17)	0.01-0.04
Riboflavin	mg	1.6-4.8	(0.08-0.24)	0.02-0.06
Vitamin B_6	mg	1.5-4.5	(0.08-0.23)	0.02-0.05
Niacin	mg	18.0-54.0	(0.9-2.7)	0.22-0.65
Folate	µg	200-600	(10-30)	2.39-7.17
Vitamin B_{12}	µg	1.4-7.0	(0.07-0.35)	0.02-0.08
Biotin	µg	100-300	(5-15)	1.19-3.58
Pantothenate	mg	4.0-12.0	(0.20-0.60)	0.05-0.14
Vitamin C	mg	45.0-225.0	(2.25-11.25)	0.54-2.69
Sodium	mg	500-3500	(25-175)	5.97-41.80
Potassium	mg	1500-4500	(75-225)	17.91-53.75
Chloride	mg	1500-4500	(75-225)	17.91-53.75
Calcium	mg	700-2100/ (1000-2000)[3]	(35-105)/ ((50-100)[3])	8.36-25.08/ (11.94-23.89)[3]
Phosphate	mg	550.0-1650.0	(27.5-82.5)	6.57-19.71
Magnesium	mg	350.0-600.0	(17.5-30.0)	4.18-7.17
Iron	mg	9.0-18.0	(0.5-0.9)	0.12-0.22
Zinc	mg	9.5-19.0	(0.5-1.0)	0.12-0.24
Copper	mg	1.1-2.2	(0.06-0.11)	0.01-0.03
Iodine	µg	130.0-260.0	(6.5-13.0)	1.55-3.11
Fluoride	mg	<4.0[5]	(<0.20)[5]	<0.05[5]
Manganese	mg	2.0-5.0	(0.10-0.25)	0.02-0.06
Chromium	µg	50.0-200.0	(2.5-10.0)	0.60-2.39
Molybdene	µg	75.0-250.0	(3.75-12.5)	0.90-2.97
Selenium	µg	55.0-110.0	(2.8-5.5)	0.67-1.31

2 Deviations from the quantities specified are admissible where special dietary requirements call for corresponding adjustments, these deviations are explicitly stated and underlying reasons given.

3 For products intended for children aged 1 to 10 years.

4 Infants (0-12 months) should be covered by the vitamin and mineral requirements of the Codex Standard for Infant Formula (CODEX STAN 72-1981).

5 It is not necessary to add this nutrient; if it is added though, it should be within these limits.

ANNEX II: MINIMUM AND MAXIMUM LEVELS[2] OF VITAMINS, MINERALS AND TRACE ELEMENTS IN FOODS FOR SPECIAL MEDICAL PURPOSES (FOR PERSONS OVER 1 YEAR OF AGE)[3,4] Basis: Daily energy intake of 1500 kcal (6279 kJ) (1 kcal = 4.186 kJ)

Nutrient					CX/NFSDU 98/8
		At 1500 kcal/day (6279 kJ)	**Per 100 kJ**	**Per 100 kcal**	**Per 100 kcal (Basis: 2000 kcal/d)**
Vitamin A	µg	700-1400	11.15-22.30	46.7-93.3	(35-70)
Vitamin D	µg	5.0-10.0/ (20.0-40.0)[3]	0.08-0.16/ (0.32-0.64)[3]	0.33-0.67 (1-2)[3]	(0.25-0.5)/ ((1-2)[3])
Vitamin E	mg	10.0-50.0	0.16-0.80	0.67-3.33	(0.5-2.5)
Vitamin K	µg	50.0-100.0	0.80-1.59	3.33-6.67	(2.5-5.0)
Carotinoids	µg	< 3000[5]	< 47.78[5]	< 200[5]	(< 150)[5]
Thiamin	mg	1.1-3.3	0.02-0.05	0.07-0.22	(0.06-0.17)
Riboflavin	mg	1.6-4.8	0.03-0.08	0.11-0.32	(0.08-0.24)
Vitamin B_6	mg	1.5-4.5	0.02-0.07	0.10-0.30	(0.08-0.23)
Niacin	mg	18.0-54.0	0.29-0.86	1.20-3.60	(0.9-2.7)
Folate	µg	200-600	3.18-9.56	13.3-40.0	(10-30)
Vitamin B_{12}	µg	1.4-7.0	0.02-0.11	0.09-0.47	(0.07-0.35)
Biotin	µg	100-300	1.59-4.78	6.67-20	(5-15)
Pantothenate	mg	4.0-12.0	0.06-0.19	0.27-0.80	(0.20-0.60)
Vitamin C	mg	45.0-225.0	0.72-3.58	3.0-15.0	(2.25-11.25)
Sodium	mg	500-3500	7.96-55.74	33.3-233.3	(25-175)
Potassium	mg	1500-4500	23.89-71.67	100-300	(75-225)
Chloride	mg	1500-4500	23.89-71.67	100-300	(75-225)
Calcium	mg	700-2100/ (1000-2000)[3]	11.15-33.44 (15.93-31.85)[3]	46.67-140 (50-100)[3]	(35-105)/ ((50-100)[3])
Phosphate	mg	550.0-1650.0	8.76-26.28	36.67-110	(27.5-82.5)
Magnesium	mg	350.0-600.0	5.57-9.56	23.3-40.0	(17.5-30.0)
Iron	mg	9.0-18.0	0.14-0.29	0.6-1.2	(0.5-0.9)
Zinc	mg	9.5-19.0	0.15-0.30	0.63-1.27	(0.5-1.0)
Copper	mg	1.1-2.2	0.02-0.04	0.07-0.15	(0.06-0.11)
Iodine	µg	130.0-260.0	2.07-4.14	8.67-17.33	(6.5-13.0)
Fluoride	mg	<4.0[5]	<0.06[5]	<0.27[5]	(<0.20)[5]
Manganese	mg	2.0-5.0	0.03-0.08	0.13-0.33	(0.10-0.25)
Chromium	µg	50.0-200.0	0.80-3.19	3.33-13.33	(2.5-10.0)
Molybdene	µg	75.0-250.0	1.19-3.98	5.0-16.67	(3.75-12.5)
Selenium	µg	55.0-110.0	0.88-1.75	3.67-7.33	(2.8-5.5)

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