

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 4 (a)

CX/NFSDU 06/28/4-Add.3
August 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES Twenty-eighth Session

PROPOSALS OF THE WORKING GROUP ON SECTION 3: ESSENTIAL COMPOSITION AND QUALITY FACTORS (At Step 6 of the Procedure)

(prepared by Germany)

Governments and interested international organizations are invited to submit comments or information on the document below and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Fifteenth Edition*) preferably by email, **to:** Dr Rolf Grossklaus, Director and Professor, Federal Institute for Risk Assessment (BfR), P.O. Box 33 00 13, 14191 Berlin, Germany (fax: +49 1888 529-4965; email: ccnfsdu@bmvel.bund.de), with a copy **to:** Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by fax +39-06-5705-4593 or email codex@fao.org **not later October 1, 2006¹**.

Background

During its 19th session in 1995, CCNFSDU decided that a revision of the current Standard for Infant Formula (CODEX STAN 72-1981) should be undertaken. After endorsement of this new task by CAC, a first draft was prepared by the Netherlands and circulated for comments before the 20th session of CCNFSDU in 1996. Since then the Draft Revised Standard for Infant Formula has been on the agenda of every session of CCNFSDU. Electronic Working Groups (eWG) and ad-hoc Working Groups convening before the plenary sessions of the Committee have been in place since 2000 and 2002, respectively. An International Expert Group (IEG) reviewed the proposed compositional criteria for infant formula in 2005 and published a report of proposals (Koletzko et al. 2005, JPGN 41: 584-599), which was discussed during the 27th session of CCNFSDU in 2005.

However, because still no agreement could be reached, the Committee decided to keep the entire Section 3 in square brackets and to ask the eWG under the chairmanship of Germany to look especially at the discrepancies between the proposed maximum values and the amounts of nutrients currently used in infant formula in member countries, with the understanding that comments on this matter and other issues raised on Section 3 be sent to the Delegation of Germany by 15 February 2006. The Observer from ESPGHAN was

¹ Note: Comments submitted to the Electronic Working Group in response to CL 2005/53-NFSDU would be available at the meeting as CRD.

asked by the Committee to provide an opinion on the discrepancies. The Observer from ISDI proposed to submit global data for currently applied maximum values for infant formula. The delegation of Germany would prepare a revised Section for consideration by the next session of the Committee.

The eWG² had two rounds of comments in 2006. ISDI provided a report in March 2006 on analytical values, measured between 2000 and 2005 in infant formulas as part of the quality monitoring performed by five major manufacturers producing in Asia, Central America, Europe, North America and South America. These products were sold in Africa, Asia, Central America, Europe, North America, the Middle East, Oceania and South America. While the current draft of the section on essential composition specifies minimum and maximum levels for 31 nutrients – 3 macronutrients, 13 vitamins, 12 minerals and 3 others, a comparison of nutrient levels in current products with proposed levels showed that there was no discrepancy for 16 nutrients. For 15 nutrients, however, levels in current products exceeded the proposed maximum levels. Those 15 nutrients are vitamin A and K, thiamin, riboflavin, niacin, vitamin B6, folic acid, vitamin B12, vitamin C, biotin, iron, copper, manganese, potassium and iodine. Levels of these 15 nutrients were further analysed and data (expressed as per 100 kcal) were presented as ranges of means and standard deviations. Milk-based liquid, milk-based powder, soy-based liquid and soy-based powder formula were investigated. ESPGHAN provided a detailed discussion of the ISDI report and on the proposals made in this report by the end of June 2006.

A compilation of all comments sent to the chair of the eWG with the reports by ISDI and ESPGHAN attached as appendices (in English only) will be made available to all participants and the *Ad-Hoc* Working Group convening on 28 October before the 28th session of the Committee.

The Delegation of Germany has prepared a revised version of Section 3 of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants according to the opinions and proposals of the members of the eWG and this is presented to the Committee. The Delegation of Germany hopes that the format of this revised draft will aid the Committee in concentrating on those issues, which are important and need to be decided with priority.

In order to illustrate the degree of dissent which still exists after ten years of deliberation in the Committee, only text and numbers which have not been disputed by any member of the eWG are given in bold. In addition, consensus or non-consensus is indicated in a column to the right of every item. More details can be found in the compilation of comments and its appendices mentioned above. Some mistakes have been corrected. A minor problem, namely the degree of precision in converting numbers per 100 kcal to per 100 kJ is indicated with an *.

