codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 (a) **CX/NFSDU 05/27/6-Add.2**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
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DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS: SECTION A DRAFT REVISED STANDARD FOR INFANT FORMULA

- ***Comments at Step 6 of the Procedure –***

Comments from

EUROPEAN COMMUNITY
IRAN
KUWAIT

IDF - International Dairy Federation

EUROPEAN COMMUNITY

SECTION 3.1 "ESSENTIAL COMPOSITION"
The provisions in paragraphs **3.1.2 and 3.1.3** on the essential composition and the general principles for establishing minimum and maximum values in **Annex II** are being considered by the Working Group on the essential composition of infant formula. Representatives of the EC intend to participate in the meeting of the Working Group which is scheduled to take place on 19 November 2005.

SECTION 3.6 SPECIFIC PROHIBITION
The wording "contain commercially hydrogenated oils and fats…" is in square brackets. In the current draft of the revised Standard under section 3.1.3 b) it is proposed that there should be a restriction on the amount of *trans* fatty acids in the product. The EC believes that such a restriction should be sufficient to deal with the issue of the addition of commercially hydrogenated oils and fats to infant formula.

SECTION 4 FOOD ADDITIVES
The EC has the following comments on the proposed list of additives included in the document CX/NFSDU 05/27/6-Add.1 prepared by the Electronic Working Group (EWG) led by Switzerland.

The EC notes that JECFA has expressed the opinion that children should not be exposed to food additives before the age of 12 weeks, and that the ADI does not apply to children below the age of 12 weeks[1]. The EC Scientific Committee on Food (SCF) has endorsed the principle that technological additives should not be used in food for infants and young children[2], although exceptional technological circumstances may justify the use of an additive. Therefore, the EC scientific advisory committees have always performed a new risk assessment on evaluated food additives when the proposed use is for foods intended for infants and young children. Infant formulae may be the only food for infants during their first months of life. For this reason it is imperative that this food only contains additives for which there is a rigorous technological justification.

- Based on these general principles the Commission does not support the inclusion of the following additives in the proposed list of additives in Section A: Infant Formula:

4.1 Thickeners
410 Carob bean gum (Locust bean gum).

1412 Distarch phosphate, 1414 Acetylated distarch phosphate, 1413 phosphated distarch phophate, 1440 Hydroxypropyl starch.

407 Carrageenan – The European Community does not support the use of carrageenan in infant formula. This is based on the the Opinion of the Scientific Committee on Food on Carrageenan, expressed on 5 March 2003[3] which states that:

> "In the absence of any further information on possible absorption of carrageenan by the immature gut in the very young infant, the Committee reaffirms its earlier view (SCF, 1998) that it remains inadvisable to use carrageenan in infant formulae that are fed from birth, including those in the category of foods for special medical purposes. The Committee has no

[1] WHO (1978). Evaluation of certain food additives. Twenty-first report of the Joint FAO/WHO Expert Committee on food additives. World Health Organisation, Geneva, Technical Report series no 617.

[2] Opinion of the Scientific Committee on Food on the applicability of the ADI (Acceptable Daily Intake) for food additives to infants (expressed on 17/09/1998)

[3] Opinion of the Scientific Committee on Food on Carrageenan (expressed on 5 March 2003) (see http://europa.eu.int/comm/food/fs/sc/scf/out164_en.pdf)

objection to the use of carrageenan in foods for older infants, such as follow-on milks (SCF, 1983) and weaning foods."

415 Xanthan gum – There is no technological need for this additive in infant formula intended for infants in good health.

4.3 Acidity Regulators
524 Sodium hydroxide, 500ii Sodium hydrogen carbonate, 500i Sodium carbonate, 525 Potassium hydroxide, 501ii Potassium hydrogen carbonate, 501i Potassium carbonate, 526 Calcium hydroxide.

- In addition the European Community has the following comments on the conditions of use for the following additives:

4.1 Thickeners
412 Guar gum – It is proposed that the use of guar gum should be restricted to use in liquid formulas containing partially hydrolysed protein instead of being permitted for use in all types of infant formula.

Packaging gas
The EWG proposal is that packaging gases should be listed as processing aids. The EC notes that packaging gas is not currently a recognised INS functional class, but there are discussions ongoing in CCFAC to include this category as a food additive. Under the EU legislation packaging gas is a food additive category and the following gases are permitted: carbon dioxide (INS 290), nitrogen (INS 941), nitrous oxide (INS 942), argon (INS 938), helium (INS 939), oxygen (INS 948) and hydrogen. The EC proposes that the additional gases should be included in the Standard.

