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**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Bonn, Germany, 21 - 25 November 2005

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

ARGENTINA
AUSTRALIA
BRAZIL
CHINA
INDIA
MALAYSIA
MEXICO
NEW ZEALAND
TURKEY
UNITED STATES OF AMERICA
VENEZUELA

CRN – Council for Responsible Nutrition
ENCA – European Network of Childbirth Associations
IACFO – International Association of Consumer Food Organizations
IBFAN – International Baby Food Action Network
ISDI – International Special Dietary Foods Industries

ARGENTINA

Article 3.1.3: It would be convenient to use the factor 6.25, because this is the most appropriate value for the convertion of nitrogen into proteins in every formula, with the exception of those which contain cow milk with a relation of 80/20 for casein/protein.
Article 3.6: We support the elimination of the square brackets, taking into account that these products should contain neither commercially hydrogenated oils nor fats because of their content of trans fatty acids and because there exists no security in their use in products for infants.
Article 4.6: It would be adequate to eliminate the square brackets, taking into account that it is reasonable to consider that in the technological process it is difficult to eliminate these components.
Article 9.1.6: It would be convenient to consider both options on iron declaration, and that they should be obligatory.
Article 9.5: From Argentina's viewpoint, all the information on compulsory declaration should be included on the label and not in a leaflet, which is generally a loose leaflet.
Article 9.6.: We support the elimination of the square brackets, due to the fact that these aliments should contain neither nutritional legends nor healing claims for sale promotion, because it is the pediatrician who should indicate which infant formula is adequate to be consumed by a child.

AUSTRALIA

Australia has confined its comments to matters that are not currently under consideration by an expert group or Codex working group, i.e. Section 3.1 and Section 4.
Paragraph 9.3

- Replace 'other' in the text by 'optional' to retain consistency.
- The redrafting of Section 9.5 at the last session is supported in general but with these specific comments:

The expression of the introductory paragraph could be improved such as -
'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.'
Paragraphs 9.5.1 and 9.5.2:
Delete text in square brackets. The directions for use and for storage after opening should be shown on the label and accompany the container at all times.
Paragraph 9.6.6
Australia supports the intent of this paragraph although it is not essential in the context of the general prohibition of nutrition and health claims at Paragraph 1.4 in the Codex *Guidelines for Use of Nutrition and Health Claim* and could be deleted. If deleted, it would be useful to provide a cross reference to the aforementioned Guidelines to ensure that there is no misunderstanding of the intent.
General Principles for establishing Minimum and Maximum Values for Essential Composition.
Principle 4 should be confined to the establishment of maximum values only. The first sentence could therefore be deleted and the text in square brackets modified to:
'Maximum values for nutrients will be determined using a science-based assessment approach, considering evidence of adverse health effects or other risks.' The rest of the text remains unchanged.

BRAZIL

Observations: - proposals of additions to the text are underlined
- proposals of elimination of the text are ~~crossed~~
- explanations and justifications are ***in italic*** and in **bold.**

3.1.3.
a) Protein
(i) Protein content = nitrogen content x 6.25]
~~(i) Protein content = nitrogen content x 6.25]~~
Brazil proposes to exclude the item: (i) Protein content = nitrogen content x 6.25]
[Protein content = nitrogen content x 6.38 for cows' mik protein]

To keep the item and to remove the square brackets
[Protein content = nitrogen content x 6.25 for soy or vegetable protein]
To keep the item and to remove the square brackets
[Protein content = nitrogen content x 6.38 for hydrolysates of cows' mik protein]
To keep the item and to remove the square brackets
[Protein content = nitrogen content x 6.25 for hydrolysates of cows' mik protein and of soy or vegetable proteins].
- To delete "for" and to add after 6.25, the sentence: "of mixture of", keeping the square brackets. The text would be read as follow:
[Protein content = nitrogen content x 6.25 ~~for~~ of mixture of hydrolysates of cows' mik protein and of soy or vegetable proteins]".

Table of minimum and maximum amounts of nutrients per 100 kcal.

Nutrients (per 100 kcal, unless otherwise stated)			
a) Protein[1] [g]	**Minimum**	**Maximum**	Comments/Justification
Cow's milk protein	1.8 [2]	3	
Soy protein	2.2		Considering the recommendation of 2,2 per 100 kcal for children under 03 months.
Partial hydrolysates of milk protein		3	
L-carnitine [mg]	1.2 ≥ 3 to formula composed with soy.	N.S.[4]	***Considering the absence in the main component of the formula.***
Taurine [mg]	[0]	12	***Maximum level justified in the available scientific studies.***
Nucleotides[4] [mg]	N.S.	[5]	
Uridine 5'-monophosphate (UMP)	N.S.	1.75	
Adenosine 5'-monophosphate (AMP) N.S.	N.S.	1.50	
Guanosine 5'-monophosphate (GMP) 6 "	N.S.	0.50	
Inosine 5'-monophosphate	N.S.	1.00	
b) Fat and fatty acids			
Total fat [g]	4.4	6.0	***To established the levels in CODEX STAN 72/81. It does not have evidences to modify this level.***
[Phospholipids]	N.S.	[2g/L]	
[Inositol] [mg]	[4]	[40]	
[Lauric and myristic acids]		[Together ≤ 20% of total fatty acids]	
Linoleic acid [g]	0.5	1.2	***Scientific studies point out the recommendation of 4.4 to 4.6g/day, so the minimum level of 0,5g would be the range of 3 to 4 g/day.***
[Formulae without added LCPUFA]			
∝-linolenic acid [mg]	50	N.S	**The level of 50mg/100kcal guarantees close values to the recommendation cited in**

			literature (400mg/day). Levels of 100mg/100kcal increase the risk of rancification and oxidation of the product, affecting its stability.
Linoleic/∝-linolenic ratio	5	15	
[Formulae with added LCPUFA]			
∝-linolenic acid [mg][5]	[≥ 50]		
[Linoleic/∝-linolenic ratio[6]	5	15	
n-6 LCPUFA	[≤ 2% of total fatty acids]		
Arachidonic acid	N.S.	[1% of total fatty acids	
[n-3 LCPUFA]	[2% of total fatty acids]		
[DHA]	N.S.	[0.5% of total fatty acids]	
[Ratio EPA/DHA (wt/wt)]	[<1]		
[Cottonseed/sesame oils	No use of these type of oil]		***The use of sesame seed oil and cotton seed oil must be prohibited.***
[Conjugated linoleic acid(CLA)	No intentional addition]		
[*Trans* fatty acids	≤ 3 or 4% of total fatty acids]		***Brazil considers that the levels trans fatty acids present in milk is very low. The levels proposed are very high.*** ***The WHO recommendation is 1%.***
Erucic acid		[≤1% of total fatty acids]	
c) Carbohydrates			
Total carbohydrates [g]	9	14	
[Lactose in cows' milk protein-and protein hydrolysates formulae [g]	≥ 4.5]		
[Lactose in soy protein Formulae	No requirement]		
[Saccharose	None in cows' milk protein and soy protein formulae≤ 20% of total carbohydrates in protein hydrolysates formulae]		
[Fructose	None]		
[Glucose	No intentional addition to formulae based on intact proteins, ≤ 2g in formulae based on protein hydrolysates]		
[Maltose, maltodextrins	Unrestricted]		
[Starches	30% of total carbohydrates (≤ 2g/100mL) as precooked or		

	gelatinised naturally gluten-free starches No starches modified by enzymatic cross-linking or stabilisation]		
d) Vitamins			
Vitamin A [µg RE][6]	60	180	
Vitamin D [µg][7]	1	2.5	
Vitamin E [mg α TE][8]	≥ 0.5 mg α TE/g PUFA [(corrected for double bond, see footnote[10])], but in no case less than 0.5/100 kcal	[5]	
Vitamin K [µg]	4	[20]	
Thiamin [µg]	40	200	***To keep current level, reducing the maximum level to 200, since the suggested level [300] exceeds 8 times the daily recommendation. There is not a clear definition about its toxicity due to the excess of consumption.***
Riboflavin [µg]	60	[400]	***Scientific references does not point out associate toxic effects and the international recommendations establish the minimum level of 60µg/100kcal.***
Niacin [µg]	300	[1200]	***As niacin preformed (nicotinamide)***
Vitamin B_6 [µg]	35	[165]	
Vitamin B_{12} [µg]	0.1	[0.5]	
Pantothenic acid [µg]	300	[2000]	***To keep the current levels established in the CODEX STAN 72/81.***
Folic acid [µg]	10	[30]	***Considering that FAO/WHO adopted the recommendation of 65 to 80 µg/day in the first age of life.***
Vitamin C [mg][10]	10	30	***The recommendation proposed by FAO/WHO is 30 to 25 µg per day, observing the necessity of bigger amounts to increase the nonheme-iron bioavailability***
Biotin [µg]	1.5	[7.5]	
e) Minerals and Trace Elements			
Iron [mg]			
Cow's milk protein and protein hydrolysate formulae	0.5	1.3	
Soy protein formulae	1.0	2.0	***Formulas with soy must contain minimum: 1.0 and***

			maximum 2.0 to guarantee the adequate values absortion to infants requeriments.
Calcium [mg]	50	[140]	
Calcium/Phosphorus-Ratio	1.0	2.0	
Phosphorus [mg]	Cows' milk protein- and protein hydrolysate formulae: 25 Soy protein formulae: [30] [Bioavailable phosphorus, if measured: 20-70 mg]	90 [100]	
Magnesium [mg]	5	15	
Sodium [mg]	20	60	***To keep the relation between chloride and sodium in 2.5.***
Chloride [mg]	50	150	
Potassium [mg]	60	160	
Chromium [µg]	No recommended minimum and maximum levels		
Manganese [µg]	5	[100]	
Molybdenum [µg]	No recommended minimum and maximum levels		
Fluoride [µg]	N.S	[100]	
Iodine [µg]	10	[50 -100]	***To consider the recommendation proposed by FAO/WHO in 100 µg /litre.***
Selenium [µg]	**1**	[9]	***The adoption of 1 µg/100kcal considers the reference presented by FAO/WHO document of a minimum value of 10 µg/day for Infant Formula.*** ***The range concentration of selenium in human milk depends on food ingestion by mother. So, it is very difficult to establish a standard for recommendation.***
Copper [µg][11]	35	100	***The 35 µg/100kcal value guarantees the daily recommendation of 210 µg for the six months of life.***
Zinc [mg]			
Cow's milk protein and protein hydrolysate formulae	0.5	[1.5]	
Soy protein formulae	0.75	2.4	
f) Choline [mg]	7	30	***Maximum level adequate (30) related to the corporal weight and metabolic activities of infants based on scientific studies.***

Brazil considers as essential and non essential the following nutrients:

Essential	**Non Essential**	
	Protein	**Comments**
Cow´s milk protein Soy protein L-carnitina Taurine	Nucleotides Cytidine (CMP) Urinide (UMP) Adenosine (AMP) Guanosine (GMP) Inosine	
	Fat and Fatty acids	
Lauric and myristic acids Linoleic acid	Phospholipids Inositol	
Formulae without added LCPUFA		
α linolenic linoleic/α linolenic ratio		
Formulae with added LCPUFA		
α linolenic linoleic/α-linolenic ratio	n-6 LC PUFA arachidonic acid n-3 LC PUFA DHA Ratio EPA/DHA ~~Cottonnseed/sesame~~ ! Conjugated linoleic acid Trans fatty acids Erucic acid	***- to exclude cotton seed and sesame*** ***1) Brazil considers that the levels trans fatty acids present in milk is very low. The levels proposed are very high.*** ***The WHO recommendation is 1%.***
Carbohydrates		
Total carbohydrates [g] Lactose in cow´s milk protein and protein hydrolysates formulae (g)	Lactose in soy protein formulae Saccharose Frutose	
Glucose ≤ 2g in formulae based on protein hydrolysates	Glucose No intestional addition to formulae based on intact proteins.	
Maltose		
	Starches ≤ 30% of total carbohydrates (≤ 2g/100 mL) as precooked or gelatinised naturally gluten-free. No starches modified by enzymatic cross-linking or stabilisation	
Vitamins		
All		
	Minerals and Trace Elements	
	Chromium Molybdenum Fluoride	

Item 3.6
To remove the square brackets.

4. Food Additives
TABLE – WORKING GROUP´S PROPOSALS
The guar (INS 412), carob bean (410) and carrageenan (407) gums must not be used in Infant Formula.
Justification: Studies on safety and use for lactant and young children must be elaborated to justify their use on Infant Formula. In Brazil, these gums are not allowed to infant formula.
The phosphates (INS 338, INS 339i, 339ii and 339iii, INS 340i, 340ii and 340iii) have numerical ADI, and must present the use numerical limit.

5.2 Other Contaminants
Infant formula shall not contain contaminants or undesirable substances (e.g. ~~biologically active substances~~) in amounts which may represent a hazard to the health of the infant.
To substitute the expression: "biologically active substances" by "anabolic or antibiotics between others ". The text would be read as follow:
"Infant formula shall not contain contaminants or undesirable substances (e.g. anabolic or antibiotics between others) in amounts which may represent a hazard to the health of the infant".
9.1.6 ~~[Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labelled "Infant Formula with added Iron"].~~
or
[Products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]
To exclude the sentence: "[Products containing not less than 0,5 mg Iron (Fe)/100 kilocalories shall be labeled "Infant Formula with added Iron"]".
To add in the second sentence after "additional sources" the sentence: "This product does not provide the iron daily intake requirement". The text would be read as follow:
[Products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.] "This product does not provide the iron daily intake requirement".

Item 9.5
To keep the item.
9.5.1.
To keep the item and to remove the sentence: "[or in the accompanying leaflet]".
9.5.2.
To keep the item and to remove the sentence: "[or in the accompanying leaflet]".
Justification: It must be mandatory the information related to safety use presented on the label. The accompanying leaflet must be supplementary, not a substitution of the essential information on the label.

9.6.6.
To keep the item and to remove the square brackets

[Annex I]
Essential and semi-essential amino acids in breast milk
To remove the square brackets

[Annex II]
GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA

4.
To add after "comprehensible]" the sentence: "The maximum values must be the recommendation proposed by World Health Organization - WHO," The text would be read as follow:

In addition to the principles set out in No. 3, when setting minimum and maximum values, consideration will also be given to evidence of adverse health effects. [Maximum values for nutrients with a documented risk of adverse health effects will be determined using a science-based risk assessment approach. [Maximum values for those nutrients without evidence of adverse effects serve as guidance levels for manufacturers. The approach to setting maximum levels for guidance purposes shall be made transparent and comprehensible]. "The maximum values must be the recommendation proposed by World Health Organization - WHO."

