codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

Agenda Item 6 (b) **CX/NFSDU 05/27/7**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

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DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PUPOSES INTENDED FOR INFANTS: SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

- ***Comments at Step* 3 *of the Procedure*** –

Comments from:

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

ENCA – European Network of Childbirth Associations
IACFO – International Association of Consumer Food Organisations
IBFAN – International Baby Food Action Network
ISDI – International Special Dietary Foods Industries

ARGENTINA

Article 1.1: Argentina agrees on the elimination of the square brackets, taking into account that the compounds for special medical use could be a substitute for mother's milk such as a formula for infants if a pediatrician indicates this according to the infant's requirement.
Article 3.2.3: We support the elimination of the square brackets.
Article 3.6: Argentina supports 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 because there exists no security in their use for products for infants.
Article 9.6.4: Argentina agrees on the elimination of the square brackets, reaffirming the same principles of the International Codex of Substitutes of breast milk.
Article 9.6.5: Argentina agrees on the elimination of the square brackets.

AUSTRALIA

1.3 Scope
The cross reference to paragraph 1.3 in Section A is inappropriate and should be drafted relevant to Section B. The following text is suggested:
'Only products that comply with the criteria laid down in the provisions of this section of this standard would be accepted for marketing as formula for special medical purposes intended for infants. No product other than formula for special medical purposes intended for infants may be marketed or otherwise represented as suitable for satisfying by itself the special nutritional requirements of infants that are due to disorders, diseases or other medical conditions during the first months of life.'

2.1.2 Product Description
The cross reference to Section A2.1.3 is incorrect as it no longer exists. If cross reference to A2.1.2 was intended, then Section B should have its own paragraph, based on A2.1.2 in which 'infant formula' is replaced by 'formula for special medical purposes intended for infants'.

3.1.1 Essential Composition

- Insert 'and' in reference to synthetic compounds, that is: and/or synthetic compounds, to remove ambiguity.
- Australia will await the advice on micronutrient composition for Section A, Infant formula, but notes that chromium and molybdenum may need to specify minimum and maximum levels, possibly be met by addition to formula for special medical purposes intended for infants because of insufficient content of the basic ingredients.
  Current values in Australian regulations are: chromium 0.35 – 2.0ug/100kJ, and molybdenum 0.36 – 3.0 ug/100kJ.

3.2.3 Optional Ingredients
Delete square brackets and replace the text with either the simpler form of expression in Section A3.2.3 or alternatively cross reference to A3.2.3.

Section 9 Labelling

- The equivalent of section 9.5 in Section A is not represented in Section B. This should be addressed by including at 9.6.1, a cross-reference to Section 4.4.2 (adequate directions and storage) of CODEX STAN 180-1991.
- Reference to Section 4.4.3 of CODEX STAN 180-1991 is not necessary in 9.6.1 but should be listed in 9.6.3.
- Delete the brackets surrounding 9.6.4 and 9.6.5.

CHINA

PROPOSED MODIFICATION OF ALINORM 05/28/26, Appendix IV(B)	**COMMENTS AND JUSTIFICATION**
1. SCOPE	
1.1 This section of the standard applies to Formula for Special Medical Purposes Intended for Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk **[**or infant formula**]** in meeting the special nutritional requirements arising from the disorder, disease or medical condition for whose dietary management the product has been formulated.	Delete [ ]. In some cases neither breast milk nor infant formula is suitable for feeding the infant
1.4 See section A 1.4 The application of this section of the Standard **cannot** ~~should~~ take into account **in its entirety** the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA 54.2 (2001).	Rephrase to "cannot take into account in its entirety"... Reason: WHO Code which applies to products marketed as breast milk substitutes intended for "healthy" infants below 6 months of age. However, FSMP's are destinated to infant patients with limited or impaired absorption, digestive, and/or metabolic capacity and therefore some of the provisions within the Code are NOT appropriate. i) FSMPs are specially needed products by some infant patients, not recommended as alternative of breastmilk; ii) FSMPs are required in response to a clinically / medically identified problem that requires dietary intervention. iii) FSMPs are used on recommendation of a healthcare worker / medical professional. Therefore the following provisions from the Code are not applicable: - *Art 4: Information & Education* *4.2 Important notice about the superiority of breastfeeding, etc.* In some situations, breast milk or infant formula, is **NOT** the most appropriate food for an infant requiring an FSMP. Such statements would be misleading, confusing and may even be distressing, additionally. - *Art 6: Health Care System* *6.1 Appropriate measures to encourage and protect breastfeeding should be taken* In some cases, the use of an FSMP for infant is in conjunction with breastfeeding/formula. In others, breastfeeding would be contra-indicated. *- Article 7: Health Workers* *7.2 Information provided by manufacturers and distributors should not imply or create an belief that bottle-feeding is equivalent or superior to breastfeeding, etc.* Informations about FSMP should indeed be restricted to scientific and factual matters,

