

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 8

**CX/NFSDU 01/8
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES Twenty-third Session Berlin, Germany, 26-30 November 2001

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)

The 22nd Codex Session of the Committee on Nutrition and Foods for Special Dietary Uses held in Berlin from 19 to 23 June 2000 agreed that the German Delegation would prepare a document on general principles for the selection and determination of amounts of vitamins and minerals. Member Governments were requested to contribute to the document by providing information on national criteria and practice in the respective countries. The decision was based on the outcome of the discussion of the last Codex session, which is summarised hereunder:

1. The Committee did not come to a decision regarding the future status of the document, i.e. whether a Standard or Guidelines be developed on this issue.
2. In general, it was welcomed that minimum levels for vitamins and minerals be established. However, concern was raised as to whether maximum levels should be derived exclusively from risk assessment considerations rather than from scientific and nutritional data.
3. The purpose of and necessity for such a document was questioned, especially with regard to the detailed recommendations for nutrient limits. However, as there is a wide range of products available on the market, it was indicated that the development of general manufacturing principles/guidance would be useful.

Based on the above, the Committee should determine, prior to any further discussion, whether a Standard or Guidelines be established to legalise the vitamins and minerals in foods for special medical purposes.

With regard to the preparation of the document on general criteria for the selection of vitamins and minerals for foods for special medical purposes, there was very little response from Member Governments and other delegations. Until July Germany had only received three comments, none of them providing the requested information on the national criteria.

Going on the assumption that there is still interest in a continuation of discussions on the topic, Germany herewith wishes to recapitulate some of the major principles and considerations formerly presented in the discussion papers of 1998 (CX/NFSDU 98/8) and 2000 (CX/NFSDU 00/09):

INTRODUCTION

Foods for special medical purpose are a category of foods which are intended for the feeding of patients with limited or impaired capacity to take, digest, absorb or metabolise ordinary foods, or who suffer from a variety

of diseases, disorders or medical conditions and have thus special medically determined requirements. The special foods are used when dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two. Conditions or diseases may include trauma patients unable to consume conventional foods to meet nutritional needs, patients with chronic renal failure, or patients with malabsorption conditions such as short bowel syndrome. It is noteworthy that hospital patients are often at risk of developing disease-related malnutrition.

Generally, insufficiency of amounts administered, malabsorption, increased excretion, increased demand, and altered distribution in tissue are precipitating factors demanding for the use of foods for special medical purposes to ensure replacement of lacking nutrients.

BASIC PRINCIPLES

Depending on the condition, foods for special medical purposes are produced either as standard nutrient formulations or as disease adapted formulations (for the management of specific diseases). They are intended to be consumed enterally and require ongoing physician oversight to ensure that the particular nutritional requirements of the patient are effectively met.

When used in accordance with manufacturers' instructions, foods 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 recognised scientific data. Foods for special medical purposes may only be composed of nutrients evaluated and considered safe for human consumption by scientifically recognised international agencies. Furthermore, it must be assured that appropriate quality control and sanitation standards and procedures are in place.

Foods for special medical purposes are numerous and their composition may differ substantially depending on the specific disease, disorder or medical condition of the patients, and the age and sex of the patients. Because of the diversity of such foods and the rapidly evolving scientific knowledge on which they are based, it is not appropriate to lay down detailed compositional rules. The scope of this Codex document should therefore not be extended. Macroelements and other nutrients should not be included.

RECOMMENDED LEVELS OF VITAMINS AND MINERALS

The recommendations presented in the following are intended for complete formula foods only. Thus, they are formulated in such a way as to serve as the sole source of nourishment.

As the foods must very often be consumed over prolonged periods of time, they should be formulated and manufactured in such a way as to assure on the one hand that nutritional requirements are adequately met and preclude an unnecessary high nutrient intake on the other. They must contain all essential vitamins, minerals and trace elements in order to meet at least existing physiological needs. Formulation of such foods, including the vitamin and mineral content, should be based on sound medical and nutritional principles.

The values for levels of vitamins and minerals originally proposed by Germany in the documents of 1998 (CX/NFSDU 98/8) and 2000 (CX/NFSDU 00/9) are based on the recommendations for the daily nutrient intake. Minimum values 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.

For unproblematic nutrients, the upper value was defined to be the threefold (300%), for nutrients known to be problematic it was twice the amount (200%) of the lower value in order to prevent excessive intake or overdose. Since certain patients might have a greater need for electrolytes and vitamins, the fivefold of the lower level was established for sodium and vitamins E, C and B12 respectively. Exceptions are proposed for calcium and vitamin D for children aged 1 to 10 years.

The proposed ranges for complete formula foods are summarised in the annexes I and II. The values are based on an energy intake of respectively 2000 and 1500 kcal/day, with calculations of the nutrient level/100 kcal and 100kJ). Both annexes are kept in square brackets.

In order to respond to specific requirements, deviations from the composition of complete formula foods, i.e. from the established minimum and maximum levels, are admissible in one or more nutrients.¹ However, these deviations should be explicitly stated and well justified (e.g. no added vitamin A and lower levels of phosphate and potassium for patients with renal insufficiency).

Any nutrients contained in these special foods that are not subject to disease-specific adjustments shall be covered by the same recommendations as those applying to complete formula foods.

REFERENCES

- Commission Directive 1999/21/EC on dietary foods for special medical purposes. Official Journal of the European Commission. Brussels, Luxembourg, 1999.
- Deutsche Gesellschaft für Ernährung (DGE): Empfehlungen für die Nährstoffzufuhr. 5. Auflage. Umschau Verlag, Frankfurt, 1991.
- Grossklaus, R.: Noble, P.: Regelungen fuer bilanzierte Diaeten in der Diaetverordnung. Akt. Ernaehr.-Med. 15: (9-16), 1990.
- FDA: Regulation of medical foods. Federal Register, Vol. 61, No. 231, 1996.
- Joint FAO/WHO Expert Consultation on Human Vitamin and Mineral Requirements. Preliminary report on nutrient intakes. FAO. Bangkok, Thailand, 1998.
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- Moore, R.: Medical Foods for Celiac Patients. Lifeline, 1997.
- National Research Council (NRC): Recommended dietary allowances. 10. Auflage, National Academic Press, Washington D.C., 1989.
- Okada, A. et al.. Trace element metabolism in parenteral and enteral nutrition. Supplement to Nutrition, Vol. 11: (106-13), 1995.

¹ The Directive of the European Commission also allows for deviations when special dietary requirements call for adjustment (Commission Directive 1999/21/EC).

[ANNEX I: MINIMUM AND MAXIMUM LEVELS² OF VITAMINS, MINERALS AND TRACE ELEMENTS IN FOODS FOR SPECIAL MEDICAL PURPOSES (FOR PERSONS OVER 1 YEAR OF AGE)³⁴

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

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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 LEVELS² 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)

		CX/NFSDU 98/8			
Nutrient		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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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).

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