Justification: ***maximum levels must established taking into consideration the results from Nutrient Risk Assessment Project of FAO/WHO, which is still in elaboration.***

CHINA

ALINORM 05/28/26, Appendix IV (A)	JUSTIFICATION
SECTION A: INFANT FORMULA	
[3.1 ESSENTIAL COMPOSITION	
3.1.1 Infant formula is a product based on milk of cows or other animals and/or other ingredients which have been proven to be suitable for infant feeding. **~~[All ingredients and food additives used shall be gluten-free.]~~ Allergen declaration requirements prescribed in Codex *General Standard for the Labelling of Prepackaged Foods* shall be followed**	Allergen is a food safety concern and should be addressed in a standardized way, that is by the allergen declaration requirements prescribed in Codex *General Standard for the Labelling of Prepackaged Foods*, Therefore, change the text in bracket into "Allergen declaration requirements prescribed in Codex *General Standard for the Labelling of Prepackaged Foods* shall be followed", or put it under Section 9 "Labelling".
a) PROTEIN	
3.1.3 a) Protein (i) [Protein content = nitrogen content x 6.38 for milk proteins **and their partial hydrolysates]** [Protein content = nitrogen content x 6.25 for soya protein or vegetable protein, **and their hydrolysates]**	A nitrogen conversion factor of 6.38 should be kept for milk proteins, whereas a nitrogen conversion of 6.25 should be applied for soya. Rationale: – A conversion factor of 6.38 is used for milk proteins by the present Codex Standard, and is consistent with those applied by the AOAC Official Methods and by the Joint ISO/IDF (International Dairy Federation) Standards, and standards of China. Changing conversion factor will change the definition of milk, as well as the reorganization of protein intake by infant. – The internationally applied conversion factors are different for milk and other protein sources, and should be set separately. - The nitrogen content of intact and moderate protein hydrolysates are not significantly different. Therefore the conversion factors should be the same.
3.1.3 a) Protein (ii) 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 1); nevertheless, for calculation purposes, the concentration of methionine and	Delete sentence of "**[**unless the methionine to cystine and the tyrosine to phenylalanine ratio exceeds 2.0] ", because: - Formulas based on unmodified milk protein have a methionine to cystine ratio of about 3 and would be limited by this criterium. While Casein-predominant infant formula, prepared from unmodified cow's milk protein, have been for many years on the market make up a considerable

cystine, ~~[~~and of tyrosine and phenylalanine ~~]~~ may be added together ~~[unless the methionine to cystine and the tyrosine to phenylalanine ratio exceeds 2.0] .~~	part of the infant formula. Its long historical use has demonstrated the adequate supports to the growth during early life. - Growth parameters do not differ between casein-predominant and whey-adapted formula with the same protein content. - Expert recommendations(FAO/WHO, LSRO) agree with the addition of methionine and cystine for the calculation of protein quality. - Tyrosine can be derived from phenylalanine metabolically and thus the requirement for the two amino acids should be determined as the sum of both, as for methionine and cystine.
Footnote 1 and a) Protein in the table of Nutrients: ~~1~~ ~~[1 Calculation of protein content : N x[6.25 or 6.38] ; [non-protein nitrogen (formulae made from intact protein) <15% of total protein]~~	Delete entire footnote 1 Reason: - Human milk contains 25% of non protein nitrogen (NPN) . - NPN covers a broad range of different substances, including free amino acids and peptides, present inprotein hydrolysates and soy-based formulas (Free amino acids, as well as choline and L-carnitine, are usually added to soy-based formulas). All these factors will increase the NPN level. - Minimam levels for essential amino acids have been set in this standard and serve as an assurance on the nutritional value of the formula.

ALINORM 05/28/26, Appendix IV (A)			**JUSTIFICATION**
Nutrients (per 100 kcal, unless otherwise stated)	***Minimum***	***Maximum***	
~~**Cow's milk**~~ **Milk** protein **and its hydrolysates**	1.8[2]	3	Milk proteins of cow, buffalo, and goat have similar nutritional quality and should be covered by the Standard. Delete the word "~~**Cow's**~~". Add "its hydrolysates". There is no scientific evidence to distinguish between intact milk proteins and their hydrolysates.
Soy protein **and its hydrolysates**	**2.25**	3	Add "its hydrolysates" for the same reasons as above.
b) Fat and fatty acids			
~~[~~Phospholipids~~]~~	N.S.	~~[~~**2** g/L~~]~~	**Agree to set maximum level for phospholipids as 2g/L in order to achieve a nutritionally relevant concentration of essential LCPUFA's (AA and DHA).**
~~[~~Inositol~~]~~ [mg]	~~[4]~~ **N.S.**	40	No science evidance to support the proposed minimum level. Change it to "N.S."
Linoleic acid [g]	~~[~~0.3~~]~~	[1.2]	Agree to keep minimum linoleic acid level of 0.3g/100 kcal as in current standard, which is well above that required to prevent deficiency.
~~***[Formulae without added LCPUFA]***~~			There is no science basis to differentiate formulas with or without LCPUFA. This also brings unnecessary complexity to the Standard. Delete this classification.
~~[~~α-linolenic acid~~]~~ [mg]	~~[~~≥ 50 ~~**or 100]**~~	N.S.	Agree with minimum level of α-linolenic acid

			50 mg/100 kcal which is above the level that adequate to visual and psychomotor development.
Linoleic/α-linolenic ratio	5	~~15~~ **20**	Propose to change maximum 15 into 20. Reasons: - A ratio of 5-20 between LA and ALA ascertains a proper balance between the precursors of the respective n-6 and n-3 fatty acid series. - The proposed range sustains the nutritional requirements for both formulas with and without added LCPUFA.
~~*[Formulae with added LCPUFA]*~~			Delete for above reason.
~~[α-linolenic acid]~~ [5]	~~[≥ 50 mg]~~		
~~[Linoleic/α- linolenic ratio]~~ [5]	~~5~~	~~15~~	
[n-6 LCPUFA]	**N.S.**	[2% of total fatty acids]	Agree with proposed maximum level
[Arachidonic acid]	**N.S**.	[1% of total fatty acids]	
[n-3 LCPUFA] [DHA]	**N.S.**	[2% of total fatty acids] [0.5 of total fatty acids]	
[Ratio EPA/DHA (wt/wt)]	~~[<1]~~	1	
[Cottonseed/sesame oils]	**[No use of these type of oils]**		Agree with it.
~~[Conjugated linoleic acid(CLA)~~	~~No intentional addition]~~		Delete this section. At the present moment, no enough scientific data on the effects of CLA during early life. Therefore it is not suitable to add CLA to infant formulae.
[*Trans* fatty acids	~~≤ 3 or 4% of total fatty acids]~~	4% of total fatty acids	Agree with the maximum level of 4% of total fatty acids. Reason: - No scientific data have established a causal relation between trans fatty acid intake and changes in early development. - Natural trans fatty acid level of cow's milk fat are often > 5% and vary geographically. - Trans fatty acids in human milk were reported to vary considerably (Spain: 1.3 - 7.2 % ; Canada: 0.1 – 17%). - Milk-based formulae with more than 60% of the fat as milk fat are not unusual. A maximum trans fatty acid level of 4% seems more appropriate and justified within the context of a global standard.
c) Carbohydrates			

┼ Lactose in ~~cows'~~ milk protein-and protein hydrolysates formulae [g]	≥ 4.5 ┼		Delete "*cows*'" for reasons indicated above.
~~┼**Fructose**~~	~~**None]**~~		Agree with this□ 同意此条。
┼Glucose	No intentional addition to formulae. ~~**based on intact proteins, ≤ 2 g in formulae based on protein hydrolysates ┼**~~		Glucose should not be added as such to infant formulae. Delete "based on intact proteins,≤2g in formulae based on protein hydrolysates". " based on intact proteins,≤2g in formulae based on protein hydrolysates". Rationale : - Addition of glucose increases osmotic pressure of the formula and risk of Maillard reaction. - A small amount of glucose may come from the use of glucose syrups.
┼ Maltose, maltodextrins**, glucose syrup**	Unrestricted ┼		Agreement with proposal, suggestion to add glucose syrups. Rationale: - Glucose syrup is used as a replacement for lactose in soya protein based infant formula, to assist with palatability.
┼ Starches	30% of total carbohydrates (≤ 2 g/100 mL) as precooked or gelatinised naturally gluten-free starches No starches modified by enzymatic cross-linking or stabilisation ┼		Agreement with proposal. Remove [ ]
d) Vitamins			Agreement with the setting of minimum and maximum levels. Should pay high attention to: - The range takes into account the natural variations in vitamin levels of the raw materials. - The proposed levels take into account losses during shelf life. - In general, vitamin requirements are similar for infant formulas and formulas for special medical purposes intended for infants. - The use of a single vitamin blend is also desirable for technological and safety reasons.
Vitamin E [mg α TE]	≥0.5 mg α TE/g PUFA ~~┼~~(corrected for double bond, see	~~┼~~5 ┼	Delete part of the footnote ~~per g of polyunsaturated fatty acids, expressed as linoleic acid~~ because it is not meaningful.

	footnote[9])**],** but in no case less than 0.5/100 kcal		
Vitamin K [µg]	4	**[** 20 **]**	Agree with max. 20
Thiamin [µg]	**[** 40 **or 60]**	**[** 300 **]**	Agree with min. 40
Riboflavin [µg]	**[** 60 **or 80]**	**[400] 450**	Agree with Min. 60, and max. 450
Niacin [µg]	**[** 300 **or 800]**	**[**1200**]**	Agree with min. 300
Vitamin B6 [µg]	35	**[165] 300**	Propose max. 300
Vitamin B12 [µg]	0.1	**[** 0.5 **]**	Agree
Pantothenic acid [µg]	**[** 300 **or 400]**	**[** 2000 **]**	Agree min. 300
Folic acid [µg]	**[** 4 **or 10]**	**[** 30 **]**	Agree with min. 4
Vitamin C [mg]	**[** 8 **or 10]**	**[30] 40**	Agree with minimum level of 8 mg/100 kcal,(same as current standard), but recommendation for a higher maximum level of 40 mg/100 kcal.(max. level is not specified in current standard).
Biotin [µg]	1.5	**[7.5] 20**	Propose max. 20
e) Minerals and Trace Elements			
Iron [mg] **Cow's milk protein and protein hydrolysate formulae** **Soy protein formulae**	**0.5** **[0.3 or 0.5]** **[0.45 or 1.0]**	**2.5** **[1.3 or 1.5]** **[1.9 or 2.0]**	Suggest to establish a single level of iron for all infant formulas with the minimum at 0.5 mg/100 kcal and the maximum at 2.5 mg/100 kcal. A minimum 0.5 mg/100 kcal is appropriate to fulfill iron requirements of infants during the first six months of life. Although a level of 0.3 mg/100 kcal seemed to fulfill iron requirements of infants in optimal environmental conditions during the first six months of life, it has been considered prudent to provide a higher level of iron fortification to prevent the risk of iron deficiency anaemia. Therefore the minimum level of 0.5 mg/100 kcal has been selected.
Calcium [mg]	50	**[** 140**]**	Agree
Calcium/Phosphorus-Ratio	1.0	**[2.0 or** 2.2 **]**	High levels of phosphorus in infant formula are undesirable. We support max. Ca/P ratio of 2.2. This value is physiological and is regularly found in breast milk.
Phosphorus [mg]	**Cows' milk protein and protein hydrolysate formulae: 25** **Soy protein formulae: [30]** **[Bioavailable phosphorus, if measured: 20-70 mg]** **25**	**90** **[100]** **100**	A single level of phosphorus is favoured with the minimum at 25 mg/100 kcal and the maximum at 100 mg/100 kcal.
Chloride [mg]	50	**[125 or** 160 **]**	Support for the maximum of 160 mg/100 kcal.

Potassium [mg]	60	[~~145 or 160~~] **200**	The maximum level of 200 mg/100 kcal for potassium in current Codex Standard (72-1981) is safe to infant, and is technologically necessary for the production of hydrolysed formula, and should be kept. - Potassium is the major solute of intracellular water, whereas sodium and chloride are the major solutes of extracellular water. - The potassium to sodium ratio in human milk is remarkably constant at 3.1, and similar to that in cows' milk. This implies that there is a physiological ratio between those two electrolytes. - Since in this standard, the sodium maximum level is set at 60 mg/100 kcal, the potassium maximum level should be at least around 186. As the human milk potassium to sodium ratio often exceeds 3.1 a maximum level of 200 mg/100 kcal seem appropriate for infant formulas.
Manganese [µg]	[1 ~~or 5~~]	[100]	A minimum of 1 µg/100 kcal is justified. In agreement with maximum.
Fluoride [µg]	N.S.	[100]	In agreement with proposal.
Iodine [µg]	[5 ~~or 10~~]	[50]	A minimum of 5 µg/100 kcal is justified. In agreement with the maximum of 50µg/100kcal.
Copper [µg]	[20 ~~or 35~~]	[~~80 or~~ 100]	
Zinc [mg]	**0.5**	**2.40**	We propose a single level of zinc for all infant formulas with the minimum at 0.5 mg/100 kcal and the maximum at 2.4 mg/100 kcal. Scientific data support above proposal.
~~**Cow's milk protein and protein hydrolysate formulae**~~	~~**0.5**~~	~~**[1.5]**~~	
~~**Soy protein formulae**~~	~~**0.75**~~	~~**2.40**~~	
f) Choline [mg]	7	[~~30 or~~ 50]	A maximum of 50 mg/100kcal is necessary in case of arachidonic acid (AA) supplementation
[Nucleotide [mg]]			Agreement with the proposal from ISDI to increase max. limits.
Cytidine 5'-monophosphate(CMP)	N.S.	~~2.50~~ **6.5**	
Uridine 5'-monophosphate(UMP)	N.S.	~~1.75~~ **3.7**	
Adenosine 5'-monophosphate(AMP)	N.S.	~~1.50~~ **3.0**	
Guanosine 5'-monophosphate(GMP)	N.S.	~~0.50~~ **3.5**	
Inosine 5'-monophosphate(IMP)	N.S.	~~1.00~~ **1.0**	

ALINORM 05/28/26, Appendix IV (A)	**JUSTIFICATION**
3.6 SPECIFIC PROHIBITIONS	
The product and its components shall not [contain commercially hydrogenated oils and fats and shall not] have been treated with ionizing radiations.	Delete the brackets and keep the bracketed text.
4. FOOD ADDITIVES	
4.1 Thickening Agents	

4.1.2. INS 410: Carob bean gum (locust bean gum) 0.1 g in all types of infant formula ~~REQUEST FOR 0.5G~~	A level of 0.1 g/100 ml is sufficient for regular infant formula. Delete request. There is no scientific evidence that a level of 0.5 g/100 ml would be needed for technological reasons.
4.2 Emulsifiers	
4.2.5 INS 472e: Diacetyltartaric and fatty acid of esters of glycerol GMP	Add "Diacetyltartaric and fatty acid of esters of glycerol"new additive to ensure product quality.
4.4 Antioxidant	
4.4.3 INS 309: Gamma-tocopherol **INS 308: Delta-tocopherol** **1 mg in all types of infant formula singly or in combination**	Add "**INS 309: Gamma-tocopherol, INS 308: Delta-tocopherol". These** are effective in preventing oxidation of vulnerable fatty acids.
4.6 CARRY-OVER OF FOOD ADDITIVES	
[4.6 Carry-over of Food Additives ~~No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exemption:~~ ~~(a) of the food additives listed under Sections 4.1 to 4.4 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 within the limits of the maximum levels stipulated in that List~~] **CODEX** *Principle Relating toCarry-over of Additives into Foods* **shall apply.**	CODEX *Principle Relating toCarry-over of Additives into Foods* shall apply to infant formula. To restrict all carry-over of food additives is not practicable, and also makes it difficult to develop new formula with certain desired beneficial qualities.
9. LABELLING	
9.1.3 ~~The source of protein in the product shall be clearly shown on the label~~ ~~9.1.4 If cow's milk is the only source of protein, the product may be labeled as "Infant Formula Based on Cow's Milk".~~ ~~9.1.5 A product which contains neither milk or any milk derivatives shall be labeled as "contains no milk or milk products".~~ **If 90% or more of the protein is derived from whole or skim cow's milk, the product may be labelled "Infant Formula Based on Cow's Milk".**	Suggest to retain text of current Standard Infant Formula (72-1981) "**If 90% or more of the protein is derived from whole or skim cow's milk, the product may be labelled "Infant Formula Based on Cow's Milk".**
~~9.1.6 [Products containing not less than 0.5 mg Iron (Fe)/100 kcal shall be labelled "Infant Formula with added Iron"]~~ ~~**or**~~ ~~**[Products containing less than 0.5 mg Iron (Fe)/100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources]**~~	Delete this section, it is not necessary now that a min. level for iron has been required for all infant formulas.