4.6 Carry-over of food additives
The EC believes that the list of food additives that may be used in nutrient preparation should be part of the Advisory List of the substances and therefore agrees with the principle under 4.6 (b).

In addition, the EC proposes that with respect to the drafting of this standard consideration should be given to the suggestion of the Committee on Food Additives and Contaminants that section 4.10 of the Draft Revised Standard for Processed Cereal-based foods for Infants and Young Children should be redrafted and included as the introductory paragraph before the table of food additives (see ALINORM 05/28/12 (Appendix 5, part 2)).

SECTION 5.2 OTHER CONTAMINANTS
It is proposed that in the first paragraph "Infant formula" should be changed to "The product" to be consistent with wording in other sections of the Standard.

The EC questions whether it is necessary to include the level for lead in the Standard as it is already covered by the reference to "maximum levels established by the Codex Alimentarius Commission" which would include Maximum Levels for Lead (CODEX STAN 230-2001 Rev.1 2003) which establishes a maximum level for lead in infant formula. If future revision of the Codex standards on contaminants introduces a change in the maximum level of lead in the product a discrepancy between the two standards could be created.

SECTION 7 PACKAGING
If packaging gases are included in the section 4.5 food additives, the final part of paragraph 7.1 "nitrogen and carbon dioxide may be used as packing media" should be deleted. If packaging gases are to be included in this section the EC requests that nitrous oxide (INS 942), argon (INS 938), helium (INS 939), oxygen (INS 948) and hydrogen be included in the list.

SECTION 9 LABELLING
9.1.5 As indicated in previous EC comments the EC does not believe that this mandatory labelling requirement is necessary. The EC notes that the General Standard on the Labelling of Pre-packaged

Foods (Codex Stan 1-1985) means that ingredients that contain milk and milk products (including lactose) must be declared in the list of ingredients. Therefore, the need for the specific labelling requirement that if a product contains neither milk nor milk derivative it shall be labelled "contains no milk or milk products", or an equivalent phase, is not clear. The EC proposes that this provision should be deleted. However, if it is considered that such a provision is necessary it should be facilitative not mandatory and it is proposed that "shall" should be changed to "may".

9.3 Declaration of Nutritive Value

The EC notes that once the revision of section 3 on the essential composition and quality factors has been agreed the wording of section 9.3 on the declaration of nutritive value will need to be reviewed and updated, for example it may be necessary to list the additional nutrients that are included in section 3.1.3.

9.5 Information for Use

During the last session of the Committee section 9.5 Information for Use was expanded by regrouping the relevant provisions that had been dispersed in the previous version of the standard. In the light of this change the EC has the following comments on this section.

a) The first unnumbered paragraph was previously part of the description of infant formula, therefore the wording is not in a form that is suitable for the section on instructions for use. The principle that products should be reformulated with safe water is important and the EC believes that the paragraph 9.5.1 should be reviewed to ensure that this principle is reflected.

b) Paragraph 9.5.2 concerns the storage of the product after opening. It would be logical to have the paragraphs concerning the preparation of the product one after another (i.e. 9.5.1, 9.5.3 and 9.5.4), therefore, the EC proposes that paragraph 9.5.2 should be moved to the end of the section and the paragraphs of the section renumbered accordingly.

9.6 Additional Labelling Requirements

With respect to the paragraph 9.6.6 the European Community considers that the recently adopted Codex Guidelines on the Use of Nutrition and Health Claims, which indicate that such claims can be specifically provided for in Codex standards or in national legislation, apply. The proposed text would be in contradiction with the above Guidelines and, therefore, should be deleted.

KUWAIT

PROPOSED MODIFICATION OF ALINORM 05/28/26, Appendix IV (A)	**JUSTIFICATION**
4. FOOD ADDITIVES	
4.1 THICKENING AGENTS	
INS 410 : Carob bean gum (locust bean gum) ~~0.1~~ g in [0.5g] all type of formula	We can eccept (0.5g) as long as there is no side effects.
4.2 EMULSIFIERS	
INS 472e : Diacetyltartaric and fatty acid of esters of glycerol GMP	ADD THIS EMULSIFIER Rationale : Retains homogeneity of liquid products and liquid reconstituted powder especially of formulas where whole proteins are not used. Has a high HLB, works better in combination with additive 322 and 471. Has a GRAS status in the US
4.4 ANTIOXIDANTS	
INS 309 : GAMMA- TOCOPHEROL	Add these antioxidants.