	however in some situations FSMPs have to be recommended to replace breast-feeding for medical purposes. Likewise, in such cases information as specified in Article 7.2 is not relevant. - *Article 9: Labelling* *9.2 Manufacturers... of infant formula should ensure that each container has a readable and understandable message .... including the following points a) the words "Important Notice" or the equivalent... etc"…* In some situations FSMPs have to replace breast-feeding for medical purposes, thus the "Important Notice" could be misleading.
2. DESCRIPTION	
2.1 PRODUCT DEFINITION	
2.1.1 Formula for Special Medical Purposes Intended for Infants ~~means a breast milk substitute that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and~~ **is a category of foods which are specially processed or formulated and presented for the dietary management of patients and used under medical supervision. It is intended for the exclusive feeding or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements. It** is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.	Modifify the defination of FSMP as "**is a category of foods which are specially processed or formulated and presented for the dietary management of patients and used under medical supervision. It is intended for the exclusive feeding or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements.**" Reason: - To keep consistant with Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) in the description. The last sentence of the definition of FSMPs has been modified in order to emphasize that FSMPs need to fulffil the special nutritional requirements of all infants patients, i.e. both whether they receive FSMP's as part of exclusive or partial feeding. There are many diverse types of formula/foods for special medical purpose for infants. In particular, there are basically two categories: 1. Formulas modified in some essential characteristics, but which can be used as the sole source of nutrition (e.g., formulas for preterm infants, extensively hydrolyzed or amino acid formulas for certain disorders). 2. Formulas for inborn errors of metabolism that cannot be used as the sole source of nutrition. (e.g., product that must omit an essential amino acid such as phenylalanine for use with infants with phenylkentonuria (PKU)). Strongly recommend that Section B of this Standard applies only to category 1 "Formulas modified in some essential characteristics, but which can be used as the sole source of nutrition".

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS	
3.1 ESSENTIAL COMPOSITION	
3.1.1 Formula for Special Medical Purposes Intended for Infants is a product based on ingredients of animal and/or plant origin **and/**or on synthetic compounds suitable for human consumption. All ingredients and food additives shall be gluten-free.	Add "and/".
3.2 OPTIONAL INGREDIENTS	
3.2.3 ~~[~~Only L(+) producing lactic acid cultures may be used in formulas for special medical purposes ~~if shown to be safe and appropriate for use in these vulnerable populations]~~.	Delete last part of this section which is redundant with section 3.2.2; and delete [ ].
4. FOOD ADDITIVES	
see Section A 4. The following additional food additives are permitted in the preparation of Formula for Special Medical Purposes Intended for Infants (**to be filled in**).	Detailed comments on this section can be found at the end of this document.
9. LABELLING	
9.6 ADDITIONAL LABELLING REQUIREMENTS	
~~[~~9.6.4 Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended.	Delete [ ].
9.6.5 The product shall be labelled in such a way as to avoid any confusion between formula for special medical purposes intended for infants, infant formula and follow-up formula~~]~~.	Delete [ ].

INDIA

1. Scope

1.1 REWORD to read:

This section of the standard applies to Formulas for Special Medical purposes Intended for Infants, in liquid or powdered form, intended, where necessary, as a substitute for human milk in meeting the nutritional requirements of infants when medically indicated for a specific period.

REASON: The terms "disorder, disease or medical conditions" are vague and undefined.

1.2 REWORD to read:

This section of the standard contains compositional, quality and safety requirements for Formulas for Special Medical Purposes Intended for Infants.