9.3. DECLARATION OF THE NUTRITIVE VALUE	
(b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.2 and any ~~other~~ **optional** ingredient **if added** as listed in paragraph 3.2 of this Standard per 100 grammes of the food or per 100 milliliters of the food as sold as well as per 100 mililiter of the food ready for use, when prepared according to the instructions on the label.	Add "optional ingredients if added" to avoid misinterpretation
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.**	Instructions for use are very important to consumers, especially powder formulas that most widely used. We suggest to modify the sentence as follows: **"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."**
~~**9.6.5. The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.**~~	This provision is redundant with the requirements of 9.1. In addition there cannot be any risk of confusion between products which have different names, different Codex Standards, different composition, different labeling. Delete sentence.
9.6.6 ~~**[No [nutrition and]health claims shall be made regarding the dietary properties of the product]]**~~	Delete the whole article and the article number. Rationale: It is necessary to provide nutrition and/or health claim of some ingredients used in the foods for the sake of the consumer's right of knowing.
Nutrition and health claims shall be permitted for the products covered by this standard, where they have been demonstrated beyond doubt in rigorous studies with adequate scientific standards, and the evidence has been accepted by an independent scientific body reviewing the data.	We therefore recommend new wording. Rationale: – All claims that are scientifically substantiated, with the substantiation validated through independent scientific review, should be allowed. – There is no nutrition-based rationale for placing a severe restriction on claims for these products. These claims – should be allowed as long as they are scientifically substantiated and are expressed in a manner that is understood by and is not misleading to the parent or caregiver. Claims on products for infants and young children can provide parents and caregivers with important information about the composition and properties of a product that is specially designed for this age category. There is no justification for denying them information that is based on scientific substantiation.
[ANNEX 1]	
Essential and semi-essential amino acids in breast milk	This table should be reviewed by ESPGHAN in light of latest scientific knowledge

For the purpose of this Standard the essential and semi-essential amino acids in breast milk, expressed in mg per 100kJ and 100kcal, are the following: ***TABLE***	
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**	5b) and 5c) are talking about the same matter. Suggest to put together as: **"total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients and their variability in the ingredients and added nutrients"**

INDIA

1. Scope:

1.1 The report of the 27th session of CAC at paras 79 to 82 highlights including references to the International Code of Marketing of Breast- Milk Substitutes and subsequent WHA Resolutions which support and promote exclusive breastfeeding in the first six months of life. India's concern for including the clause "when it is not possible to exclusively breastfeed the infant for the first six months of life in section 1.1" has also been highlighted in para 80.

India, therefore, reiterates its stand that the standard for infant formula and formulas for special medical purposes is covered by the provisions of the international code of marketing of breastmilk substitutes and subsequent WHA Resolutions which clearly emphasise the need to protect, promote and support exclusive breastfeeding for the first six months of life. The World Health Assembly Resolutions 54.2 (2001) and 55.25 (2002) and the adoption of Global Strategy on Infant and Young Child Feeding have already set the pace for standards for infant formula and for cereal based foods for infants and young children.

In the light of above, it is necessary to replace the words 'where necessary' with the following clause in the sentence at 1.1:-

"When it is not possible to exclusively breastfeed the infant for the first six months of life".

Also delete the word 'normal' from the sentence at 1.1.

1.3 The word "six" may be added in the last sentence of 2nd para, between the words "first months" to read as "first six months" and delete the word "healthy".

1.4 Replace the words "should take into account" with the words "shall be in conformity with". Add "WHA Resolution 55.25 (2002)" also and make the word "Resolution" as "Resolutions", to read:

"The application of the Standard shall be in conformity with the recommendations given to countries under the International Code of Marketing of Breast-Milk Substitutes, the Global Strategy for Infant and Young Child Feeding, World Health Assembly Resolution 54.2(2001), WHA Resolution 55.25(2002) and subsequent relevant resolutions of the WHA".

2. Description

2.1 Product definition

2.1.1 The word "six" may be added between the words "first months" and replace the word "upto the introduction of appropriate complementary feeding" by the following words:

"when it is not possible to exclusively breastfeed"

The clause may be reworded as under:

"Infant formula means a breastmilk substitute especially manufactured to satisfy, by itself, the nutritional requirements of infants during the first six months of life, when it is not possible to exclusively breastfeed".

2.1.2 Delete the words "is so processed by physical means only" and replace with "must be processed" and add photodegradation, to read as under:

"Infant formula must be so processed and packaged as to prevent spoilage, photodegradation, and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold".

3. Essential Composition and Quality Factors

3.1 Essential Composition

3.1.1 In the first line, the words "milk of cows or other animals", be read as "milk of cows and buffalos or a mixture there of".

3.1.2 The calorific value of the formula should be expressed both per 100 g. as well as 100 ml.

3.1.3 Milk fat should not be less than 12% by weight of total fat since

cholesterol, which is found in milk fat, is essential for human babies.

India, therefore, wants the following to be added:

"No hydrogenated fat containing trans fatty acids should be added to the product and milk fat shall not be less than 12% by weight of total fat."

(c) Carbohydrates

Lactose is the predominant carbohydrate found in human milk, which contains on average 7.3 g/dl or 10g/100kcal to provide about 40% of the infants energy needs. Additionally human milk carbohydrates are made up of small amounts of 50 olligosaccharides of varying structures.

The Lactose content in all routine infant formulas should be as close to the level in human milk as possible

Starches are not present in human milk and infants under the age of six months do not have the enzymatic capacity to digest starches. Therefore starches should not be permitted for infant formulas promoted for use by infants less than six months of age.

e) Minerals and Trace Elements

Iron

India recommends the higher value in each case for both minimum as well as maximum levels, i. e., 0.5 mg. minimum and 1.5 mg. maximum.

3.2 Optional Ingredients:

3.2.1 Change text to read:

"In addition to the compositional requirements listed under 3.1, 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".

No nutrition or health claims or comparative claims may be made for these infant formulas.

3.2.2 Change text to read:

"The suitability of ingredients that may be added for the particular nutritional uses for infants, must be demonstrated through independently funded research, to be bio-available, safe, have no unintended side effects and have the ability to achieve the intended effect, taking into account the levels present in human milk as appropriate".

3.5 Purity Requirements

Change to read:

"All ingredients shall be clean and free from chemical and microbial contamination as far as possible, of good quality, safe and suitable for ingestion by infants. They shall conform to optimal quality requirements, such as colour, flavour and odour".

3.6 Specific Prohibition

Delete the square brackets and retain text with additions to read:

"The product and its components shall not contain commercially produced hydrogenated oils and fats, shall not have been treated by ionizing radiation and shall not contain ingredients modified through genetic engineering".

4. Food Additives

4.1 Thickening agents.

4.1.1 to 4.1.6 Infants do not need dietary fiber from nutritional angle. Further the addition of thickening agents may chelate micronutrients making them unavailable, thus resulting in micronutrients deficiency, which may affect growth and cognitive function.

So thickening agents should not be added to infant formula.

4.1.7 Carrageenan

4.1.8 It has adverse effect on the gut causing ulceration of cecum of both rats and guinea pigs when it was added to their diets. Hence its safety is doubtful in the case of human beings.

4.2 It is desirable to exclude emulsifiers in infant formula

4.3 pH Adjusting Agents.

It is desirable to exclude all the phosphates containing additives in the infant formulae as it upsets the calcium phosphate ratio, which has adverse effect on bone metabolism.

Phosphoric acid and its salts should not be permitted as pH adjusting agents.

4.4 Antioxidants

The total intake should not exceed the RDA.

4.5 Packaging gas (Propellants)

The relative risk/benefit of gases other than Nitrogen need safety evaluation. It is preferable to use nitrogen gas of food grade quality.

4.6 Carry-over of Food Additives

There is no need to keep sentences at (a) & (b) and hence the square brackets alongwith the bracketed text may be deleted.

The sentence may now read as:

"No food additives shall be present as a result of carry-over from raw materials and other ingredients".

5. Contaminants

5.1 Pesticide Residues

The existing para may be replaced by the following text:-

"The product shall be free from residues of hormones, antibiotics, N-nitrosamines, nitrates, heavy metals, mycotoxins, as determined by agreed analysis, and free from other contaminants, especially pharmacologically active substances such as phyto-estrogens".

6. Hygiene

6.2 After the existing sentence, the following text may be added;

"and shall be free from pathogenic microorganisms, parasites and any other hazardous or deleterious substances".

9. Labeling

9.1. The name of the Food

9.1.6 The square brackets may be removed from the first option and "0.5 mg" changed to "1.5 mg." in the sentence.

Delete the second option.

9.6 Additional Labelling Requirements

9.6.1b The following statement may be inserted after the words 'a similar statement' like

"Breast milk is the best food for your baby, breastfeeding benefits both baby and mother".

9.6.4 The age of six months for introduction of complementary foods as per WHA Resolution 54.2 (2001) may be included in the sentence instead of appropriate age.

The sentence may be reworded as under:

"Information shall appear on the label to the effect that infant should receive complementary foods in addition to the formula, from the age of six months for their specific growth and development needs".

9.6.6 Both the square brackets may be deleted.

MALAYSIA

Section 3: Essential Composition and Quality Factors

Paragraph 3.1.3 b) Fat and fatty acids

Malaysia proposes to delete the square brackets and reduce the level of *trans* fatty acids in infant formula to not exceeding 1% of the total fatty acids. This paragraph is to read:

	Minimum	Maximum
Trans fatty acids	**≤1%** of total fatty acids	

Rationale:

- The last 26th Session CCNFSDU meeting had discussed the definition of *trans* fatty acids and had agreed that the definition would exclude the conjugated *trans* fatty acids which means that the naturally present conjugated *trans* fatty acids found in animal fats and dairy products including conjugated linoleic acid (CLA) would be excluded from the definition. The definition also had been agreed by 33rd Session CCFL with several editorial changes for clarification purposes.
- As such, the level of *trans* fatty acids resulting from the use of commercially hydrogenated oils and fats should be kept to the minimum as these fatty acids have been proven to be detrimental to human health.

Footnote 10 - Minimum level of Vitamin E

Malaysia would like to seek clarification on Footnote 10 whether the symbol should be 'α' rather than 'γ'.
"[10] [0.5 mg α-TE/1 g linoleic acid 918:2n-6); 0.75 mg α-TE/1 g **α**-linoleic (18:3n-3); ……..]"

Paragraph 3.6 Specific Prohibition

Malaysia would like to reiterate her position to prohibit the use of commercially hydrogenated oils and fats and adopt the text contained therein. This paragraph is to read:
"The product and its components shall not contain commercially hydrogenated oils and fats and shall not have been treated by ionizing radiation."

Rationale:

- The use of commercially hydrogenated oils and fats should be prohibited because they contain *trans* fatty acids.

Section 9: Labelling

Paragraph 9.6.6

Malaysia proposes that the sentence should be amended in line with *Codex Guidelines for Use of Nutrition and Health Claims* to read:
"Nutrition and health claims shall not be permitted except where specifically provided for in national legislation."

MEXICO

3.6 Specific Prohibition
- We suggest deleting the square brackets.
- We suggest deleting the square brackets and the text "not less than" from item 9.1.6 so that it reads as follows: "Products containing 0.5 mg Iron (Fe)/100 kilocalories shall be labelled Infant formula with added Iron". Delete the second sentence.
- We suggest to delete the square bracket from section 9.5 as well as the wording "or in the accompanying leaflet" from all the sub points.

Furthermore, we suggest deleting the square brackets from Annex II, item 4.

NEW ZEALAND

New Zealand recommends replacing any reference to "cow's milk"in the draft standard to "animal milk".

Detailed comments on section 3.1 Essential Composition and Quality Factors are as follows:

Protein
New Zealand remains concerned about proposed changes to the nitrogen conversion factor. We support a modification of the options presented as follows:
Protein content = nitrogen content x 6.38 for animal milk protein and hydrolysates of animal milk protein; and
Protein content = nitrogen content x 6.25 for soy and vegetable protein.
New Zealand does not support a change in the nitrogen conversion factor from 6.38 to 6.25 as suggested by the EU Scientific Committee for Foods. We strongly believe that there is inadequate justification to support such a change. However if such a change was considered it would need to be applied for all milk products and not just infant formula. The factor 6.38 is used in the Codex standards for casein, whey powder and fermented milk, and in the class name "milk protein" in the *General Standard for the Labelling of Prepackaged Foods*. The factor is consistent with the AOAC official methods and joint ISO/IDF methods recognised in Codex, is scientifically supported, and is used wordwide to calculate the milk protein content of foods.
Adopting a conversion factor of 6.25 would underestimate the actual protein content of milk and require manufacturers of infant formula to add an additional 2 – 3% of protein to their formula.
A better estimation of the protein content in infant formula, based on its contribution to growth, development and health of the infant, would be desirable. This would need to take account of the quality of the protein (CAAS), its digestability and its biological activity. This ideal is currently a long way from realisation: scientific development is needed, and the cost of implementation and consumer education needs to be considered. Until further information allows clear progress towards this goal, the current well-established and well-understood methods for protein estimation should remain.

Carbohydrates
New Zealand proposes that there should be no minimum lactose requirement for lactose free formula. This may appear unnecessary but should be clarified in the table or a footnote.

Fat and Fatty Acids
The trans fatty acid content should be raised to "should not exceed 5% of the total fat content". Milk fat can contain up to 6% trans fatty acids and it can be desirable to manufacture infant formula with a fat mix containing 80% milk fat. Long chain polyunsaturated fatty acids should remain optional additions.

Micronutrients
Vitamin B_{12}: New Zealand proposes that the maximum limit for vitamin B_{12} should be increased from 0.5 μg/100kcal to 1.5 μg/100kcal. New Zealand manufactured infant formula may have a natural vitamin B_{12} level greater or equal to 0.5 μg/100kcal and at the end of the season this may increase to more than 1.4 μg/100kcal.
Niacin: New Zealand supports the minimum level for Niacin of 300 μg/100kcal.
Iron: New Zealand supports a range of for iron of 0.3 - 1.5 mg/100kcal in animal milk protein and protein hydrolysate formula.
Selenium: New Zealand does not support the proposed minimum levels for selenium.
The proposed level of 0.7 μg/100kJ is much higher than would be acceptable in New Zealand and much higher than levels found in breastmilk. New Zealand would support a minimum level of 0.2 μg/100kJ (0.84 μg/100kcal) as recommended by the LSRO report which is based on the estimated mean minus one standard deviation value for the selenium concentration of human milk in countries where selenium deficiency has been recognised.
Ca:P: New Zealand strongly supports a maximum calcium to phosphorus ratio of 2:2.