² Argentina, Australia, Costa Rica, European Community (EC), Guatemala, Japan, Malaysia, Mexico, New Zealand (NZ), Norway, United states of America (USA), Venezuela, European Network of Childbirth Associations (ENCA), European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN), International Dairy Federation (IDF), International Special Dietary Foods Industries (ISDI), and World Sugar Research Organisation (WSRO).

REVISED DRAFT OF SECTION 3 OF THE DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS, SECTION A

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS				eWG conclusion
3.1 Essential Composition				
3.1.1 Infant formula is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten-free.				No consensus
3.1.2 Infant formula prepared ready for consumption in accordance with instructions of the manufacturer shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy.				Consensus
3.1.3 Infant formula prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper¹ levels, as appropriate. The general principles for establishing these levels are identified in Annex II of this standard.				Consensus
¹ Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of safe use. They may be adjusted based on relevant scientific or technological progress.				No consensus
a) Protein				
Protein²⁾ (g)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Max	Min	Max	
1,8^{3), 4)}	3.0	0.45^{3), 4)}	0.7	

<p>2) [For the purpose of this standard, the calculation of the protein content should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular nitrogen source.] The protein levels set in this standard are based on a nitrogen conversion factor of 6.25.</p> <p>3) [Infant formulae based on non-hydrolysed cows' milk protein containing less than 2 g protein/ 100 kcal and infant formula based on hydrolysed protein containing less than 2.25 g protein/ 100 kcal should be clinically evaluated.]</p> <p>4) Minimum value applies to cows' milk protein. For infant formula based on non-cows' milk protein other minimum values may need to be applied. For infant formula based on soy protein isolate a minimum value of 2.25 g/100 kcal (0.7 g/100 kJ) applies.</p>	<p>No consensus</p> <p>No consensus</p> <p>Consensus</p>												
<p>3.1.4 For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of methionine and cysteine and of tyrosine and phenylalanine may be added together [unless the methionine to cysteine or the phenylalanine to tyrosine ratio are outside the range of 0.7-1.5 : 1].</p>	<p>Consensus on first part</p> <p>No consensus</p>												
<p>3.1.5 Isolated amino acids may be added to Infant Formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.</p>	<p>No consensus</p>												
<p>b) Lipids</p> <p>Total fat⁵⁾ (g)</p> <p>Commercially hydrogenated oils and fats shall not be used in infant formula.</p>	<p>Consensus</p>												
<table border="1"> <thead> <tr> <th colspan="2">Per 100 kcal</th> <th colspan="2">Per 100 kJ</th> </tr> <tr> <th>Min</th> <th>Max</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>4.4</td> <td>6.0</td> <td>1.05</td> <td>1.4</td> </tr> </tbody> </table>	Per 100 kcal		Per 100 kJ		Min	Max	Min	Max	4.4	6.0	1.05	1.4	<p>Consensus</p>
Per 100 kcal		Per 100 kJ											
Min	Max	Min	Max										
4.4	6.0	1.05	1.4										
<p>⁵⁾ Lauric and myristic acids are constituents of fats, but combined should not exceed 20% of [total fatty acids]. The content of trans fatty acids shall not be higher than [3 %] of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to [3%] of trans fatty acids is intended to allow for the use of milk fat in infant formulae. The erucic acid content shall be less than 1% of total fatty acids.</p>	<p>No consensus</p>												

Linoleic acid (g)				
Per 100 kcal		Per 100 kJ		No consensus on Max
Min	Max	Min	Max	
0.3	1.2	0.07	0.3*	
a-Linolenic acid (mg)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Max	Min	Max	
50	N.S.	12	N.S.	
N.S. = NOT SPECIFIED				Consensus
Ratio linoleic/ a-linolenic acid				
Min	Max	Min	Max	Consensus
5:1	15:1	5:1	15:1	
c) Carbohydrates				
Total carbohydrates⁶⁾				
Per 100 kcal		Per 100 kJ		Consensus
Min	Max	Min	Max	
9.0	14.0	2.2	3.3	
⁶⁾ Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches may be added to Infant Formula up to 30% of total carbohydrates or up to 2 g/100 ml. [Sucrose, unless needed, and the addition of fructose particularly should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance.]				No consensus