INS 308 : Delta- tocopherol 1 mg in all types of infant formula singly or in combination	Rationale : Alone or in combination to stabilise preparations containing fats and vitamins. Synergistic effect with additives 304 and 305. They are used as natural antioxidants and are much more effective in preventing oxidation of vulnerable fatty acids than alpha tocopherol.
4. 6 CARRY - OVER OF FOOD ADDITIVES	
NO food additives shall be present as a result of carry - over from raw materials and other ongredients with the exception : (a) of the food additives listed under Sections 4.1 to 4.9 of this standard within the limits of the maximum levels stipulated in this standard ; and (b) [of the carrier substances mentioned in the Advisory List of Vitamin compounds for Use in Foods for infants and children (CAC/GL 10-1979) within the limits of the maximum levels stipulated in that List.]	DELETE [ ] Rationale : We acknowledge that CCFAC is currently considering to establish a new additive functional class for nutrient carriers. However, we believe that the list of nutrient carriers should remain as presently the case, namely at the end of the advisory list of mineral salts and vitamin compounds for the use in foods for infants and young children. As this list is currently under revision by CCNFSDU we consider that this list of nutrient carriers should also be reviewed.
9. LABELLING	
9.1 NAME OF THE PRODUCT	
9.1.3 The sources of protein in the product shall be clearly shown on the label.	The sources and types of protein , lecithin , Mono- and di-glycerides and gelatin in the product shall be clearly shown on the label
9.1.6 [~~ products containing not less than 0.5 mg iron (Fe) / 100 kilocalories shall be labeled " infant formula with added iron "~~] ~~Or~~ [products containing less than 0.5 mg iron (Fe) / 100 kilocalories shall be labeled with a statement to the effect that when the product is given to infants over that age of four months, their total iron requirements must be met from additional sources.]	Delete (or) and put (and if the) Rationale : The two options are needed to explain the excess or the reduction of iron .
9.3 DECLARATION OF THE NUTRITIVE VALUE	
(b) the total quantity of each vitamin , mineral, choline as listed in paragraph 3.1.2 of this Standard and any ~~other~~ optional ingredient if added as listed in paragraph 3.2 of this Standard per 100 grammes of the food as sold as well as	**“** optional ingredients if added **“**Add Rationale : Adding **“** optional **“** is in line with section 3.2. including " if added " avoids misinterpretation. **“**
per 100 milliliter of the food ready for use. when prepared according to the instructions	

on the label .	
9.5 INFORMATION FOR USE	
~~[products in liquid form may be used either directly or prepared with safe water and previously boiled water before feeding according to directions for use . products in powder form also requires safe and previously boiled water for preparation.~~ All products should be used according to instructions for use. products in powder form and concentrated liquids should be prepared with safe and previously boiled water before feeding . Ready to use liquid formula may be used directly according to instructions for use .	Reword and change the order the sentence. Rationale : Instructions for use require outmost attention and clarity. Powdered infant formula are most widely used.
ANNEX 2	
GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA	
5. when establishing minimum and maximum amounts, the following should be taken into account: a) bioavailability, processing losses and shelf-life stability from the ingredients and formula matrix, ~~b) total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients in the ingredients and added nutrients,~~ ~~c) the inherent variability of nutrients in ingredients and in water that may be added to the infant formula during manufacture.~~ b) total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients and their variability in the ingredients and added nutrients.	Reword this section Rationale: Point 5b) and point 5c) address the same matter of ingredient variability,
7. In establishing minimum or maximum amounts of nutrients per 100 kcal (or per 100 KJ) of infant formula based on consideration of reference values for the nutrients expressed as units **per daily intake or per kilogram of body weight, the following assumptions will be used:** **~~a~~)The mean intake of prepared** **formula for infants from birth to six months of age is750 ml per day. This is based on the ~~following~~ assumptions of :**	

~~i~~) a representative body weight for an infant over this period would be 5 kg and a representative caloric intake would be 500 kcal per day (or 100 kcal/kg/day) over the first six months ; resulting in a formula providing about 67 kcal/100 ml] **~~[ii) prepared formulas provide about 67 kcal/100 ml]~~** **Modifications of the approach may be needed when there is justification for deviating from one or more of these assumptions with regard to the specific** **formula product or specific infant population group.**	**Editorial changes**

IRAN

TITLE:
The dietary needs of infants with special medical conditions can be varied and by their very nature require specialist attention of their own. It is felt that infant formulas for special medical purposes is beyond the scope of its normal counterpart and hence should be covered by a separate standard altogether .