TURKEY

PROPOSED MODIFICATION OF ALINORM 05/28/26, Appendix IV(A)	JUSTIFICATION
PREAMBLE .....Section B deals with formulas..	**F**ormulas for **S**pecial **M**edical **P**urposes **I**ntented for **I**nfants

	(first letters should be capital in letters)
1.SCOPE 1.4 ....resolution	1.4 ...**R**esolution
3. ESSENTIAL COMPOSITION AND QUALITY FACTORS	
[3.1 ESSENTIAL COMPOSITION	
ESPGHAN will review the ESSENTIAL COMPOSITION and will prepare a paper as the basis for the compositional discussions at the 27th Session of CCNFSDU. This review will be available by June 2005.	We will send detailed comments upon the availability of the ESPGHAN review by June 2005.
4. FOOD ADDITIVES	
4.1 THICKENING AGENTS	
INS 410: Carob bean gum (locust bean gum) 0.1 g ~~[0.5g]~~ in all type of formula	Delete this request. Rationale: - A level of 0.1 g/100 ml is sufficient as thickening purposes. - There is no scientific evidence that a level of 0.5 g/100 ml would be needed for technological reasons.
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 in 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 **INS 308: Delta-tocopherol** **1 mg in all types of infant formula singly or in combination**	Add these antioxidants. 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 ingredients with the exception: (a) of the food additives listed under Sections 4.1 to 4.4 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 THE NAME OF THE FOOD	**9.1 Name of the Product**

9.1.6 ~~[Products containing not less than 0.5 mg Iron (Fe) /100 kilocalories shall be labelled "Infant formula with added iron"]~~ ~~Or~~ [Products containing less than 0.5 mg Iron (Fe) /100 kilocalories shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from additional sources.]	Delete this sentence Delete the bracket[ ]. Rationale: The corrected wording in option 2 is more relevant for caregivers. Indeed infants above the age of 4 months may be at risk for insufficient iron intakes if fed products containing less than 0.5 mg of iron/100 kcal.
9.3. DECLARATION OF THE NUTRITIVE VALUE	
(b) the total quantity of each vitamin, mineral, choline as listed in paragraph ~~3.1.2~~ **3.1** 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 per 100 mililiter of the food ready for use, when prepared according to the instructions on the label.	Should be paragraph 3.1 Add "optional ingredients if added" Rationale: Adding "optional" is in line with section 3.2. Including "if added" avoids misinterpretation.
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 of the sentence. Delete the brackets Rationale: Instructions for use require outmost attention and clarity. Powdered infant formula are most widely used.
9.6 ADDITIONAL LABELLING REQUIREMENTS	
9.6.3 9.6.6 [No ~~[nutrition and]~~ health claims shall be made regarding the dietary properties of the product] **Nutrition claims shall be permitted for foods for infants and young children where they have been demonstrated in scientific evidence based studies.**	Should be another intend Delete (nutrition and) Delete the brackets in 9.6.6 Add this second sentence after 9.6.6

ANNEXES I & II

PROPOSED MODIFICATION OF ALINORM 05/28/26, Appendix IV(A)	**JUSTIFICATION**
[ANNEX 1]	**ANNEX I**
Essential and semi-essential amino acids in breast milk	
For the purpose of this Standard the essential and semi-essential amino acids in breast milk, expressed in mg per 100kJ and 100kcal, are the following: ***TABLE***	This table should be reviewed by ESPGHAN (Eurepean Society for Peadiatric

	Gastroenterology, Hepatology and Nutrition)
ANNEX II	
GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA	
4.	Delete the brackets
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 is 750 ml per day. This is based on the following assumptions : **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; ~~[~~**ii)** prepared formulas should 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.**	Delete the brackets

UNITED STATES OF AMERICA

I. General Comments

The United States notes that this request for comment (CL 2004/53-NFSDU) excluded Section 3, Essential Composition and Quality Factors, and accordingly we have not made comments on this section in response to this circular letter.

In addition, we have not made comment on Section 4, Food Additives. Those comments will be made to the Electronic Working Group on Food Additives coordinated by the Delegation of Switzerland.

We also note the language in square brackets in item #4 in the General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula (Annex II, p. 61, ALINORM 05/28/26).

We propose the following edits for item 4:

4. ~~In addition to the principles set out in No. 3, when setting minimum and maximum values, consideration will also be given to evidence of adverse health effects.~~

[Maximum values for nutrients ~~with a documented risk of adverse health effects~~ will be determined using a science-based risk assessment approach**, considering evidence of adverse health effects or other risks**. ~~Maximum values for those nutrients without evidence of adverse effects serve as guidance levels for manufacturers.~~ The approach to setting maximum levels ~~for guidance purposes~~ shall be made transparent and comprehensible.]

Comment: It appears that item 3 has already addressed the concept and approach for establishing minimum values. Thus, we believe that item 4 should focus on establishment of maximum levels of nutrients in infant formulas.

Rationale: We continue to believe that all numbers for maximum values should be based on science based risk assessment. We also note that this approach is consistent with Section 3.2.2(a) for establishing

maximum levels of vitamins and minerals in the Draft Guidelines for Vitamin and Mineral Food Supplements.
It is also important to consider other risks in addition to adverse health effects in establishing maximum values for infant formulas.

II. Specific Comments

3.6 Specific Prohibition

The product and its components shall not [contain commercially hydrogenated oils and fats and shall not] have been treated by ionizing radiation.
Comment: We propose deletion of the text in square brackets.
Rationale: Section 3.1.1 stipulates that all ingredients used in infant formulas must have been proven to be suitable for infant feeding. Thus, it is not necessary to include individual ingredients in Section 3.6.

9. Labelling

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1-1993) and the Guidelines for Use of Nutrition and Health Claims the following specific provisions apply:
9.1 The Name of the Food
9.1.6 [Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labelled "Infant Forumula with added Iron"].
Or
[Products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]
Comment: Iron levels in the infant formula standard remain to be established. Appropriate label information should be discussed after the iron levels are established.
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.
9.5.1 Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, i. e. that formula remaining after feeding should be discarded, shall appear on the label [or in the accompanying leaflet].
9.5.2 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label [or in the accompanying leaflet].
9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.
9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation.]
Comment: We recommend deleting the language in 9.5.1 that would allow information to be contained only in a leaflet that would accompany the product.
Rationale: This information should be on the label, which is affixed to the can or container. An accompanying leaflet can easily become separated from the product.
Editorial comment: Delete the word “water” in the first paragraph for clarity.
9.6 Additional Labelling Requirements
9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product.]
The United States notes that the Guidelines for Use of Nutrition and Health Claims that were adopted at the 27th session of the Codex Alimentarius Commission (ALINORM 04/27/41, para 51) contain the following provision:
1.4 Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.
It appears that an exception in Section 1.4 provides the opportunity for this Committee to consider whether claims may be permitted in standards for foods for infants and young children under certain circumstances. Section 1.4 also allows for nutrition and health claims where specifically provided for in national legislation. However, the bracketed text as written in 9.6.6 would eliminate any consideration of nutrition and health claims for infant formulas by this Committee, and is also inconsistent with Section 1.4 which at a minimum provides for nutrition and health claims permitted by national legislation.

We suggest that this Committee use the opportunity provided by the language in Section 1.4 to allow further discussion about the wording of any provisions in this standard that address nutrition and health claims relative to the goals of Codex. For example, claims that further the Codex goal of protecting consumer health in addition to encouraging fair international trade in food might be considered for infant formulas.

10. METHODS OF ANALYSIS AND SAMPLING

Comment: Table 10 remains to be updated for the draft revised infant formula standard, Section A. The following table incorporates AOAC methods that are current and applicable for use with infant formula.

10. METHODS OF ANALYSIS AND SAMPLING

Analyte	**Method**	**United States Comments on Methods**
Dietary fibre, total	**AOAC 991.43**	Current method
Iodine (milk-based formula)	**AOAC 992.24**	Current method
Pantothenic acid	**AOAC 992.07**	Current method
Pantothen-ic acid	~~*The Analyst 89* (1964)(1) 3-6,232~~	This is an old method (US Department of Agritulture. Agriculture Handbook 97 (1965)) that should not be used
Vitamin A	~~AOAC 974.29~~	This is an old colorimetric method. Methods AOAC 992.04 or AOAC 992.06 should be used.
Vitamin A (retinol)	**AOAC 992.04**	Current method
Vitamin A (retinol)	**AOAC 992.06**	Current method
Vitamin A / carotenes	~~AOAC 942.15~~	Method 942.15 is a method for titratable acidity in fruit products. It is not suitable as a method for Vitamin A/carotenes
Vitamin K	**AOAC 992.27**	Current method
Vitamin D (D_3, milk based infant formula)	**AOAC 992.26**	Current method
Vitamin E	~~AOAC 971.30~~	This is a colorimetric method dating from 1971 that should not be used

Analyte	Method	United States Comments on Methods
Vitamin E - milk-based formula	**AOAC 992.03**	Current method
Vitamin B12	~~AOAC 952.20~~	This is an old method (1952) that should not be used. Newer and more appropriate method is listed in next row of table
Vitamin B12	**AOAC 986.23**	Current method
Vitamin B6	~~AOAC 961.15~~	This is an old method (1961) that should not be used. Newer and more appropriate method is listed in next row of table
Vitamin B6	**AOAC 985.32**	Current method
Vitamin C	~~AOAC 967.22~~ ~~AOAC 967.21~~	This titrimetric method is applicable only to vitamin preparations and should not be used with infant formulas. See next row of table for appropriate method
Vitamin C	**AOAC 985.33**	Current method
Determination of Choline	**AOAC 999.14**	Current method
Determination of Vitamin K	**AOAC 999.15**	Current method
Detection of Irradiated foods	Codex general methods	
Determination of Lead	Codex general methods	
Calcium	**AOAC 984.27**	Current method
Chloride	**AOAC986.26**	Current method
Carbohydrates	method described in CAC/VOL	

Analyte	Method	United States Comments on Methods
	IX Ed 1, Part III	
Crude protein	Method described in CAC/VOL IX Ed 1, Part III	
Fat	CAC/RM 55-1976	
Fatty Acids	**AOAC 996.06**	Current method and suitable for nB6 and B3 long-chain fatty acids
Fill of containers	CAC/RM 46-1972	
Folic acid	~~AOAC 944.12~~	This is an old method (1944) that should not be used. Newer and more appropriate method is listed in next row of table
Folic acid	**AOAC 992.05.**	Current method
Linoleate (glycerides)	~~AOAC 922.06~~ ~~AOAC 969.33~~ ~~AOAC 963.22~~ ~~AOAC 979.19~~	AOAC 922.06, AOAC 963.22, and AOAC 979.19 are older chromatograpic and spectrophotometric methods that should not be used AOAC 969.33 is a method for preparation of methyl esters and not an analysis of fatty acids
Linoleic acid	**AOAC 992.25**	Current method
Loss of drying	~~AOAC 934.01~~ ~~AOAC 925.23~~	
Nicotinamide (non-milk) Nicotimamide (milk-based)	~~AOAC 961.14~~ ~~AOAC 944.13~~	These are old methods (1961 and 1944) that should not be used. Newer and more appropriate method is listed in next row of table

Analyte	Method	United States Comments on Methods
Niacin and nicotinamide	**AOAC 985.34**	Current method
Phosphorus	**AOAC 986.24**	Current method
Protein efficiency ratio (PER)	**AOAC 960.48**	Current method . Rat bioassay
Riboflavin	~~AOAC 970.65~~	This is an old method (1970) that should not be used. Newer and more appropriate method is listed in next row of table
Riboflavin	**AOAC 985.31**	Current method
Sodium and potassium	~~ISO 8070~~ ~~IDF 119A~~	These are old methods (1987) that should not be used. Newer and more appropriate method is listed in row below
Sodium and potassium	**AOAC 984.27**	Current method
Thiamine	~~AOAC 942.23~~	This is an old method (1942) that should not be used. Newer and more appropriate method is listed in next row of table
Thiamin	**AOAC 986.27**	Current method
Total dietary fibre	**AOAC 985.29**	Current method

VENEZUELA

PROPOSED CHANGES TO ALINORM 05/28/26 APPENDIX IV (A)	JUSTIFICATION
Title: Draft Revised Standard for Infant Formula and Formulas for Special ~~Medical~~ Purposes Intended for Infants It would read: DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL **DIETARY** PURPOSES INTENDED FOR INFANTS. SECTION A: DRAFT REVISED STANDARD FOR INFANT FORMULA. **This comment applies to the whole text of the document**.	Substitute … (Applies to Spanish version only. Translator's note) Change the word "Medical" to "Dietary". Explanation**:** (See above. Applies to Spanish version only. Translator's note) The understanding is to emphasize the importance of the food to a health-related condition without suggesting it has healing or medicinal properties. An alternative would be to substitute "**DIETARY USES**" for "**MEDICAL PURPOSES**", as the wording "DIETARY USES" implies the compliance with certain principles, which are necessary in order to provide a sufficient, complete, balanced and adequate nutrition.
1.- **AMBITO DE APLICACIÓN**	
1.3 Only products that comply with the criteria laid down in the provisions of this section of this standard would be accepted for marketing as infant formula. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of [normal] healthy infants during the first months of life.	Delete [] Explanation: It is redundant and irrelevant.
2. **DESCRIPTION**	
2.1 **Product Definition**:	
2.1.1 Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction **[, at its due time,]** of complementary feeding appropriate **[[**for their age]]**.**	Include [ ] Include [[ ]] Other options would be: …"appropriate complementary feeding **in order to progressively change over to a healthy diet"** or to delete the word "appropriate" and replace it with "...in order to ensure an adequate nutrition".
2.2 **Other Definitions**: The term infant means a person ~~not more than~~ 12 months of age. The sentence would read as follows: "The term infant means a person up to 12 months of age."	Substitute "**up to**" for "**not more than**". Explanation: Rewrite the sentence in the positive sense.
3. **ESSENTIAL COMPOSITION AND QUALITY FACTORS**	
[3.1 **Essential Composition**	
It was noted that this part of the document would be further elaborated by the Electronic Working Group.	We will send detailed comments on the ESPGHAN document of June 2005.