d) Vitamins				
Vitamin A ($\mu\text{g RE}^7$)				
Per 100 kcal		Per 100 kJ		No consensus on Max
Min	Max	Min	Max	
60	180	14	43	
⁷⁾ expressed as retinol equivalents (RE). 1 $\mu\text{g RE} = 3.33 \text{ IU Vitamin A} = 1 \mu\text{g all-trans retinol}$. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.				Consensus
Vitamin D₃ (μg^8)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Max	Min	Max	
1	2.5	0.25	0.6*	
⁸⁾ Calciferol. 1 $\mu\text{g calciferol} = 40 \text{ IU vitamin D}$				Consensus
Vitamin E (mg a TE⁹⁾)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Guidance upper level	Min	Guidance upper level	
0.5¹⁰⁾	5	0.12¹⁰⁾ *	1.2	
⁹⁾ 1 mg a-TE (alpha-tocopherol equivalent) = 1 mg d-a-tocopherol ¹⁰⁾ Vitamin E content shall be at least 0.5 mg a-TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg -TE/g linoleic acid (18:2 n-6); 0.75 a-TE/g a-linolenic acid (18:3 n-3); 1.0 mg a-TE/g arachidonic acid (20:4 n-6); 1,25 mg a-TE/g eicosapentaenoic acid (20:5 n-3); 1.5 mg a-TE/g docosahexaenoic acid (22:6 n-3).				Consensus
Vitamin K (μg)				
Per 100 kcal		Per 100 kJ		No consensus on GUL
Min	Guidance upper level	Min	Guidance upper level	
4	25	1	6	

Thiamin (µg)				
Per 100 kcal		Per 100 kJ		No consensus on GUL
Min	Guidance upper level	Min	Guidance upper level	
60	300	14	72	
Riboflavin (µg)				
Per 100 kcal		Per 100 kJ		Almost consensus on GUL of 600 µg/100 kcal
Min	Guidance upper level	Min	Guidance upper level	
80	400	19	100*	
Niacin¹¹⁾ (µg)				
Per 100 kcal		Per 100 kJ		No consensus on GUL
Min	Guidance upper level	Min	Guidance upper level	
300	1500	70*	360*	
¹¹⁾ Niacin refers to preformed niacin				Consensus
Vitamin B₆ (µg)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Guidance upper level	Min	Guidance upper level	
35	175	8.5*	45*	
Vitamin B₁₂ (µg)				
Per 100 kcal		Per 100 kJ		No consensus on GUL
Min	Guidance upper level	Min	Guidance upper level	
0.1	0.5	0.025	0.12	

Pantothenic acid (µg)				
Per 100 kcal		Per 100 kJ		No consensus
Min	Guidance upper level	Min	Guidance upper level	
60	300	15	75	
Folic acid (µg)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Guidance upper level	Min	Guidance upper level	
10	50	2.5	12	
Vitamin C¹²⁾ (mg)				
Per 100 kcal		Per 100 kJ		No consensus on Max/GUL
Min	Max/[Guidance upper level	Min	Max/Guidance upper level	
10	30	2.5	7*	
¹²⁾ expressed as ascorbic acid				Consensus
Biotin (µg)				
Per 100 kcal		Per 100 kJ		No consensus on GUL
Min	Guidance upper level	Min	Guidance upper level	
1.5	7.5	0.4	1.5	
e) Minerals and Trace Elements				
Iron (formula based on cows' milk protein and protein hydrolysate) (mg)				No consensus
Per 100 kcal		Per 100 kJ		No consensus
Min	Max	Min	Max	
0.3 ¹³⁾	1.3	0.07 ¹³⁾	0.3	
¹³⁾ In populations where infants are at risk of iron deficiency, iron contents higher than the minimum level of 0.3 mg/100 kcal may be appropriate and recommended at a national level.				Consensus

Iron (formula based on soy protein isolate) (mg)				No consensus
Per 100 kcal		Per 100 kJ		No consensus
Min	Max	Min	Max	
0.45	2.0	0.1*	0.5	
Calcium (mg)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Max	Min	Max	
50	140	12	35	
Phosphorus (formula based on cows' milk protein and protein hydrolysate) (mg)				No consensus
Per 100 kcal		Per 100 kJ		Consensus
Min	Guidance upper level	Min	Guidance upper level	
25	90	6	22	
Phosphorus (formula based on soy protein isolate) (mg)				No consensus
Per 100 kcal		Per 100 kJ		No consensus on Min
Min	Guidance upper level	Min	Guidance upper level	
30	100	7	25	
Ratio calcium/ phosphorus				
Per 100 kcal		Per 100 kJ		Consensus
Min	Max	Min	Max	
1:1	2:1	1:1	2:1	
Magnesium (mg)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Guidance upper level	Min	Guidance upper level	
5	15	1.2	3.6	