2.1.2 Delete the square bracket .

3.1.2 We accept not Less than 60 kcal and not more than 70 kcal of energy for 100ml .

3.1.3 a) we approved 6.38 because Infant formula based on Cows' milk .

3.1.3 a) (ii) Delete the square bracket .

Nutrients (per 1ookcal, unless otherwise stated)		
a) protein (g)	Minimum	Maximum
Soy protein protein hydrolysates	2.25	3
L-Carnitine mg	>= 0.7	N.S.
Taurine mg	15.8	24.6
Nucleotides , if added mg	0	5
b)Fat and fatty acids		
Total fat g Total saturated fatty acids g/100 g fat	4.4 40	6.0 45
Total Monounsaturated Fatty acids g/100g fat	37	40
Total polyunsaturated fatty acids g/100g fat	13	18
Inositol mg	4	40

Lauric and myristic acids		Together<= 20% of total fatty acids and contain 40% lauric acid and 60% myristic acid
Linoleic acid	0.3	1.2
Formula without added LCPUFA α- Linolenic acid mg	 >=50	 N.S.
Formula with added LCPUFA α – Linolenic acid mg Linoleic/α – Linolenic ratio n-6 LCPUFA Arachidonic acid n-3 LCPUFA Linseed because of containing over 50% Linolenic acid, safflower because it contains over 70% Linoleic acid, sesame seed oil because of the presence of phenolic compounds and Rapeseed oil because of the presence of Erucic acid and peanut oil because of high level in allergic agents and Arachidic acid	 >= 50 5 <= 2% of total fatty acids <=1% of total fatty acids <=1% of total fatty acids	 20 No use of these type of oils
Hydrogenated oils trans fatty acids Erucic acid	None <= 1% of total fatty acids none	
C)carbohydrates lactose in Cow's milk protein- and protein hydrolysates formulae g	 >= 8.1 90 % of total carbohydrates	
Saccharose Fructose Glucose Focus-Glucoseamine-Galactoseamine–polysaccharides contain nitrogen – Maltodextrins and oligosaccharides in human milk g Starches	None None None <,= 0.9 None	

D) VITAMINS		
Vitamin A µgRE	75	180
Vitamin D µg	1	2.5
Thiamin µg	40	[300]
Riboflavin µg	60	[400]
Niacin µg	300	[1200]
Pantothenic acid µg	300	[2000]
Folic acid µg	4	[30]
Vitamin c mg	8	[30]
E) MINERALS AND TRACE ELEMENTS		
Iron mg		
Cow's milk protein and Protein hydrolysate formula	0.3	1.5
Soy protein formula	1.0	2.0
Calcium mg	60	140
Calcium/phosphorus-Ratio	1.0	2.0
Phosphorus mg	Cows milk protein - and protein hydrolysate Formula : 30 20	90
Sodium mg	50	35
Chloride mg	80	125
Potassium mg	5	145
Manganese µg	10	25
Iodine µg	1.5	50
Selenium µg	20	3
Copper µg	0.5	80
1.1. Zinc mg Cow's milk protein And protein hydrolysate Formula		1.5

3.6 DELETE THE SENTENCE IN THE SQUARE BRACKET

4.1.2 Carob bean gum 0.1 g in all types of infant formula
4.5 We approve this section
5.2 Heavy metals = 0
7. Packaging 7.1 should be changed to read :
The product shall be packed in containers, with a Suitable functional recap, which will safeguard ….
Justification :
Some of the containers used for the packaging of infant formula do not unfortunately offer an adequate possibility of re- cap after opening . Much effort is made to ensure that such products are prepared in compliance with the highest hygienic standards: It would only be logical to also try to maintain that standard, to prevent product re- contamination during handling and after partial use of the packet contents .

9.1.5 Delete the square bracket
9.1.6 we approve each two sentences together
9.6.6 Delete the sentence in the square brackets
10- Methods of Analysis and sampling
In This section there aren't any refrence for Determination of Biotin, Iron, Magnesium, chloride, chromium, manganese, molybdenum, Fluorid, selenium, Copper, Zinc

IDF - International Dairy Federation

SUMMARY
The following comments of the International Dairy Federation (IDF) relate to Section 3 Essential Composition and Quality Factors, 3.1 Essential Composition, para. 3.1.3 of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants : Section A (ref. Codex ALINORM 05/28/26, Appendix IV (A)**.**