3.1.1 Change the sentence: "All ingredients and food additives used [shall be] gluten-free." (Applies to Spanish version only. Translator's note)	(Applies to Spanish version only. Translator's note)
3.1.3 ii).	It is known that, when cystine and tyrosine are present in the diet, the requirements for methionine and phenylalanine are reduced; thus, cystine and tyrosine are considered as semi-indispensable or semi-essential aminoacids. On the other hand, it has been noted that infants seem to need cystine and tyrosine in addition to the aminoacids which are essential for adults. In fact, the cystine requirements would be secondary to the belated development of the key enzyme activity in the conversion of methionine to cystine that does not reach the same levels as in adults before the age of at least 4 months. It is therefore considered important to substantiate the use of the expression "semi-essential" or "essential" for these aminoacids depending on whether it is deemed necessary or unnecessary to provide these aminoacids in an infant's diet.
Nutrients (per 100 kcal, unless otherwise stated)	
e) **Minerals and Trace Elements**	
Iodine [µg]	Add the unit of measurement []. (Applies to Spanish version only. Translator's note)
3.4 Consistency and Particle Size 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.	Delete the word "**young**" and keep the rest of the wording, or consider - replacing the word "**young**" by a specific reference to the age of the infants in months; - retaining the text and including in item 2.2 the definition of "**young infant**" and, consequently, the definition of "**older infant**"**.**
3.6 Specific Prohibition We agree with moving the reference to the prohibition of the presence of commercially hydrogenated oils and fats to section 3.1.3, provided that a list of prohibitions is drawn up**.**	
4. FOOD ADDITIVES	
4.1 Thickening Agents	
INS 410: Carob bean gum (Locust bean gum) 0.1 g [~~0.5 g~~] in all types of infant formula	Delete this request [ ]. Explanation: The level of 0.1 g /100 ml is sufficient for the proposed purpose. There is no scientific evidence that a level of 0.5 g/100 ml is necessary for technological reasons.
4.2 Emulsifiers	
INS 472 e: Diacetyltartaric and fatty acid esters of glycerol GMP	Include this emulsifier. Explanation: Retains homogeneity of liquid products and liquid reconstituted powders, especially in formulas not containing whole protein. Has a high HLB, works better in

	combination with mono- and diglycerides.
4.4 Antioxidants:	
INS 309: Gamma-tocopherol INS 308: Delta-tocopherol 1 mg in all types of infant formula singly or in combination	Include these antioxidants. Explanation: Singly or in combination they stabilise preparations containing fats and vitamins. They have a synergistic effect with L-Ascorbyl palmitate (304) and Ascorbyl Stearate (305). They are used as natural antioxidants and are much more effective in preventing oxidation of fatty acids than alpha tocopherol.
4.6 Carry-over of Food Additives	
a) "of the food additives listed under Sections 4.1 to 4.4 of this standard within the maximum limits [levels] stipulated in this standard."	Delete the word in [ ] Explanation: The wording "within the maximum limits" is sufficiently clear.
b) [of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.]	Delete [] Add the words "**Mineral Salts and** ..." immediately after "Advisory List" in order to be consistent with the name of the document (CAC/ GL 10-1979 (amended 1983, 1991)).
5. CONTAMINANTS	
5.1 Pesticide Residues	We are concerned about the wording "… are reduced to the maximum extent possible" at the end of the paragraph. This should be much more specific. It is noted that no reference is made to the maximum limits set for these contaminants.
5.2 Other Contaminants	
	In the text, reference is made to maximum levels without specifying the respective substances. At the end of the paragraph, the maximum level for lead is given for no apparent reason.
6. HYGIENE	
6.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods	Substitute ….. (Applies to Spanish version only. Translator's note)
7. PACKAGING	
7.1 The product shall be packed in containers which will safeguard [the hygienic and other qualities] of the food. …	Substitute "**the safety and quality**" for the wording in []. Explanation: The wording "and other qualities" is too vague.
9. **LABELLING**	
9.1.6 ~~[Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labelled "Infant Forumula with added Iron"].~~ ~~Or~~ [Products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]	Chose the second version and delete [] Explanation: This wording implies a warning that it is necessary to give additional iron to infants older than four months in order to meet their requirements.

9.2 List of Ingredients	
9.2.1 "A complete list of ingredients shall be declared on the label..., and within these groups the vitamins and minerals need not be listed in descending order of proportion.	Substitute …. (Applies to Spanish version only. Translator's note)
9.3 Declaration of Nutritive Value	
(b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.2 and any ~~other~~ **optional ingredient if added as listed in paragraph 3.2 of this Standard, ...**"	Add "optional ingredients, if added," Explanation: Add "optional …" to be in line with 3.2.
9.4 Date Marking and Storage Instructions	
9.4.2 "In addition to the date, any special conditions for the storage of the food shall be indicated ~~if the validity of the date depends thereon~~. Where practicable, storage instructions shall be in close proximity to **the marking of the date of minimum durability**.	Delete: "... if the validity of the date depends thereon." Explanation: It is always necessary to indicate the special storage conditions in order to make sure the product is adequately handled. Include the wording … "**minimum durability**" at the end of the paragraph..
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 require safe and previously boiled water for preparation. **All the products have to be prepared according to the information for use. Products in powdered form and concentrated liquids have to be prepared with previously boiled drinking water. Ready-to-eat liquid products may be used directly in accordance with the information for use.**	Reformulate as proposed. Explanation: The information for use needs to be clear.
9.5.1 Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, i. e. that formula remaining after feeding should be discarded, shall appear on the label [or in the accompanying leaflet]. **Clear directions for the appropriate preparation and use of the product, including its storage and the disposal of leftovers after feeding the infant, shall appear on the label [or in the accompanying leaflet].**	Reformulate as proposed.
9.6 Additional Labelling Requirements	
9.6.1 c) "a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use." **c) a statement that the product should only be used on advice of a pediatrician**.	Reformulate as proposed. In our opinion, only a pediatrician is qualified to give advice on the use of the product.
9.6.4 "Information ..., as advised by an independent health worker ... age of ..." Information ... as advised by a pediatrician ... age of ...	Reformulate as proposed and substitute "pediatrician" for "independent health worker.

9.6.6 ~~[No [nutrition and] health claims shall be made regarding the dietary properties of the product.]~~ **Nutrition and health claims shall be permitted in foods for infants and young children where they have been demonstrated in rigorous studies with adequate scientific standards.**	Delete the sentence in square brackets and replace it by the wording on bold letters. There is no reason to prohibit the communication of relevant information through labelling as this is in line with the practices established in the WHO International Code on the Marketing of Breast-milk Substitutes.

ANNEX II

GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA

2.- "A ... formula ...consistent with science based standards…"	Modify: (Applies to Spanish version only. Translator's note)
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, and added nutrients.**	Reformulate as proposed Explanation. 5b) and 5c) refer to the same matter concerning 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 is 750 ml per day. This is based on the following assumptions: **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; **on the basis of a formula that provides 67 kcal/100 ml** ~~ii) prepared formulas provide about 67 kcal/100 ml~~	Reformulate, and delete item ii)

CRN – Council of Responsible Nutrition

9.6.6 ~~[No [nutrition and] health claims shall be made regarding the dietary properties of the product.]~~ **Nutrition and health claims shall be permitted when supported by a sound and sufficient body of scientific evidence to substantiate such claims as established by the Codex Committee on Nutrition and Food for Special Dietary Uses.**

Rationale

The Council for Responsible Nutrition (CRN) believes it is important to include in the Infant Formula Standard at 9.6.6, a statement permitting appropriately substantiated nutrition and health claims. Prohibiting factual, science-based nutrition information from labeling does nothing to protect the health of the formula-fed infant. Removing an important incentive for research and development of infant formula may actually slow improvements that do protect and optimize the health of formula fed infants. The prohibition threatens to quiet productive scientific and technological research needed to improve infant formulas and thus protect and benefit the health of consumers of the product.

Codex Committee on Food Labeling's (CCFL) Guidelines allow CCNFSDU to decide about Claims

The qualifier that would allow nutrition and health claims, as stated in the Guidelines, "…where specifically provided for in relevant Codex Standards or national legislation" provides the opportunity, in the infant formula standard, to allow for nutrition and health claims in a way that is fully consistent with the Codex guiding principles of sound science, protection of the health of consumers and fair trade. Nutrition and health claims for infant formula meet the criteria for such claims as defined in the CCFL's Guidelines

If 9.6.6 were accepted, as written, any description of the role of a nutrient in infant development would be banned regardless of the level of scientific evidence behind the statement. Infant formula labeling is an important source of nutrition information and education to consumers. Manufacturers rely on labeling statements to identify recent science-based changes in composition, changes supported by clinical evidence.

Claims made on the labels of infant formula meet the criteria of both nutrition and health claims as specified in the CCFL's Draft Guidelines for Use of Nutrition and Health Claims (Alinorm 04/27/22). These guidelines define a *nutrition claim* to mean any representation which states, suggests or implies that a food has a particular nutritional properties, a *nutrient content claim* is a nutrition claim that describes the level of a nutrient contained in a food and a *nutrient comparative claim* is a claim that compares the nutrient levels of two or more foods. As the infant formula standard dictates the labeling requirements, infant formula inherently has supportable nutrition and nutrition content claims. Such nutrition claims for infant formula provide consumers with meaningful information about the benefits of infant formula relative to other less nutritious alternatives. As written, 9.6.6. would prohibit such nutrition and nutrient content claims as "contain nucleotides", "contains docosahexaenoic acid (DHA)" or "a good source of selenium." The presence of these claims on labels allows mothers and health professionals to identify beneficial components in infant formula.

CCFL defines *health claim* as any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health. Health claims include *nutrient function claim*, which is a nutrient claim that describes the physiological role of the nutrient in growth, development and normal functions of the body. Nutrient function claims which describe the role of the nutrients in infant formula in growth and development can be supported by basic textbook statements of fact, e.g. calcium is needed to form bones; iron is a component of hemoglobin. Other nutrient function claims can be supported by clinical evidence published in peer-review journals e.g. DHA has been shown to optimize visual and mental development. Such statements about the role of nutrients in growth and development in the context of feeding of infants, provide valuable point of use nutrition education.

According to the CCFL guidelines" health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers …" Manufacturers of Codex-compliant infant formulas can provide sound scientific evidence to support appropriate nutrition and health claims because these formulas are required to have been scientifically demonstrated to support growth and development of infants as per section 3.1. This is especially relevant to nutrition and health claims related to optional ingredients as per 3.2.2 "The suitability for the particular nutritional uses of infant and safety of these substances shall be scientifically demonstrated." The Codex Infant Formula Standard inherently requires scientific substantiation of any product improvement to insure the continued safety and adequacy of infant formula. It should be noted that manufacturers are required to conduct clinical studies as per section 3.1 of the Infant Formula

Standard but would be prohibited from communicating the information gained from these studies as per Section 9.6.6.

Users of infant formula should be supported in their choice, which includes provision of valid, meaningful information

The World Health Organization (WHO) recognizes that women should be supported in their feeding choices. The WHO also recognizes that these choices may include use of breast milk substitutes. Article 1 of the 1981 WHO Code on the Marketing of Breast Milk Substitutes (WHO Code) states "The aim of this Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and *by ensuring the proper use of breast-milk substitutes, when these are necessary on the basis of adequate information and through appropriate marketing and distribution*." (*Emphasis added)*. Restriction of appropriate scientifically based nutrition and health claims prevents users of infant formula from receiving the adequate information they are entitled to as per the WHO Code. As stated in an article about proper use of infant formula "little attention has been paid to the second part of the Code's aim, either in practice or research (Renfrew 2003)."

More recently the WHO's Global Strategy for Infant and Young Child Feeding (2003) states, "Women have the right to proper nutrition, to decide, *how to feed their children and to full information* and appropriate conditions that will enable them to carry out their decisions. These rights are not yet realized in many environments" (*Emphasis added*). The Global Strategy calls for "Ensuring that all who are responsible for communicating with the general public, including educational and media authorities, provide accurate and complete information about appropriate infant and young child feeding practices, taking into account prevailing social, cultural and environmental circumstances." The prohibition of nutrition and health claims conflicts with a woman's right to full information. The WHO Expert Consultation on the Optimal Duration of Exclusive Breastfeeding (2001) recommended that mothers exclusively breast feed for six months, but "The Expert Consultation recognizes that some mothers will be unable to, or chose not to, follow this recommendation (to exclusively breast feed for six months). These mothers should also be supported to optimize their infant's nutrition." The prohibition of nutrition and health claims on infant formula prevents these mothers from being fully informed about these products and their benefits as compared to less nutritious alternatives.

The stakeholders (i.e. consumers who use infant formula for whatever reason and health care professionals) should be involved in the decisions about the use of such claims. No HCPs were involved with the development of the Guidelines by CCFL. Codex should solicit the opinion of such bodies such as the American Academy of Pediatrics, and the European Society of Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) who participated at CCFSDU. Consumer groups representing mothers whom, for whatever reason are using infant formula, also should be queried about the usefulness of nutrition and health claims.

Nutrition and health claims are valuable to mothers and HCPs.

Infant formula labeling is an important source of nutrition information and education to consumers. Nutrient comparative claims provide valuable information about nutrients in formula that are not present in cow's milk or other liquids. Many infants under 3 months of age continue to receive cow's or other milks despite worldwide initiatives to discourage the use of such milks during the first year of life. For example, 9% of infants 0-1 month of age in Sub Saharan Africa and 12% of Indian infants age 0-1 month receive other milks (Demographic and Health Surveys 2005). These figures increase to 20% by 3 months of age. Infant formula is an excellent source of many nutrients not found in cow's milk including iron, zinc, vitamins C and D, and essential fatty acids. With the inclusion of these nutrients, infant formula has contributed to the improvement of the health of the non-breast fed infant (Fomon 2001). It is well recognized that the use of iron fortified infant formula instead of unmodified cow's milk has been responsible for the decline in iron deficiency anemia in developed countries (Fomon 2001). Nutrient comparative claims and nutrient function claims about the benefits of infant formula as compared to other milks on the labels of infant formula are necessary to educate mothers about appropriate feeding choices and to continue to improve public health. Such claims should be substantiated in order to ensure that factual scientific nutrition information is provided to mothers.

The medical and scientific community *expects* infant formula manufacturers to demonstrate and communicate benefits related to innovations, i.e. nutrition and health claims. Nutrient function claims are precisely the kind of factual information that is the object of pediatric nutrition research. There is a long heritage of advances in infant feeding and formula development contributing to the improvement of infant nutrition. In a review of the history of pediatric nutrition, leading pediatricians state " The history of infant feeding and formula development is given

special emphasis because in many ways it is synonymous with the early history of the science of pediatric nutrition and also because of its importance in the practice of pediatrics in the past century" (Kleinman et al 2003.) In recent years, infant formula manufacturers continue to contribute to the advancement of the health and nutritional status of infants. Pediatric nutrition research has focused on the possible benefits of adding "other substances" in human milk because of their possible effects on development (Fomon 2001) in accordance to Section 3.1.
The European Union's Scientific Committee of Food (SCF) (2003) recommended, "modifications to an infant formula or a follow-on formula beyond the established standards should be based on and justified by defining an expected ***benefit*** (nutritional, functional, technological, or other)." Comments by leading academic pediatricians at the Second World Congress on Pediatric Gastroenterology and Nutrition in July 2004 emphasized the need for manufacturers to provide meaningful information to both consumers and health care professionals on the nutrition of infants and young children.

Nutrition and Health Claims do not interfere with a mother's feeding decision
The vast majority of mothers (at least 80%) decide about feeding either prior to pregnancy or very early in pregnancy (Arora et al 2000, Shaker et al 2004) long before they are exposed to labeling claims.