Sodium (mg)				
Per 100 kcal		Per 100 kJ		Consensus on levels No consensus on Max/GUL
Min	Guidance upper level	Min	Guidance upper level	
20	60	5	14	
Chloride (mg)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Guidance upper level	Min	Guidance upper level	
50	160	12	38	
Potassium (mg)				
Per 100 kcal		Per 100 kJ		No consensus on GUL
Min	Guidance upper level	Min	Guidance upper level	
60	160	14*	38	
Manganese (µg)				
Per 100 kcal	Per 100 J			No consensus on GUL
Min	Guidance upper level	Min	Guidance upper level	
1	50	0.25*	12	
Iodine (µg)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Guidance upper level	Min	Guidance upper level	
10	75	2.5	18	
Selenium (µg)				
Per 100 kcal		er 100 kJ		Consensus
Min	Guidance upper level	Min	Guidance upper level	
1	9	0.24*	2.2	

Copper (μg)¹⁴⁾				
Per 100 kcal		Per 100 kJ		No consensus
Min	Max	Min	Max	
35	80	8.5	19	
¹⁴⁾ Adjustment may be needed in these levels for infant formula made in regions with a high content of copper in the water supply				Consensus
Zinc (mg)				
Per 100 kcal		Per 100 kJ		No consensus on Max
Min	Max	Min	Max	
0.5	1.5	0.12	0.36	
f) Other Substances				
Choline (mg)				
Per 100 kcal		Per 100 kJ		Consensus Max or GUL?
Min	Max	Min	Max	
7	50	1.7	12	
Myo-Inositol (mg)				
Per 100 kcal		Per 100 kJ		Consensus Max or GUL?
Min	Max	Min	Max	
4	40	1	9.5	
L-Carnitine (mg)				
Per 100 kcal		Per 100 kJ		Consensus
Min	Max	Min	Max	
1.2	N.S.	0.3	N.S.	
3.2 Optional ingredients				Consensus
3.2.1 In addition to the compositional requirements listed under 3.1.3, other ingredients may be added in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies.				Consensus Addition?

3.2.2 The suitability for the particular nutritional uses of infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.		Consensus Addition?
3.2.3 The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100 kJ) in the Infant Formula ready for consumption shall not exceed:		No consensus
Taurine mg		
Per 100 kcal	Per 100 kJ	Consensus
12	3*	Min?
Total [added] nucleotides mg		
Per 100 kcal	Per 100 kJ	No consensus
5	1.2	
Cytidine 5'-monophosphate (CMP) mg		
Per 100 kcal	Per 100 kJ	No consensus
2.5	0.6	
Uridine 5'-monophosphate (UMP) mg		
Per 100 kcal	Per 100 kJ	No consensus
1.75	0.4	
Adenosine 5'-monophosphate (AMP) mg		
Per 100 kcal	Per 100 kJ	No consensus
1.5	0.36	
Guanosine 5'-monophosphate (GMP) mg		
Per 100 kcal	Per 100 kJ	No consensus
0.5	0.12	
Inosine 5'-monophosphate (IMP) mg		
Per 100 kcal	Per 100 kJ	No consensus
1.0	0.24	

Phospholipids mg		
Per 100 kcal	Per 100 kJ	Consensus
300 (or 2g/L)	72	
Docosahexaenoic Acid¹⁵⁾ (% of fatty acids)		
Maximum		No consensus
0.5		
¹⁵⁾ If docosahexaenoic acid (22:6 n-3) is added to infant formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which is not a desirable constituent of infant formula but can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid.		No consensus
Fluoride (µg)		
Per 100 kcal	Per 100 kJ	Consensus
60	14	
3.2.4 Only L(+)-lactic acid producing cultures may be used.		Consensus
3.3 Vitamin Compounds and Mineral Salts		Consensus
Vitamins and minerals added in accordance with Section 3.1.3 (d and e) and 3.2.1 should be selected from the Advisory List: [Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children].		
3.4 Consistency and Particle Size		Consensus
When prepared according to the label directions for use, the product shall be free of lumps and of large coarse particles and suitable for adequate feeding of young infants.		
3.5 Purity Requirements		No consensus
All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.		
3.6 Specific Prohibitions		No consensus
The product and its component shall not have been treated by ionizing irradiation.		