1.1 Key Points

i. There continues to be no valid scientific justification for lowering the current nitrogen conversion factor for dairy proteins from 6,38 to 6,25 for evaluation of infant formulas.
ii. Changes to the standard for protein determination of infant formula should be based on nutrition and not chemical analysis, unless such analysis has been calibrated with nutritional quality.
iii. In the abscence of nutritional arguments, no change should be made to the chemical analysis-based method of determining the protein content of infant formula.
iv. However, if a chemical analysis-based method is to be used to determine the protein content of infant formula, then values of 6,38 for the nitrogen conversion factor for dairy protein and 5.71 for the nitrogen conversion factor for soy protein should be used.
v. Use of the default 6,25 factor results in both underestimation by about 2-3 % of the actual protein content for milk, and serious overestimation of the protein content of proteins from plant sources. In the case of soy protein, the actual protein content would be overestimated by approximately 9 %.
vi. The Codex Committee of Milk and Milk Products and the Codex Committee of Methods of Analysis and Sampling must be consulted before making any change to the standard related to milk and the analytical method for determining the protein content in milk.

1.2 Concerning the nitrogen conversion factor

In the current standards for infant formulas, there are 2 nitrogen conversion factors: 6,38 for milk and 6,25 for vegetableprotein. The factor 6,38 is used in the Codex international standards for milk and milk products, in the Codex international methods of analysis, and also in World Customs Organization harmonization system, and has been implemented in the dairy and food sector throughout the world.
IDF recommends no change should be made to the nitrogen conversion factor for dairy protein in infant formula. If such a change would be proposed, there should be an independent study where the experimental design includes the comparison of the **protein contents** of soy-based versus dairy-based infant formula.
IDF respectfully disagrees with the proposal to lower the present conversation factor for milk protein from 6,38 to 6,25. Indeed from detailed investigation of protein content in infant formulas it is shown that 6,38 is the more accurate factor compared to 6,25. The protein method with the 6,38 factor results in noticeably increased accuracy compared to 6,25.

1.3 Concerning the nutritional quality of proteins

If a change in the protein requirements for the composition of infant formulas would be proposed, there should be an independent study where the experimental design includes the comparison of the **nutritional quality (ability of infants to thrive)** of soy-based versus dairy-based infant formula.

GENERAL SCIENTIFIC BACKGROUND

The determination of the protein content in milk, or in other foodstuffs, is commonly done by analysis of total nitrogen according to the reference method of *Kjeldahl*. Total nitrogen in a foodstuff is the sum of nitrogen derived from amino acids included in the proteins and the main portion of peptides, which generally represent the vast majority of nitrogen sources, and that from non-protein nitrogen (NPN) sources. The latter are generally a minor component. The total nitrogen content estimated from the analysis is converted to protein content by multiplying by a factor, which takes into account the nitrogen content of a known, or average, amino acid composition.
A conversion factor of 6,38 for milk and milk products, based on a total nitrogen content of 15,67%, has been widely accepted and is consistent with the AOAC Official Methods (2005 edition of "Methods of Analysis for Nutrition Labelling"), and with the Joint ISO/IDF Standards for Milk:

Determination of Nitrogen Content, Part 1 to 3 [4]. Soy protein has a protein nitrogen content of 17,5 %, giving a conversion factor of 5,7 [5]. Proteins from other plant sources have factors between 5 and 6 [6]. It must be recognized that all these factors represent an approximation. The ideal analytical approach would be to apply a specific conversion factor according to the true chemical composition of each protein. However, this approach is currently difficult to apply in practice.
FAO and WHO have previously documented the use of nitrogen conversion factors of 6,38 for milk and milk products, 5,71 for soy, and 6,25 for foods not included in Table 32 within their report (WHO Technical Report Series No. 552 / FAO Nutrition Meetings Report Series No. 52 – Energy and Protein Requirements, 1973) or when mixed sources of protein are used[7]. This FAO/WHO report continues to be incorrectly used to simplify the nitrogen conversion factor instead of concentrating on the nutritional aspect of infant formulas. In that report, it is stated that protein of foods **not** included in the list is derived by multiplying nitrogen content by the factor of 6,25 on the assumed 16 % average nitrogen content of protein. The report further states that it is common knowledge that this 16 % average is not accurate, therefore the protein determination method based on this assumption is imprecise.