Prohibition of truthful, scientifically substantiated nutrition function claims may have an adverse effect on health, by limiting the flow of useful nutrition information to consumers.
Nutrition and health claims on the labels allow new scientific information on product composition and product attributes to reach consumers in a timely way. For example, the inclusion of the long chain polyunsaturated fatty acid, DHA, in infant formulas was rapid across the marketplace, providing visual acuity benefits to infants. Thus, appropriate, science-based nutrition and health claims can directly contribute to the health of consumers.
Numerous authoritative bodies now recommend the addition of DHA and a related fatty acid, arachidonic acid (AA) to infant formula. Such groups include FAO/WHO Joint Expert Consultation of 1994, the Child Health Foundation (Koletzko 2001) and the EU SCF report (2003). These recommendations are based on a growing body of literature demonstrating the benefits of improved cognitive and visual function amongst infants fed formula supplemented with DHA and AA. Birch and colleagues found significantly better visual function as measured by visual acuity amongst infants fed DHA fortified formula for 4 months (Birch 1998) and up to 12 months (Birch 2005). A meta-analysis of all available data through 2000 supports the modest efficacy of DHA on early visual system development (San Giovanni 2000). Similar improvements in cognitive function as measured by problem solving tests at 10 months (Willatts 1998) and global intelligence at 18 months (Birch 2000) have been demonstrated with DHA and AA fortified formula. These studies provide significant scientific evidence to support a nutrition function claim for DHA in infant formula helping to optimize cognitive and visual development.
Similarly research studies have documented the benefits of nucleotide-supplemented formula. Two major randomized masked prospective clinical trials have shown that nucleotide supplementation to infant formula enhances immunoglobulin titers in
response to vaccines (Pickering et al., 1998; Makrides et al., 2004). These studies provide sufficient support to permit a nutrient function claim. Communication of the benefits of nucleotides through appropriate claims on the label of infant formula has been beneficial to the many users of infant formula.
In conclusion, the scope of the infant formula standard states, "No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life." The infant formula standard is intended to insure the optimal nutrition of the infant who is not breast-fed, and to develop the standard in ways that encourage further improvements to formulas for the health of these infants. Therefore we support language in 9.6.6 that allows use of scientifically substantiated nutrition and health claims.

Other comments:
Annex II General Principles for Establishing Minimum and Maximum values for the Essential Composition of Infant Formula.
4. In addition to the principles set out in No.3, when setting minimum and maximum values, consideration will also be given to evidence of adverse health effects. [Maximum values for nutrients with a documented risk of adverse health effects will be determined using a science-based risk assessment approach. Maximum values for those nutrients without evidence of adverse effects

serve as a guidance levels for manufacturers. The approach to setting maximum levels for guidance purposes shall be made transparent and comprehensible.]

Rationale

In keeping with the science-based approach at Codex for setting upper limits on vitamin and mineral supplements; the setting of upper limits for nutrients in infant formula should be based on biology, not an arbitrary multiplication constant. CRN supports the statement in square brackets in No.4 of Annex II, maximum values for nutrients with a documented risk of adverse health effects will be determined using a science-based risk assessment approach.

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ENCA - European Network of Childbirth Associations

Section A: Draft revised standard for Infant formula

1. SCOPE

1.1 delete the word "normal" to be in line with the product definition in 2.1.1.
Infant formula is not the biological norm of the nutritional requirements of infants

1.2/1.3 The Draft revised standard as circulated in the draft report at the end of the last meeting had only 3 subsections in the scope. We notice that in the actual document 1.2 was split into 1.2 and 1.3. We don't know if this was a choice by the secretariat or if it happened during the lay out. We want to draw the attention to the fact that section B contains a reference to the former 1.3 if the numbering will be kept as it is now in the actual document related to section A then we need to change the reference in section B to 1.4

New 1.3 delete the words "normal healthy" as they have no definition in Codex Alimentarius nor in WHO. The Scope of section B further defines the conditions of infants needing the products of section B, as both sections are to be read together this defines that section A covers all the other infants

1.4 (former 1.3) Delete brackets and r**eword** to read:
The application of the Standard **shall be in conformity with** the recommendations given to countries under the International Code of Marketing of Breast-Milk Substitutes (1981) the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution 54.2 (2001) and WHA Resolution 55.25 (2002).
Reinsert the WHA resolution 55.25 This is in line with the request of the Commission (report Alinorm 04/41 para 83) and the request of the Executive Committee (report Alinorm 01/4, paras 38-39)

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.1 The wording of the definition as in the previous draft with all possible ingredients named should be kept, as this gives the best information to consumers. Any shorter version is vague and hides information.
"Infant formula is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding.
Add to the second sentence: "by independently funded peer reviewed research" to read: The nutritional safety and adequacy of infant formula shall be scientifically demonstrated by independently funded peer reviewed research to support growth and development of infants

Soy as a possible main ingredient should be reviewed.

Infant formula based on soy protein should be considered as a potential exposure of infants to **Phytoestrogens** as they may be during the first six months the only nutritional intake and a major part of intake during the following year for an infant and young child. The effect of phytoestrogens will add to the exposure to endocrine disruptors occurring in the prenatal phase of life.
Here are some scientific reports questioning the use of soy or highlighting that there is no evidence that soy is safe for infant feeding. Here the references:

- Report of the UK Committee on Toxicity (COT) and the report of the Scientific Advisory Committee on Nutrition (SACN) on Phytoestrogens and Health (http://www.food.gov.uk), regarding the potential risks of soy as a constituent of infant formula

The SACN report states:

"Conclusion

20. Based on the evidence cited in the report, SACN is in agreement that the use of soy-based infant formulae is of concern. Whilst there is clear evidence of potential risk, there is no evidence that these products confer any health benefit or therapeutic advantage over products based on cow's milk protein isolates….there are no substantive medical or clinical indications for the use of soy-based formulae and, secondly on grounds of potentially important sequelae, principally amongst young infants. If the use of soy-based formula is to continue on "clinical" grounds, responsibility is placed upon health professionals rather than the industry and consumers. The issue appears to be one of consumer choice, but there must be an onus on industry to better inform firstly the general public and, secondly, through a health professional, parents actually using these products to feed their infants."

Comité de nutrition de la Société française de pédiatrie: Préparations pour nourrissons et préparations de suit à base de protéines de soja : données actuelles. D. Rieu 2001 My translation of some quotes: For the moment there is no study on the endocrine development of infants and children raised or being raised on soy infant formula regarding their fertility in adult life. It seems to be safer to eliminate phytoestrogens from soy formula.

- The report of the scientific committee on food on the revision of essential requirements of infant formulae and follow-on formulae (SCF/CS/NUT/IF/65 final from 18 may 2003) has not looked into the 2 previous reports as they are not quoted in the references. Nevertheless based on other scientific evidence it stated this: http://europa.eu.int/comm/food/fs/sc/scf/outcome_en.html

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Soy protein is rich in isoflavones which can for example bind to oestrogen receptors and interact with enzyme systems influencing oestrogenic activity (Setchell, 2001). The total content in ready-for-use products in the USA was determined to be 20-47 µg/mL (Murphy *et al.*, 1997; Setchell *et al.*, 1998; Johns *et al.*, 2003), mainly the glycosides of genistein (65%) and daidzein. A four-month old infant fed such soy formula will receive 22 to 45 mg per day or 6 to 11 mg/kg body weight per day. Accordingly, plasma levels of daidzein and genistein in infants fed soy formula were significantly higher (654-1775 ng/mL), than in infants fed cows' milk formula (9.4_1.2 ng/mL) after 4 months or human milk (4.7_1.3 ng/mL) (Setchell *et al.*, 1998). It is noted that adverse effects of soy-based formulae on reproduction, development, carcinogenesis and immunology have been observed in animals (Badger *et al.*, 2002; Essex, 1996; Newbold *et al.*, 2001; Setchell *et al.*, 1998; Yellayi *et al.*, 2002). To date, despite the wide-spread use of soy-based formulae for example in the USA, there are only limited data addressing the safety of soy-based infant formulae and follow-on formulae, other than noting the absence of case reports of adverse effects in those fed soy-based infant formulae. The limited epidemiological data available are described below.

Strom *et al.* (2001a) performed telephone interviews in 811 adults aged between 20 and 34 years who had participated as infants during the years 1965 to 1978 in feeding trials with soybased formula (n=248; 120 males) or cows' milk formula (n=563; 295 males). Data were collected in adulthood for self-reported height, weight, body mass index, pubertal maturation, menstruation, reproduction and education levels. Female subjects of the original soy group had a higher rate of regular use of antiasthmatic and antiallergic drugs (18.8% *vs.* 10.1%, p=0.047), while males showed a similar but non-significant trend (15.8% *vs.* 10.2%, p=0.08).

Females previously fed on soy formulae had a lower prevalence of sedentary activities (8.9+3.4 hours/week *vs* 9.6+3.5 hours/week, p=0.05) while there was no group difference for males. There were no differences in height, weight, incidence of thyroid disease (Strom *et al.*, 2001b) or pubertal development between the groups previously fed the two types of formuale. Duration of menstruation was slightly longer (by 0.37 days) and more painful in the soy-fed group. Pregnancies were reported by 42% of women fed soy-formula and by 48% of women in the cows' milk formula group. Outcomes of pregnancies were not different, neither were there differences in the occurrence of cancer, hormonal disorders, sexual orientation or birth defects in the offspring between the groups. No conclusions can be drawn on possible effects on fertility in men previously exposed to soy-based formula, considering their relatively young age at the time of the follow-up study. The Committee notes, however, that the potential effects of exposure to oestrogenic substances during infancy on subsequent male fertility need to be evaluated.

A retrospective epidemiological study by Fort *et al.* (1990) found that children with autoimmune thyroid disease were significantly more likely to have been fed soy formulae ininfancy: the frequency of previous feedings with soy based formulae in infancy was 31% in 59 patients with autoimmune thyroid disease, but only 12% in their 76 healthy siblings ($p<0.01$) and 13% in healthy nonrelated controls ($p<0.02$). There was no group difference in the frequency and duration of breast feeding. The aglucons of genistein and daidzein were demonstrated to inhibit the activity of thyroid peroxidase purified from porcine thyroid glands when present at concentrations of 1 to 10 µM, resulting in iodinated isoflavone compounds. Four months old infants fed soy protein formulae were shown to have plasma levels of isoflavones in the range of 1 to 4 µM/L (Setchell *et al.*, 1998). The presence of at least 150 µM of iodine per litre in the incubation mixture completely protected against the isoflavone mediated thyroid peroxidase inactivation (Divi *et al.*, 1997).

A preliminary report in abstract form did not indicate any oestrogenic hormonal effects in children fed soy formula (Businco *et al.*, 2000). *(ENCA's comment: This was research sponsored by infant formula manufacturers)*

Both cows' milk protein and soy protein isolate may be regarded as nutritionally adequate in infant formula. However, in view of some remaining uncertainties on the short- and the longterm effects of a high isoflavone intake in infancy and on the potential to influence allergic and autoimmune disease, the Committee is of the opinion that soy-based formula should be reserved for specific situations only and that cows' milk-based formula should be the standard choice.

b) Fat and fatty acids

The product shall not contain palm oil or palm olein as this is a reason for a reduced bone mineralization.
Source: Reduced bone mineralization in infants fed palm olein containing formula: a randomized double blinded prospective trial WWK Koo et al
Pediatrics 2003; 111(5): 1017-23

c) Carbohydrates

Lactose is the natural sugar found in breastmilk, therefore the lactose content in infant formula should be as optimal as possible.
The carbohydrate content should not be fixed in gram/100 kcal but related to their relative sweetness compared to lactose.
Starches shall not be allowed as infants lack the capacity to digest them in the first months.
We oppose the use of starches because they mislead parents on the nutritional value and undermine breastfeeding.
For decades scientists, manufacturers and doctors have created doubts in women's ability to provide enough nutrition to her baby by breastfeeding. This doubt still persists in the head of people even now where new knowledge on the composition of breastmilk and lactation physiology is available and these doubts are fueled by starches in infant formulae.
This means that starches added to infant formula are misleading parents on the nutritional value of the product.

3.2 Optional ingredients

A standard for infants should not allow unspecified optional ingredients. All ingredients should be specified and meet Codex standards. Scientific proof should exist from independent research that there use is safe in infants. If this is not the case precaution should be applied until the evidence is available. Optional ingredients create double standards. All infants who are artificially fed should be assured the best available ingredients.
3.2.1 Optional ingredients are often used as marketing tools this is why adding the proposed sentence to 3.2.1. is important.
Add: Optional ingredients are mentioned in the ingredients list and give no right to make claims or use them in any promotional way.
3.2.2. Taking into account the levels found in human milk is not relevant as the bio availability is different therefore **add:** The bio-availability of these substances for the infant should be proved before marketing.
Add to scientifically demonstrated: scientifically demonstrated by peer reviewed research independent from a conflict of interest
3.4. "suitable for adequate feeding of young infants" needs further definition. Therefore we recommend to add: "as defined in the Global Strategy for Infant and Young Child Feeding" to read:" …suitable (as defined in the Global Strategy for Infant and Young Child Feeding) for adequate feeding of young infants"

3.5 Purity Requirements

Enterobacter contamination should be excluded

3.6. Specific Prohibition

delete brackets and retain text
3.7. We support Brazil's comment published in CX/NFSDU 03/6 on GMO's

4. FOOD ADDITIVES

There is no need for a whole range of thickening agents, emulsifiers and antioxidants in the preparation of infant formula with the exception of some special formulas where they may be necessary for product properties

4.1. Thickening agents:
We oppose the use of thickeners because in the case of infant formula the product sold on the market is not compared to another product by an other producer who has to follow the same standard, but it is compared to a product produced naturally by the mothers body herself and foreseen as a unique nutritious mixture to satisfy by itself the needs of the infant. Nature has not planned to add thickeners to breastmilk as their unique composition is tailored to meet the need of the baby.
For decades scientists, manufacturers and doctors have instaured doubts in women's ability to provide enough nutrition to her baby by breastfeeding. This doubt still persists in the head of people even now where new knowledge on the composition of breastmilk and lactation physiology is available and these doubts will be fueled by thickeners in infant formulae.
This means that thickeners added to infant formula are misleading parents on the nutritional value of the product.

5. CONTAMINANTS
5.1 Reword to read:
"The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage and processing of the raw materials or the finished food ingredient do not remain, or if technically unavoidable, **do not exceed a maximum level of 0.01 mg/kg for each substance in the product as sold**."
This is in accordance with the European legislation
5.2 Delete current text and **reword** to read: "The product shall be free from residues of hormones, antibiotics, N-nitrosamines, nitrates, heavy metals, mycotoxins, as determined by agreed analysis, and free from other contaminants, especially pharmacologically active substances such as phytoestrogens."
Infant formula is the sole food for infants for the first six months of life and should be free from all contaminants, including residues of hormones and antibiotics.

6. HYGIENE
6.1 Replace "it is recommended" by "shall be "prepared
Stating that the product shall be manufactured in accordance with these Codes of practice is stronger than a recommendation that the product be made in accordance with them.
6.2 Reword to read: "The product **shall** comply with any microbiological criteria established in accordance with the principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997; and shall be free from pathogenic microorganisms, parasites and any other poisonous or deleterious substances"
6.3 Add this new paragraph
The consumers should be informed that this is not a sterile product and that preparation shortly before feeding and discarding of left-over is needed to prevent multiplication of germs present in the product (cf. Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganisms in powdered infant formula)
Therefor the labelling section needs a special chapter on this: the label of each container has to have a clear, conspicuous and easy readable and understandable message printed on it.