1.3 Refer to A 1.3, and A1.4

DELETE the words "should take into account" and INSERT "Shall be in conformity with" and remove the square brackets around WHA Resolution 55.25 (2002) and add "and all 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, World Health Assembly Resolutions 54.2 (2001) and 55.25 (2002) and all subsequent relevant resolutions of the WHA.

2. Description

2.1 Product Definition

DELETE the phrase "infant patients" and REWORD to use the phrase "when medically indicated":
Formula for Special Medical Purposes Intended for Infants means a breastmilk substitute that complies with section 2, Description, of the Codex Standard for the Labelling of and the Claims for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy the nutritional requirements of infants during the first months of life up to the introduction of complementary feeding when medically indicted.

2.1.2 DELETE the text in the square brackets and REWORD to read:
Infant formula shall be as safe and as nutritionally adequate as possible to ensure growth and development when used to accordance with its directions for use.

A2.1.3 is not there in the report as referred here.

2.1.3 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 DELETE the phrase "synthetic compounds suitable for human consumption" and ADD "through independent research" to read:
"Formula for Special Medical Purposes Intended for Infants is a product based on milk of cows and/or buffalos 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".
NOTE: The use of soy as a major ingredient should be reviewed.
SEE APPENDIX "A"

3.1.2 REWORD to read:
The formulation of Formula for Special Medical Purposes Intended for Infants should be based on sound medical and nutritional principles. Their use should have been demonstrated by independent scientific research, to be safe and beneficial in meeting the nutritional needs of infants for whom they are intended.

3.1.3 DELETE the phrase deriving from disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specially formulated, labelled and presented" and
REWORD as under:-
The energy content and nutritional composition of Formula for Special Medical Purposes Intended for Infants shall be based on the requirements for infant formula as given in Sections A 3.1.2 and A 3.1.3 except for the compositional provisions which must be modified to meet special nutritional requirements when medically indicated.

3.2 Optional Ingredients

3.2.1 REWORD the text to re**ad:**
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 the formulation is suitable as the sole source of nutrition for the infant as medically indicted.
No nutrition, health claims or comparative claims may be made for these infant formulas

3.2.1 REWORD the text to read:
The suitability of ingredients that may be added for the particular nutritional uses for infants as medically indicated, 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.

3.4 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.
3.5 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

No ingredient should be added unless it has been demonstrated to be safe, by means of independently funded scientific research.
RATIONALE:Thickening agents, emulsifiers and antioxidants are not needed in infant formulas. These non-nutritive chemicals expose infants to further needless risks.

5. CONTAMINANTS

5.1 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 ingredients 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.
5.2 DELETE the 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 for medical purposes may be the sole food for infants under six months of age and should be free from all contaminants, including residues of hormones and antibiotics.
The use of soy-based infant formals need to be reviewed.

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.

9. LABELLING

9.1 The Name of the Food
REINSERT the following text:
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 sold.
9.1…….ADD the following text:
No nutrition, health or comparative claims may be made for products covered under Section B of this standard.
The product must not carry any symbols or logos which imply special health advantages.
9.6 Additional Labelling Requirement
Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words “IMPORTANT NOTICE” or their equivalent;
b) the statement “BREASTMILK IS THE BEST FOOD FOR YOUR BABY” or a similar statement as to the superiority of breastfeed and breastmilk;
c) a prominent statement that the products should only be used on the advice of a health worker, independent of commercial interest as to the need for its use and the proper method of use, such as “Use only when medically indicated and only under medical supervision”.
(d) instructions for appropriate preparation;

(e) a warning against the health hazards of appropriate preparation; a warning that formula remaining after each feeding should be discarded
(f) the terms "humanized", "maternalized or similar terms shall not be used;
(g) The label shall have no pictures of infants and women nor any other picture or text which idealizes artificial feeding or any symbols depicting a health advantage. The label must have graphics illustrating the method of preparation of the product and methods of feeding.

9.6.2 REWORD to read:
A statement indicting that the product may be the sole source of nutrition or be used as a supplement to breastfeeding when medically appropriate and for a specific period only.

9.6.5 REWORD to read:
The statement: Use only when medically indicated and under medical supervision for the feeding of infants with…who cannot be breastfed.
No nutrition, health or comparative claims or any symbols depicting a health advantage, may be made for the properties of these formulas.