NUTRITIONAL ASPECTS TOWARD ENHANCING THE INFANTS' ABILITY TO THRIVE

The primary objective of infant formula is to deliver a nutritionally complete product to an infant. Mother's milk was designed through evolution to optimize the delivery of nutrition and health; thus it stands as the model for formulation. This includes amino acid composition, digestibility and biological activity of its peptides derived during digestion. Ideally, protein sources will closely mimic what nature has told us.
Protein sources should exhibit relatively low levels of dispensable amino acids so as to not stress the infant's waste nitrogen handling capacity. Conversely, the amino acid profile of the indispensable amino acids must be nutritionally balanced in order to maximize complete and optimal usage of the protein. Finding a readily attainable coefficient adequately capturing these factors stands as the core question. The use of the Nitrogen Conversion Factor stands as the understood factor, but its analytical purpose is not to evaluate correctly the nutritional value of the protein in infant formulas.
Nitrogen Conversion Factor does not account for digestibility – a significant factor in protein quality. Therefore, a factor generic to specific proteins should be included in calculating Nitrogen Conversion Factors. For example, anti-protein digestion factors carried by the protein source need to be accommodated in the NCF calculation.
Metabolically active compounds e.g. peptides, carried by specific proteins need to identified in a formulation. Bioactive components of mother's milk, especially peptides, remain a highly dynamic area of research. The data relate to promoting an infant's ability to thrive. Since these bioactives depend on the primary sequence of the protein its digestibility losses due to processing or the protein source must be accounted for. During processing some of the protein in milk can be hydrolyzed to smaller peptides and amino acids. Although not proteins, these components still provide nutrition to the developing infant.

MORE ACCURATE NITROGEN ANALYSIS OF PROTEIN CONTENT

It has been suggested that the nitrogen conversion factor for evaluating protein content in infant formulas be set at the unique value of 6,25, rather than to maintain the specific value 6,38 for milk proteins as is normal for milk and dairy products[8] [9]. In contrast, Fomon and colleagues have investigated a more accurate nutritional method and values for selected formulas[10] [11]. Miera [9] has

[4] International Standards for Milk: Determination of Nitrogen Content, Part 1 to 5 (ISO 8968-1 - 5:2001 / IDF 20-1 – 5), 2001.
[5] C.V. Morr , J. (1982) Food Science 47: 1751.
[6] Mossé, J. (1990) Agric.Food Chem. 38:18.
[7] WHO Technical Report Series No. 552 / FAO Nutrition Meetings Report Series No. 52 – Energy and Protein Requirements, Table 32, 1973
[8] European Commission (2003), Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant formulas and Follow-on Formulas.
[9] Life Science Research Office (1998), Assessment of Nutrient Requirements for Infant formulas. Center for Food Safety and Applied Nutrition Food and Drug Administration, Department of Health and Human Services, Washington.
[10] Fomon, S.J., Ziegler, E.E., Nelson, S.E. and Frantz, JA (1995), What is the safe protein-energy ratio for infant formulas? *Am. J. Clin. Nutr*. 62, 358-363.

introduced the term "real protein content" ("der tatsächliche Proteingehalt") to refer to the actual protein content of infant formulas, in order to address the relationship between this and results of measurement methods. The "real protein" term was reported to include free amino acids as well as proteins and peptides.

Developing more accurate conversion factors for protein content in infant formulas requires a detailed investigation of the composition of each infant formula. Miera analysed sixteen infant formulas, that included fifteen milk-based, and one soy-based [12]. The group of milk-based infant formulas showed substantial variation in composition compared to standard milk products. This therefore provides a challenge to any simple Protein method to provide an acceptably accurate prediction of protein content in infant formulas.

The inclusion of soy-based formulas presents a further difficulty. The default Protein prediction by using the 6,25 factor results in the real protein content being overestimated by approximately 9 %: the actual lower conversion factor for soy protein is 5,71. Use of the default 6,25 factor results in both underestimation by about 2-3 % of the actual protein content for milk, and serious overestimation of the protein content of proteins from plant sources. In the case of soy protein, the actual protein content would be overestimated by approximately 9 %.

[11] Fomon, S.J., Ziegler, E.E., Nelson, S.E., Rogers, R.R. and Frantz, J.A. (1999), Infant formula with protein-energy ratio of 1.7 g/ 100 kcal is adequate but may not be safe. *J. Pediatr. Gastroenterol. Nutr.* 28, 495-501.

[12] Miera, O. (1998), Die stickstoffhaltigen Substanzen in Säuglingsanfangsnahrungen. Eine Analyse der Aminosäurenzusammensetzung und der Nicht-Proteinstickstoff-Fraktionen. PhD Thesis, Medical Faculty, Humboldt University, Berlin.