9. LABELLING
9.1 The name of the food
Add the following text: The name of the food should not be, or contain, anything which indicates or may be understood by the purchaser to be a claim of any kind or to imply a health advantage.
For example:
A milk called "Humana" deviates attention from the fact that it is infant formula for artificial feeding
HA or **Hypollergenic** added to the name are a promotional claim and not part of the name.
9.5. Information to use
Delete the square brackets from 9.5 and retain text
After the FAO/ WHO Workshop on Enterobacter Sakazakii and other microorganisms in powdered infant formula, special concern should be given to recommend adequate preparation instruction for powdered infant formula as for example "use of boiling water or by heating reconstituted formula" This is a quote from the executive summary of the mentioned workshop.
9.5.1. It is important to give consumers a rationale why prepared formula should not be stored
Add this sentence at the end:

Discard leftovers because of possible contamination of the product during manufacturing or preparation with pathogen germs which grow in the prepared product and can cause illness in the baby. Be aware that this product as sold is not sterile.
9.5.1 and 9.5.2 Delete square brackets and text, as caregivers shall have the information on the product itself to guarantee that they are available to be read by occasional care givers to assure correct preparation, storage and handling.
9.6. Additional labelling requirements
9.6.4 Reword to read:
Information shall appear on the label to the effect that infants should receive **complementary** food in addition to **infant** formula from the age **over six months onward as advised by an independent health worker to satisfy their specific growth and development needs**.
9.6.6 Delete square brackets and retain the text to read:
No nutrition and health claims shall be made regarding the dietary properties of the product.
Health claims are increasingly used by Infant formula manufacturers to market their products. They undermine breastfeeding and create a misleading perception that breastmilk and infant formula are similar or equal. In general, claims are used to idealize the product rather than to inform the consumer. This form of idealization is contrary to the International Code and therefore should not be permitted.
Example: currently claims for infant formula with LCPUFA are made by manufacturers to make health professionals and parents believe that this sort of formula enhances intellectual outcome or the view.
ISDI says in CX/NFSDU 03/6 page 27 on LCPUFA "however it is not known if increases occur in neural tissues. Some studies do show a positive effect, where others were unable to measure such effects"
This example shows clearly how claims are based on inconclusive scientific evidence. The main aim seems to achieve marketing advantages by misleading consumers.

IACFO - International Association of Consumer Food Organisations

IACFO supports all the comments made by IBFAN

IBFAN - International Baby Foods Action Network

1. SCOPE
1. DELETE the word **normal** to read:
This section of the standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the nutritional requirements of infants.
Rationale:
The word **normal** should be deleted, as it would be erroneous to assume that the full complement of nutrients required by infants can be provided by an infant formula.
1.1 INSERT the word **labelling** to read:
*This section of the standard contains compositional, quality, **labelling** and safety requirements for Infant Formula.*
1.2 DELETE the words **normal healthy** from the second sentence to read:
No product other than infant formula may be marketed to or otherwise represented as suitable for satisfying by itself the nutritional requirements of infants during the first months of life.
Rationale:
The word ***healthy*** has not been defined by the Codex Alimentarius, nor by the World Health Organization. The Scope of section B should specify the conditions of infants needing the products categorized as ***formulas for special medical purposes intended for infants***.
1.3 DELETE the words ***should take into account*** and insert ***shall be in conformity with*** and reinsert ***WHA Resolution 55.25 (2002) and subsequent relevant resolutions of the WHA*** to read:
*The application of the Standard **shall be in conformity with** the recommendations given to countries under the International Code of Marketing of Breast-Milk Substitutes (1981) the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution 54.2 (2001), WHA Resolution 55.25 (2002) and subsequent relevant resolutions of the WHA.*
Rationale*:*
Breast milk substitutes are unlike any other food on the market in that they replace breastfeeding – the optimum way to feed infants. This Codex Standard should take particular note of all WHA Resolutions

on this subject and in order to keep pace with marketing developments and scientific knowledge. Steps should be taken to ensure that revisions are made whenever any significant public health measure on infant and young child feeding is adopted by the WHA.
Scientific evidence has consistently demonstrated that artificial feeding increases mortality rates, increases rates for illnesses such as infectious diseases, chronic diseases and auto-immune diseases, offers less than optimal development and growth, lowers cognitive and visual development and increases the risk of obesity. The WHO Multicenre Growth Reference Study carried out by the WHO shows that babies not exclusively breastfed for the first six months grow differently, weigh heavier than breastfed babies and consume about 7% more energy than needed. The importance of breastfeeding extends throughout the entire life cycle. Breastfeeding and appropriate complementary feeding help fulfil the UN *Millennium Development Goals* and have the potential to reduce under-5 mortality by 19%.

2. DESCRIPTION

2.1 Product Definition

2.1.1 **Change to read:**

*Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first **six** months of life, up to the introduction of appropriate complementary feeding.*

Rationale:

This standard should be in conformity with and support the Resolution which was adopted by the World Health Assembly in 2002 and has already been incorporated into national policy by 82 countries[1].
Manufacturers should ensure that their products labels are in conformity with all WHA relevant Resolutions. This would prevent confusion over the introduction of complementary feeding and the overfeeding of infants with all the resulting consequences, including increased risk of obesity[4].

2.1.2 DELETE the words **is so processed by physical means only** and replace with **must be processed** to read:

*Infant formula **must be processed** and packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.*

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1 REWORD the first sentence to read:

*Infant formula is a product based on milk of cows or other animals and/or other **edible constituents of animal, including fish, or plant origin,** which have been proven, through independent research to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be demonstrated **by independently-funded and systematically- reviewed research** to support growth and development of infants*

Rationale:

The wording in the previous draft, which noted all possible ingredient sources, should be retained. Full informative is essential for consumers to make important and vital decisions about infant feeding.
The use of soy as a major ingredient should be reviewed. (See appended comment on the use of soy-based infant formulas.)

b) Fat and fatty acids

REMOVE the square brackets from trans fatty acids and change the text to read:
No added non biologically produced trans fatty acids should be permitted.

c) Carbohydrates

The lactose content in all routine infant formulas should be as close to the level in human milk as possible.

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1 WHA Resolution 55.25 calls on governments to :
"*.. strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding **for six months** as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding, (note 1) and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years of age or beyond."*

4. Riordan and Aerbach Breastfeeding & Human Lactation Jones and Bartlett 1999. *Artificially fed infants consume 30,000 more calories than breastfed infants by 8 months of age.*

Rationale:
Lactose is the predominant carbohydrate found in human milk, which contains on average 7.3 g/dl or 10g/100kcal to provide about 40% of the infants energy needs.
Additionally human milk carbohydrates are made up of small amounts of 50 oligosaccharides of varying structures.
Starches are not present in human milk and infants under the age of four months do not have the enzymatic capacity to digest starches. Therefore starches should not be permitted for infant formulas promoted for use by infants less than four months of age.
The use of non-human milk carbohydrates should not be fixed in gram/100 kcal but related to their relative sweetness compared to lactose.

3.2 Optional ingredients

3.2.1 CHANGE text to read:

In addition to the compositional requirements listed under 3.1, other ingredients may be added ***only if demonstrated* by independently-funded and systematically reviewed research *to be safe and essential for infant health.*** ~~***in order to provide substances ordinarily found in human milk and to ensure the formulation is suitable as the sole source of nutrition for the infant.***~~ ***No nutrition or health claims or comparative claims may be made for these infant formulas.***

Rationale:
Optional ingredients should be kept to a minimum. Ingredients should be permitted for use in breastmilk substitutes only when shown by independently-funded research to be safe and essential for infant health. Conversely, if an ingredient is essential for health and has been shown to be safe through independently-funded and systematically-reviewed research, it should be a legally required ingredient available to all infants.
The presence of numerous optional ingredients creates double standards. All infants who are artificially fed should be assured of the safest and most nutritious substitute possible. Optional ingredients also increase the likelihood of manufacturers using claims to promote different types of formulae.

3.2.2 CHANGE the text to read:

The suitability ***of ingredients that may be added*** *for the particular nutritional uses for infants,* ***must be demonstrated through independently funded and systematically reviewed research, to be bio-available,*** *safe,* ***have no unintended side effects*** *and* ***have the ability*** *to achieve the intended effect, taking into account the levels present in human milk* ***as appropriate.***

3.5 Purity Requirements

CHANGE to read:

All ingredients shall ***be as free from chemical and microbial contamination as possible****, of good quality, safe and suitable for ingestion by infants. They shall conform* ***to optimal*** *quality requirements, such as colour, flavour and odour.*

3.6 Specific Prohibition

DELETE brackets and retain text with additions to read:

The product and its components shall not contain commercially ***produced*** *hydrogenated oils and fats, shall not have been treated by ionizing radiation* ***and shall not contain ingredients modified through genetic engineering.***

4. FOOD ADDITIVES

Change the preamble to read:

No ingredient should be added unless it has been demonstrated to be safe, by means of independently funded, and systematically-reviewed scientific research.

Rationale:
Thickening agents, emulsifiers and antioxidants are not needed in infant formulas. These non-nutritive chemicals expose infants to needless additives when the infant is already exposed to a large number of foreign substances present in infant formulas. As well formula fed infants are in an immunologically deprived status and less able to handle unnecessary chemicals.
Cosmetic ingredients are frequently used to please the parents rather than providing for the infant's needs.

5. CONTAMINANTS

5.1 Pesticide Residues

REWORD to read:

The product shall be prepared with special care under good manufacturing practices, so that residues of those ***plant protection substances*** *which may be required in the production, storage and processing of the raw materials or the finished food ingredient do not remain, or if technically unavoidable,* ***do not exceed a maximum level of 0.01 mg/kg for each substance in the product as sold.***

Rationale:

This is in accordance with European legislation.

5.2 Other Contaminants

DELETE current text and **reword** to read:

The product shall be free from residues of hormones, antibiotics, N-nitrosamines, nitrates, heavy metals, mycotoxins, as determined by agreed analysis, and free from other contaminants, especially pharmacologically active substances such as phytoestrogens.

Rationale:

Infant formula may be the sole food for infants for the first six months of life and should be free from all contaminants, including residues of hormones and antibiotics. The use of soy-based infant formulas should be reviewed. See Appendix A.

6. HYGIENE

6.1 DELETE **It is recommended that** and insert **shall** to read:

The product covered by the provisions of this standard ***shall*** *be prepared and handled in accordance with….*

6.2 REWORD to read:

The product ***shall*** *comply with any microbiological criteria established in accordance with the principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997;* ***and shall be free from pathogenic microorganisms, parasites and any other hazardous or deleterious substances***

6.3 ADD this new paragraph:

Consumers should be informed through labelling of the product in the form of a warning that powdered infant formula is not a sterile product. Labels must carry, on the outside of the panel, a clear, conspicuous, easy to read and warning of possible contamination, stressing preparation instructions to minimize the risk of harm related to the lack of sterility.

Labels must highlight the need for appropriate use preparation; have explicit preparation instructions both in text and graphic and in local languages; and instruct on the need to discard left-over feed to prevent growth of microbial contaminants present in the product (cf. Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganism in powdered infant formula).

The Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganisms in powdered infant formulas recommends: "In situations where the mother cannot breastfeed, or chooses not to breastfeed for any reason, caregivers should use, whenever possible and feasible, commercially sterile liquid formula."

9. LABELLING

9.1 The Name of the Food

9.1.1 change to read:

The text of the label and all other information accompanying the product shall be written in the appropriate ***languages of the countries where the product is marketed.***

9.1.2 ADD the following text to read:

The name of the food should not be, or contain, anything which indicates or may be understood by the purchaser to be a claim of any kind or to imply a health advantage. The name should not imply that the product is like human milk.

Rationale:

For example: **HA** or **Hypollergenic** (indicating possible reduction of allergy risk**), AR, Staydown**, (indicating anti-reflux properties), **Organic, Prebiotic, Probiotic** or **Humana**. All these claims promote the product and should not be permitted. Particular properties of products are more safely conveyed through clear nutrition labelling, or independent certification stamps, alongside clear instructions which

indicate the intended use of the product. No claim implying a health advantage or regarding the efficacy of the product should be made or implied.
Trade marks should not be exempt from controls on health claims.
See: Appendix B, Allergenicity Claims

9.1.3 CHANGE the text to read:

The label of the product shall indicate the nature of the protein, fat, carbohydrate or other compositional modification, including additives and optional ingredients. This information must be presented in a clear factual and scientific manner that is not in any way promotional or idealizing.

9.1.5 ADD the following to read:

A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products". If the product is soy-based it must be labelled "Formula Based on Soya".

Rationale:

It is important for parents to know the animal or plant source of the ingredients in infant formula. A review of the use of soy-based infant formulas is needed. See Appendix A

9.5 Information for use

In the preamble, remove brackets and DELETE the first mention of the word **water** after **safe** to read:

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 require safe and previously boiled water for preparation

Rationale:

It is important that all water is previously boiled, including bottled water which manufacturers portray as 'safe'.

9.5.1 REMOVE the text in brackets ***"or in the accompanying leaflet"*** and the ADD the following paragraphs to the text in 9.5.1

*Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation****, including the following statement: "Formula remaining after feeding must be discarded" must*** *appear on the label.*

When in powdered form, a clear, conspicuous, easy to read and understandable warning must appear on the outside panel of the label that POWDERED INFANT FORMULA IS NOT A STERILE PRODUCT and that the product may have been contaminated during manufacture. Labels must clearly alert the user of the need to prepare the product according to instructions to minimize the risk of harm related to the lack of sterility and that preparation must be just before feeding. Explicit preparation instructions must appear both in text and graphics in local languages (cf. Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganism in powdered infant formula)

Rationale:

The above information MUST appear on labels, to ensure that all caregivers, including occasional care-givers, have adequate notice that powdered infant formulas are not sterile and full information on use and preparation each time the product is used. Leaflets are unacceptable and add risk of misuse as they are easily lost or discarded.

The Risk Profiles of *Enterobacter sakazakii* in Powdered Infant Formulas, tabled at the 35th and 36th sessions of the CCFH as well as the FAO/ WHO expert consultation report of the Workshop on *Enterobacter Sakazakii* and other microorganisms in powdered infant formula (February 2004), make it very clear that special concern should be given to minimize the health risks associated with the contamination of powdered infant formulas.

The revision process of the Proposed Draft Revised Recommended International Code of Hygienic Practices for Foods for Infants and Children is inadequate to address the immediate urgency of this serious health concern.

9.6 Additional Labelling Requirements

9.6.1 e) ADD the following new sub-section to 9.6.1 to read:

Powdered infant formulas may be contaminated with harmful microorganisms during manufacturing, or may become contaminated during preparation, therefore in order to reduce the risk of potential infection it is necessary to discard any unused formula immediately after every feed.

9.6.2 CHANGE to read:

The label shall have no pictures of infants and women nor any other picture or text or any symbols which depict a health advantage or idealizes artificial feeding. The label must have graphics illustrating the method of preparation of the product and methods of feeding.