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 47 mg. 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 formals 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, 1977
This Swiss Commission on Food, also issues an information sheet to all paediatricians based on a review report[5]. The 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 Jam 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.

MALAYSIA

Section 9: Labelling

Paragraph 9.1 The Name of the Food

i) Malaysia proposes that paragraphs 9.1.3 - 9.1.5 from Section A to be reinserted into the current draft as follows:

9.1.2 The sources of protein in the product shall be clearly shown on the label

9.1.3 If cow's milk is the only source of protein, the product may be labelled "Infant Formula Based on Cow's Milk"

9.1.4 A product which contains neither milk or any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase

ii) Malaysia proposes that the sentence in the paragraph 9.1.6 (1st option) from Section A to be reinserted into the current draft. Malaysia proposes to remove the square brackets and adopt the text contained therein. This paragraph is to read:

9.1.5 Products containing not less than 0.5 mg Iron (Fe)/100 kilocalories shall be labelled "Infant Formula with added Iron"

Rationale:
- These paragraphs which are in Section A should also be in Section B as they serve useful information for both medical professional and the end uses.
- This proposal is also to ensure consistency for both products for Infant Formula and Formulas for Special Medical Purposes Intended for Infant.

Paragraph 9.6 Additional Labelling Requirements

Malaysia proposes that the sentence in the paragraph 9.6.6 from Section A be inserted into the current draft under Paragraph 9.6 Additional Labelling Requirements to read as follows:

9.6.6 biz "Nutrition and health claims shall not be permitted except where specifically provided for in national legislation."

Rationale:
- This proposal is in line with *Codex Guidelines for Use of Nutrition and Health Claims.*
- This proposal is also to ensure consistency for both products for Infant Formula and Formulas for Special Medical Purposes Intended for Infant.

MEXICO

1. Scope

We propose deleting the square brackets in this paragraph.
- We suggest deleting the word "disorder(s)" in the fourth line of 3.1.3, which we consider redundant as disease(s) and medical condition(s) are already mentioned.
- We suggest deleting the square brackets around 3.2.3 .
- We suggest deleting the square brackets around 9.6.4 and 9.6.5.

TURKEY

PROPOSED MODIFICATION OF ALINORM 05/28/26, Appendix IV(B)	JUSTIFICATION
1. SCOPE	
1.1 This section of the standard applies to Formula for Special Medical Purposes Intended for Infants in liquid or powdered form intended for enteral use [or parenteral use], where necessary, as a substitute [either total or partially] for human milk ~~[or infant formula]~~ in meeting the special nutritional requirements arising from the disorder, disease or medical condition for whose dietary management the product has been formulated.	Delete [ ] Rationale: In some cases neither breast milk nor infant formula is suitable for feeding the infant.
2. DESCRIPTION	
2.1 PRODUCT DEFINITION	
2.1.1 Formula for Special Medical Purposes Intended for Infants ~~means a breast-milk substitute that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and~~ **is a category of foods which are specially processed or formulated and presented for the dietary management of patients and used under medical supervision. It is intended for the exclusive feeding or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements. It** is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.	Delete part of the current text and insert new wording. Rationale: For sake of consistancy include Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) in the description. The last sentence of the definition of FSMPs has been modified in order to emphasize that FSMPs need to fulffil the special nutritional requirements of all infants patients, i.e. both whether they receive FSMP's as part of exclusive or partial feeding. There are many diverse types of formula/foods for special medical purpose for infants. In particular, there are basically two categories: 3. Formulas modified in some essential characteristics, but which can be used as the sole source of nutrition (e.g., formulas for preterm infants, extensively hydrolyzed or amino acid formulas for certain disorders). 4. Formulas for inborn errors of metabolism that cannot be used as the sole source of nutrition. (e.g., product that must omit an essential amino acid such as phenylalanine for use with infants with phenylkentonuria (PKU)). We strongly recommend that Section B of this Standard applies only to category 1 "Formulas modified in some essential characteristics, but which can be used as the sole source of nutrition".
2.1.2 ~~see Section A 2.1.3~~	Delete: (Section A doesn't include 2. 1.3)
3. ESSENTIAL COMPOSITION AND QUALITY FACTORS	