9.6.4 CHANGE the word **'supplemental'** to **'complementary'** and change the end of the sentence to read:
Information shall appear on the label to the effect that infants should receive ***complementary*** *foods in addition to infant formula from the age* ***over six months onward as advised by an independent health worker to satisfy their specific growth and development needs.***
9.6.6 DELETE the square brackets and RETAIN the text to read:
No nutrition and health claims shall be made regarding the dietary properties of the product rationale.
Rationale:
Nutrition and health claims are increasingly used by infant formula manufacturers to market their products. These devices undermine breastfeeding and create a misleading perception that infant formula are similar to breastmilk in efficacy as it relates to health outcomes growth and development. Such claims are used to idealize the product rather than to inform the consumer. This form of idealization is contrary to *the International Code* and therefore should not be permitted.
Example: currently infant formulas with added LCPUFAs claim that these ingredients enhance intellectual outcome and visual acuity, although research does not substantiate these claims. (Note: ISDI CX/NFSDU 03/6 page 27 on LCPUFA *"however it is not known if increases occur in neural tissues. Some studies do show a positive effect, where others were unable to measure such effects")*
Rather than health claims it would be more informative and truthful to make health warnings about the increased health risks of using these products. The scientific literature makes it abundantly clear that infants who are formula fed have higher rates of infectious and chronic diseases. Any needless increase in the use of formulas will result in added risk to infant health and development.
IBFAN's monitoring report on the marketing of infant formulas and infant foods in 69 countries, *Breaking the Rules Stretching the Rules 2004*, found that 11 out of the 16 infant food industries surveyed, promoted infant formulas fortified with DHA and AHA with claims that it boosted intelligence.
ADD the following text
Statements or claims that reflect ethical or religious considerations and which influence dietary choices should not be permitted. However it is essential that manufacturers label products clearly so that all ingredients, especially those which are relevant to ethical or religious considerations are fully disclosed using QUID labelling. The products must not carry any symbols or logos which imply health advantages other than an organic or kosher certification from an independent source.
Rationale:
Given the nature of breastmilk substitutes there is a potential for any claim to promote the product over breastfeeding, Companies are already using symbols on foods – showing, for example a brain or a battery – to symbolize intelligence, energy etc.)
Religious symbols also imply a special use. The German baby food company Humana Milchunion, has agreed to an out of court settlement with parents of two Israeli infants who died from, and dozens more who were harmed by, a soy based formula that it sent to Israel without the vital vitamin B-1 missing (thiamine) that was marked on the label.All these babies would be alive or unharmed today has they been breastfed.

APPENDIX A:

Country warnings issued regarding the use of soy-based infant formulas

To date a number of countries have reviewed and issued statements of concern about the routine use of soy formulas.

UK, January 2004
Earlier this year the UK Medical Officer of Health[1] reiterated that soy formulas should not be used as the first choice for the management of infants with proven cow's milk sensitivity, lactose intolerance, galactokinase deficiency and galactosemia. The warning, based on a report by the Committee on Toxicity, notes the long-term risk posed for reproductive health linked to the high levels of phytoestrogens found in these products. The MOH also advices there are " no health benefits associated with the consumption of soy-based infant formulas".

British Dietetic Association, 2003
In an announcement published in the Journal of Family Health Care[2], the Association notes that "***Dietitians should discourage the use of soy protein in children with atopy or cow's milk allergy in the***

first six months of life to avoid sensitization to soya protein and exposure to phytoestrogens while organ systems remain at their most vulnerable. This would include the use of soy infant formula…When a soy based infant formula is used parents should be informed of current findings relating to phytoestrogens and health and on the clinical need for soy formula."
This notification follows a category of others.

Australia, March 1999
The Australian and New Zealand Food Authority[3] warn that infants fed soy formulas are exposed to 47mg of isoflavone per day and that this level is at least 240 times greater than consumed by breastfed infants. The report notes concerns about the potential to adversely affect subsequent sexual development and fertility.

New Zealand, December 1998
New Zealand's Ministry of Health recommends[4] that soy-based infant formulas should only be used under the direction of health professionals for specific medical indications. Other options should be considered first. As well clinicians are urged to be aware of the use of soy formulas and thyroid function and to consider assessment of thyroid function when satisfactory growth and development is not achieved.

Switzerland, 1997
The Swiss Commission on Food, also issues an information sheet to all paediatricians based on a review report[5]. This report too warns that very restrictive use should be made of soy formulas because of the potential harm from isoflavones.

References:

1. Department of Health CMO's Update. **Advice issued on soy-based infant formulas**. January 2004, page 2
2. The British Dietetic Association **Paediatric group position statement on the use of soya protein for infants**. J Fam Health Care 13: 93, 2003
3. ANZFA **Phytoestrogens: An assessment of the potential risks to infants associated with exposure to soy-based infant formula**. March 1999
4. Tuohy, P. **Soy-based infant formula.** Ministry of Health, Wellington, New Zealand, December 1998
5. Zimmerli B. et al. **Existence and development of isoflavones daidzein and genistien in baby food**. Communication regarding food stuffs in Hyg. 88:19-232, 1997

Appendix B:

Allergenicity Claims

Allergenicity claims such as HA are particularly problematic and would be more safely handled with a nutrition statement such as, ***contains hydrolised proteins*** alongside generic product descriptions and warnings that the product should be used only on the advice and under the guidance of an independent health professional.
When *Nan HA* was first launched in the UK in 2002, eleven leading health and consumer organisations, wrote to the Minister for Public Health, Hazel Blears to challenge the legality of HA claim. Nestlé eventually launched the product with a warning stuck on the top of the tin, stating that the product ***may cause an allergic reaction if given to an infant with diagnosed allergy to cow's milk.*** This strategy is not only inadequate, but completely contradicts the thrust of the message contained in the HA claim[2]. Since the launch the company has been reported to the UK Advertising Standards Authority (ASA) for using ***misleading and dangerous*** claims for ***hypoallergenic*** infant formula. Advertisements to health workers made claims that the product is **the starter infant formula of choice that significantly reduces the risk of allergy** and that the ***exclusive use of a hydrolysed formula is recommended to reduce the risk of developing an allergy[3].*** The adverts imply that 'partially hydrolysed' formulae have the same properties as fully 'hydrolysed' formulae. The UK Food Standards Authority has warned against using partially hydrolysed formula with allergic infants because of the risk of a reaction.

2 http://www.babymilkaction.org/press/press28july04.html

3 British Journal of Midwifery, July 2004

HA or *Hypoallergenic* claims are not permitted in North America following Nestlé/Carnation's launch of *Good Start HA* in the US in 1988, when several allergic babies suffered from anaphylactic shock. Nine US States and the Food and Drug Administration investigated and forced Nestlé to stop using 'hypoallergenic' claims which they said were: *"Misleading and deceptive...Those babies who had severe reactions to Carnation Good Start have paid a high price for the company's irresponsible conduct."*
The claims for hydrolysed proteins and the development of the market for infant formulae containing partially hydrolysed proteins was underpinned by the work of Dr R.K.Chandra, a Canadian researcher who has in recent years been discredited and whose entire body of work is now under investigation.[4]
Leading Swedish allergy specialist, Prof Bengt Bjorksten, questioned the European ESPGHAN support for hypoallergenic milks in 1993: *"The conclusions drawn by the Committee [ESPGHAN]...differ substantially from what most American and European researchers suggest, and they are almost identical to those suggested by the company marketing the partially hydrolysed product direct to the public... Why did the Committee not properly address this important controversy but merely uncritically quote a review published in a company sponsored book by an employee of the company?"* (*Acta Paediatrica,1993*)
The Scientific Committee for Food *Report on the Revisions of Essential requirements of Infant formulae and Follow-on Formulae* also expressed concern about the validity of the claims and on Page 48 states: "*it has been shown for some products that they were nutritionally inadequate. It is unknown if such products were removed from the market. The inherent claim that hydrolysates result in less allergic diseases cannot be deduced from technical data alone and needs substantiation in clinical trials. Surprising is the total lack of clinical studies published on follow-on formulae based on partially hydrolysed proteins."*
and on pages 50 & 51: "*To our knowledge there are no systematic studies to assess growth and biological parameters of infant formulae with partially hydrolysed protein to determine the minimal safe protein content."*
and Page 161*: "The Committee concludes that there is no scientific foundation to base a claim that a formula induces 'reduction of risk of allergy to milk proteins' or is 'hypoallergenic' on a content of immuno-reactive protein of less than 1% of nitrogen-containing substances, as is presently the case."*
The properties of the product – for example, that it contains hydrolysed proteins, can be conveyed through clear nutrition labelling alongside clear instructions which indicate its intended use. No claim regarding the efficacy of the product should be made or implied.

ISDI – International Special Dietary Foods Industries

ISDI PROPOSAL	JUSTIFICATION
TITLE: Proposed revised standard for infant formula ~~[~~and ~~formulas~~ **food** for special medical purposes intended for infants~~]~~	Replace "formula" by "foods" Rational: while it is clearer that this section of the Standard covers products intended to be used as the sole source of nutrition, using the word "food" is consistent with the Codex Standard for the labelling of and claims for foods for special medical purposes (CODEX STAN 180-1991).
PREAMBLE ~~[~~This standard is divided into two sections. Section A refers to Infant Formula, and Section B deals with ~~Formulas~~ **Foods** for special medical	Replace "formula" by "foods" Rational: consistent with the Codex Standard for the labelling of and claims for foods for special

4 Canadian medical journals such as *Nutrition*, have called for an investigation into Chandra's entire body of research on the basis that his research on vitamins and dementia is fundamentally flawed. The *British Medical Journal* refused to print Chandra's work saying the paper had: ***"All the hall marks of being entirely invented."*** An editorial in *Nutrition* said Chandra failed to provide raw data so that experts could check his statistics: "*As a journal, we regret that our peer-review process failed to identify these problems before publication,"* acknowledging that the incident reflected badly on the peer-review process: *"Sometimes the peer reviewers…just* [take] *the data for face value. They aren't statisticians."* www.cbc.ca/stories/2004/06/10/sci-tech/chandra040610, www.biomedcentral.com/news/20040511/02, http://bmj.bmjjournals.com/cgi/eletters/328/7431/67#48196,

purposes intended for Infants~~]~~	medical purposes (CODEX STAN 180-1991)
Section A: Infant Formula	
3.1.3	ISDI has provided extensive comments to the electronic working group chaired by Germany, in charge of reviewing this section. These comments can be found in ISDI document 04/450.
3.2.1 In addition to the compositional requirements listed under 3.1.3, **which ensure that the formulation is suitable as the sole source of nutrition for the infant,** other ingredients may be added in order to provide substances ordinarily found in human milk **or biological benefits similar to human milk** ~~and to ensure that the formulation is suitable as the sole source of nutrition for the infant~~.	Reword and add "or biological benefits similar to human milk. Rational: Human milk is a complex biological fluid and many of the traditional nutrients are in different forms in human milk than in formulas (e.g., folate, vitamin B_6, protein, lipid, etc.), yet the infant grows and develops. As we learn more about the specific benefits of human milk, substances are identified that can be added to formula to help achieve the same benefits as human milk. The substances are not necessarily the same chemical entities due to commercial availability, ability to process into a product and maintain in a stable form, and cultural and consumer preferences (e.g., avoidance of genetically modified materials). This is in line with the fact that the European SCF, in 2003, has based its evaluation of infant formula on the comparison between the **outcome** in infants fed formula and the outcome in infants exclusively breast fed for 4 to 6 months, and not only on the comparison between the composition of formula and the composition of breast milk.
3.6 Specific prohibitions The product and its components shall not ~~[~~contain commercially hydrogenated oils and fats and shall not~~]~~ have been treated with ionizing radiations	Remove [ ]
3. FOOD ADDITIVES **4.1 Thickening agent** ~~4.1.1~~ INS 412 Guar gum ~~4.1.2~~ INS 410 Carob bean gum . . .	For simplification, the sub-numbering system for each additive can be deleted since they are already identified by their INS number.
INS 410: Carob bean gum (locust bean gum) ~~0.1g~~ **0.5g** in all type of formula	Change the level of INS 410 Non caloric thickening agent. Emulsion stabiliser, adjustment of viscosity. Used in some anti regurgitating formulas. If a lower level is used, the solution separates very quickly in phases. Carob bean floats to the upper level of the solution very quickly, so a minimum viscosity is needed to prevent this phenomenon.
INS 472e: Diacetyltartaric and fatty acid of esters of glycerol GMP	Addition of INS 472e Retains homogeneity of liquid products and liquid reconstituted powder especially in 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

INS 308: Delta-tocopherol **INS 309: Gamma-tocopherol** **1 mg in all types of infant formula singly or in combination**	Addition of INS 308 and 309 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 ingredients with the exception: (a) of the food additives listed under Sections 4.1 to 4.4 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 within the limits of the maximum levels stipulated in that List.~~]~~	Delete [ ] Rational: While acknowledging that CCFAC is currently considering establishing a new additive functional class for nutrient carriers, ISDI believes that the list of nutrient carriers should remain where it is currently i.e. at the end of the advisory list of mineral salts and vitamin compounds for the use in foods for infants and young children currently under revision by CCNFSDU. ISDI believes that this list of nutrient carriers should also be reviewed.
9.1.6 ~~[Products containing not less than 0.5 mg Iron (Fe) /100 kilocalories shall be labelled "Infant formula with added iron"]~~ Or [Products containing ~~not~~ less than 0.5 mg Iron (Fe) /100 kilocalories shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from additional sources.]	**Retain option 2 and delete "not"** **Rational: the wording in option 2 is more relevant for caregivers.**
9.3. Declaration of 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 per 100 mililiter of the food ready for use, when prepared according to the instructions on the label.	Add "optional ingredients if added" Rational: adding "optional" is in line with section 3.2. Including "if added" avoids misinterpretation.
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**	Reword and change the order of the sentence. Rational: adds clarity and powdered formula are the most commonly used type of formula around the world.

used directly according to instructions for use.	
9.6. Additional labelling requirements **9.6.4.**and in any case from the age **of** ~~over~~ six months	Grammatical correction
9.6.6 ~~[No [nutrition and] health claims shall be made regarding the dietary properties of the product~~] **Nutrition and health claims shall be permitted for foods for infants where they have been demonstrated in rigorous studies with adequate scientific standards.**	**Reword into a positive statement** **Rational: ISDI proposed wording is in support of the wording proposed by Switzerland (Alinorm 05/28/26 para 83).** **It is of the utmost importance that information on the dietary properties of infant formula can be communicated as:** • Claims explain the specific nutritional characteristics of the different formula • Claims do not interfere with a mother's decision to breast feed. Prohibiting claims on these products cannot be justified by public health grounds. • Providing factual, science-based nutrition information on labelling protects the health of the formula-fed infants by differentiating the composition of formula from less nutritious alternatives. • Some countries already allow certain health and nutrition claims on infant formula. • Provisions ensuring that claims for foods for special dietary uses are appropriately used, have already been detailed in Section 3.1 of Codex STAN 146-1985. • Finally, there is no reason to prohibit the communication of relevant information through labelling and literature if it complies with the above mentioned criteria and as long as this communication remains in line with national practices and the WHO International Code on the Marketing of Breast-milk Substitutes.

ANNEX1
Essential and semi-essential amino acids in breast milk

For the purpose of this Standard the essential and semi-essential amino acids in breast milk, expressed in mg per 100kJ and 100kcal, are the following:….	The present table should be reviewed in light of latest scientific knowledge and would need to be considered by the working group of scientific experts looking at essential composition.

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~~	Reword Rational: Point 5b) and point 5c) address the same matter of ingredient variability,

~~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**	
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 is 750 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