3.1 ESSENTIAL COMPOSITION	
3.1.1 Formula for Special Medical Purposes Intended for Infants is a product based on ingredients of animal and/or plant origin and/or on synthetic compounds suitable for human consumption. All ingredients and food additives ~~shall be gluten-free~~. should be gluten-free in products intended for gluten sensitive enteropati patients.	Delete [ ]. Shall be gluten free and instead continue as indicated.
3.1.2	Does this apply to the high density energy products.
4. FOOD ADDITIVES	
see Section A 4. The following additional food additives are permitted in the preparation of Formula for Special Medical Purposes Intended for Infants (**to be filled in**).	Detailed comments on this section can be found at the end of this document.
9. LABELLING	
9.6 ADDITIONAL LABELLING REQUIREMENTS	
~~[~~9.6.4 Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended.	Delete [ ].
9.6.5 The product shall be labelled in such a way as to avoid any confusion between formula for special medical purposes intended for infants, infant formula and follow-up formula~~]~~.	Delete [ ].

Table 1 provides the justification for the use of certain additives, which should be allowed in Foods for Special Medical Purposes intended for infants, **in addition** to those foreseen in infant formula as described in Table 2.

Table 1: ***Additives in FSMPs for infants***

INS no.			**Maximum level in 1 kg or 1 L of the product**	Technological Justification
Thickening agents				
401	Sodium alginate		1g/L	Used in some liquid formula containing fibre. When used in combination with additive 412, 401, 410, 415, the hydrocolloids in the mix prevent the separation of fibre in the liquid feed. It is important during the sterilisation process that the room temperature viscosity of the product is reduced otherwise the sterilisation effect will be impaired. At the same time, the same viscosity and gelling effect must be thermoreversible in order to hold the fibres together during feeding. Single hydrocolloids do not have the necessary effect and there are no other protein free additives available for this type of application.
405	Propane 1,2-diolalginate		200 mg/L	Retains its functionality over a wide pH range and is synergistic with other emulsifiers. This property has been beneficial in the development of acidic formulations which contain fat. Thus the development of citric flavoured products is made possible; citric flavours are especially good at masking the bitter unpleasant taste of amino-acids.
410	Carob bean gum (Locust bean gum)		10 g/L	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.
412	Guar gum		10 g/L	Minimises and delays physical separation of the product, fat separation and fat globule coalescence. Guar gum is an excellent water binder, it does not form gel, which is an advantage in liquid products, it is cold water soluble and will not modify the thickening effect obtained by carrageenan.
415	Xanthan gum		1.2 g/L	Thickening for semi solid preparation. Optimum viscosity is achieved when used in conjunction with other thickening agents.

440	Pectins		10 g/L	Used a gelling agent in place of gelatine. Particularly efficient in presence of fruits and in acidic preparations. Thickening for semi solid preparation. Optimum viscosity is achieved when used in conjunction with other thickening agents.
466	Sodium carboxymethyl cellulose		10 g/L or kg	Better thickening, gel formation, solvation and a less "sandy" product is obtained with additive 466 compared to pectine. It disperses easily in water forming colloidal solutions; it can therefore be used as a suspending agent, an emulsifying agent and in the preparation of gels. Furthermore, it improves dispersion of other agents. Its technological functions are hardly influenced by temperature and metal salts have little effect on its viscosity.
1450	Starch sodium octenyl succinate		20 g/L	Viscosity and stability properties that native starch tend to lose when processed
Emulsifier				
471	Mono- and diglycerides of fatty acids		5 g/L	Natural stabiliser that retains homogeneity of liquid products and liquid reconstituted powder. Because it has an intermediate hydrophilic/lipophilic balance (HLB) value, it is suitable for emulsifying products containing fats which require intermediate HLB emulsifiers. It is a robust substance in that it can withstand harsh processing conditions, such as spray drying and UHT processing. This property has been beneficial for the development of ready-to-feed UHT liquid products providing complete nutrition. It is also used extensively for emulsifying fat and carbohydrate components. Its resistance to ionic interactions make sit suitable for use in products containing mineral and trace element ions such as nutritionally complete products.
472c	Citric and fatty acid esters of glycerol		7500 mg/kg for formulae sold as powder 9000 mg/L for formulae sold as liquid	Has an HLB value of10-12, is one of the most effective emulsifiers of oil in water emulsions. Produces a stable, milky white emulsion, giving the final product (usually products with no whole protein) superior stability, taste and organoleptic properties. Positive opinion on such usage has been expressed by the European Scientific Committee for Food in June 1997 and September 2002)

472e	Diacetyltartaric and fatty acid of esters of glycerol		0.4 g/L	Retains homogeneity of liquid products and liquid reconstituted powder especially in formulas where whole proteins are not used. Has a high HLB. It is a robust, non-ionic substance that can withstand harsh processing such as spray drying and UHT. Its resistance to ionic interactions makes it suitable for use in products containing mineral and trace element ions such as nutritionally complete products It provides a rigorous emulsification system with additives 322 and 471. Has a GRAS status in the US
Sweeteners				
950	Acesulfame potassium		450 mg/kg for infants over one year of age	In order to improve dietary compliance, mask the unpleasant taste of certain FSMPs mixtures in cases where additional sweetness from sugar is not appropriate because of: *Osmolality*: the addition of sugar increases the osmolality of the product which is not desirable in products for patients known to be at risk of diarrhoea. *Volume*: Sugar or other natural sweetening ingredients will greatly increase the bulk of a product and thus require much increased volumes of a product to be consumed to meet the dietary requirements. This may reduce patient compliance. *Effect*: Natural sweeteners e.g. sugar, dried glucose syrup, maltodextrin on their own cannot mask the unpleasant and bitter taste of many synthetic ingredients such as amino acids. *Contraindications*: the inclusion of high levels of sugars in products for young children is discouraged to avoid dental caries and may be contraindicated for some special diets e.g. energy-restricted. Natural sweetening agents (e.g. sugar, glucose syrups) are used wherever possible, sweeteners are used only when absolutely necessary.
951	Aspartame		1000 mg/kg for infants over one year of age	
954	Saccharin		200 mg/kg for infants over one year of age	
955	Sucralose		400 mg/kg for infants over one year of age	
967	Xylitol		20000 mg/kg for infants over one year of age	

Colours				
140	Chlorophylls		20 mg/kg for infants over one year of age	The mixture of amino acids, vitamin, mineral complex, unusual fats

160aii	Carotene, vegetable		30 mg/kg for infants over one year of age		or fatty acids etc. gives a non-attractive colour to the FSMP product. The link between visual appearance and taste is well known: if a product looks better the patient perceives that the product tastes better. Non compliance with the dietary regimen provided by these specialised foods may result in malnutrition, illness or rapid degeneration of the patient. Adding colours to these mixtures help dietary compliance. Positive opinion on such usage has been expressed by the European Scientific Committee for food in December 1996

Table 2: ***Additives foreseen for infant formula (ALINORM 03/26 A, Appendix II)***

	INS no.			**Maximum level in 100 mL of the ready-to-drink product**	**Technological justification**
4.1	**Thickening Agents**				
4.1.1	412	Guar gum		0.1 g in all types of infant formula	Protects from physical separation
4.1.2	410	Carob bean gum (Locust bean gum)		0.1 g in all types of infant formula	Protects from physical separation Used in some anti-regurgitating formulas
4.1.3	1412	Distarch phosphate	}	0.5 g singly or in combination in soy-based infant formula only 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based infant formula only	Viscosity and stability properties that native starch tend to lose when processed
4.1.4	1414	Acetylated distarch phosphate	}		
4.1.5	1413	Phosphated distarch phosphate	}		
4.1.6	1440	Hydroxypropyl starch	}		
4.1.7	407	Carrageenan	}	0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolyzed protein and/or amino acid-based liquid infant formula only	Thickening agent also used as an emulsifier; higher emulsifying power than lecithin and more hydrophilic capacities than mono- and diglycerides of fatty acids
4.2	**Emulsifiers**				
4.2.1	322	Lecithin		0.5 g in all types of infant formula *	Natural stabiliser, retains homogeneity
4.2.2	471	Mono- and diglycerides		0.4 g in all types of infant formula *	Natural stabiliser, retains homogeneity of liquid products and liquid reconstituted powder

4.2.3	*472c*	*Citric and fatty acid esters of glycerol*		*0.75 g in powder formula ** *0.9 g in liquid formula containing partially hydrolyzed protein, peptides or amino acids **	Higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids, especially in formulas not containing whole protein
	472e	Diacetyltartaric and fatty acid of esters of glycerol		***REQUESTED at GMP***	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
4.2.4	*473*	*Sucrose esters of fatty acids*		*12 mg in formula containing hydrolyzed protein, peptides or amino acids **	Higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids, especially in formulas not containing whole protein
				** If more than one of the substances INS nos. 322, 471, 472c and 473 are added, the maximum level for each of those substances is lowered with the relative part as present of the other substances*	
4.3	**pH-Adjusting Agents**				
4.3.1	524	Sodium hydroxide	}	Limited by GMP and within the limits for sodium and potassium in section 3.1.2(c) in all types of infant formula	Buffering capacity Improves in-processing handling and stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying. Selected depending on the pH and the composition of the formula, also used as buffering agent.
4.3.2	500 ii	Sodium hydrogen carbonate	}		
4.3.3	500 i	Sodium carbonate	}		
4.3.4	525	Potassium hydroxide	}		
4.3.5	501 ii	Potassium hydrogen carbonate	}		
4.3.6	501 i	Potassium carbonate	}		
4.3.7	526	Calcium hydroxide	}		
4.3.8	331 i, iii	Sodium citrate(s)	}		
4.3.9	332 i, ii	Potassium citrate(s)	}		
4.3.10	270	L(+) Lactic acid	}	Limited by GMP in all types of infant formula	Natural acid found fermented milk products
4.3.11	330	Citric acid	}		Buffering and chelating capacity. Stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying.
4.3.12	*338*	*Phosphoric acid (Ortho-)*	*}*	*Limited by GMP and within the limits for sodium and potassium in Section 3.1.2(c) in all types of infant formula*	
4.3.13	*339 i, ii, iii*	*Sodium orthophosphates*	*}*		

4.3.14	*340 i, ii, iii*	*Potassium orthophosphates*	*}*		Selected depending on the pH and the composition of the formula
4.4	**Antioxidants**				
4.4.1	*306*	*Mixed tocopherols concentrate*	*}*	*1 mg in all types of infant formula singly or in combination*	Protects from oxidation Synergistic effect with ascorbyl esters
4.4.2	*307*	*Alpha-Tocopherol*	*}*		
	308	Gamma-tocopherol		***REQUESTED** at 1 mg in all types of infant formula singly or in combination*	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.
	309	Delta-tocopherol			
4.4.2	*304*	*L-Ascorbyl palmitate*	*}*	*1 mg in all types of infant formula*	Protects from oxidation Synergistic effect with tocopherols.
4.5	**Packaging Gas (Propellants)**				
4.5.1	*290*	*Carbon dioxide*		*GMP*	Neutral gas used under modified packaging atmosphere in order to guarantee the quality of the product and to ensure shelf life; prevention of oxidation and rancidity.
4.5.2	*941*	*Nitrogen*		*GMP*	
4.5.3	*942*	*Nitrous oxide*		*GMP*	
4.5.4	*938*	*Argon*		*GMP*	
4.5.5	*939*	*Helium*		*GMP*	
4.5.6	*948*	*Oxygen*		*GMP*	
4.5.7	*949*	*Hydrogen*		*GMP*	

UNITED STATES OF AMERICA

I. General Comments

The United States supports the concept of Section B for formulas for special medical purposes intended for infants. It is our understanding that Section B of this standard applies only to products that can be used as the sole source of nutrition for infants.

Our comments on Section B address provisions from Section A that do not have text in square brackets. For provisions in Section A that have text in square brackets, we recommend deferring any discussions on those provisions in Section B until the brackets are removed from Section A. We have not made comments on Section 4, Food Additives, and will await a proposal for this section from the Delegation of Switzerland.

As provisions are moved from Section A to Section B, we recommend that they be placed in square brackets in Section B while they are being evaluated for inclusion in Section B.

We anticipate that further comments may be forthcoming as discussions progress.

II. Comments on Specific Sections

The United States offers the following comments and recommendations for revisions.

1. SCOPE

1.1 This section of the standard applies to Formula for Special Medical Purposes Intended for Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk [or infant formula] in meeting the special nutritional requirements arising from the disorder, disease or medical condition for whose dietary management the product has been formulated.

Comment: We suggest that the square brackets be removed in section 1.1.

Rationale: This wording clarifies that the category of products covered in Section B, formulas for special medical purposes intended for infants, is intended for use, where necessary, as a substitute for breast milk or infant formula.

1.3 A.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.

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 formula for special medical purposes intended for infants ~~infant formula~~. No product other than formula for special medical purposes intended for infants ~~infant formula~~ may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of ~~normal healthy~~ infants with special nutritional requirements resulting from disorders, diseases or other medical conditions during the first months of life.

Comment: This section should refer specifically to formula for special medical purposes intended for infants and to infants with special nutritional requirements. We suggest replacing language about infant formula and normal healthy infants with language shown above.

Rationale: This language clarifies that these are products specifically for special medical purposes intended for infants with nutritional requirements that differ from the nutritional requirements of normal healthy infants.

2. DESCRIPTION

2.1 Product definition

2.1.1 Formula for Special Medical Purposes Intended for Infants means a ~~breast milk~~ substitute for breast milk or infant formula that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.

Comment: Addition of "or infant formula" to 2.1.1 is consistent with the change recommended for 1.1.

2.1.2 see Section A 2.1.3

Comment: We request clarification as to whether the intent is to refer to Section 2.1.2 or 2.1.3. There is currently no Section 2.1.3 in Section A.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

Comment: We propose that the content of the table of essential composition in Section A be established before evaluating what type(s) of table(s) might be appropriate for Section B.
Rationale: There are unique aspects to formulas for special medical purposes for infants included in Section B that require careful consideration.

3.1 Essential Composition

3.1.1 Formula for Special Medical Purposes Intended for Infants is a product category based on ingredients of animal, ~~and/or~~ plant and/or synthetic origin ~~or on synthetic compounds~~ suitable for human consumption. All ingredients and food additives shall be gluten-free.
Editorial Comment: We suggest addition of the word "category" and the rearrangement in wording for clarity.

3.1.3 The energy content and nutrient composition of Formula for Special Medical Purposes Intended for Infants shall be based on the requirements for infant formula as given in Sections A 3.1.2 and A 3.1.3, except for the compositional provisions which must be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specially formulated, labelled and presented.
Comment: We agree with the concept and wording in Section 3.1.3. Resolution and clarity on the table of essential composition in Section A should be established before referencing it in section B.
Rationale: There are many formulas for special medical purposes for infants. These products differ substantially from routine infant formulas and from each other. Therefore, referring to Section A must be done very carefully.

3.2 Optional Ingredients

3.2.3 [Only L(+) producing lactic acid cultures may be used in formulas for special medical purposes for infants if shown to be safe and appropriate for use in these vulnerable populations].
Comment: We suggest removing the square brackets on 3.2.3.
Rationale: All ingredients in formulas for special medical purposes intended for infants should be shown to be safe and appropriate for use in vulnerable populations.
Editorial Comment: We suggest removing the word "only" for clarity.

3.6 Specific Prohibition

see Section A 3.6
Comment: Section 3.6 in Section A contains square brackets. We recommend deferring any discussions on Section 3.6 in Section B until the brackets are removed from Section A.

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 following specific provisions apply:

9.1 he Name of the Food

9.1.1 The name of the product shall be "Formula for Special Medical Purposes Intended for Infants" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

A9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).
Comment: Section 9.1.1 from Section A shown above is applicable to Section B. We recommend its addition as 9.1.2 in Section B.

9.1.3 Labels for Formula for Special Medical Purposes Intended for Infants in which the essential characteristics involves a specific modification of the content or nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the protein, amino acid, fatty acid or carbohydrate profile, when necessary.
Comment: This wording for Section 9.1.3 was proposed in the draft standard for Section B for the 2004 CCNFSDU meeting. It is not in the draft in ALINORM 05/28/26. We suggest that it be considered for incorporation into Section B and suggest the added wording for clarity.
Rationale: This information is critical for correct use of these types of products and needs to be stated on the label.

A9.1.4 If cow's milk is the only source of protein, the product may be labelled "Infant Formula Based on Cow's Milk".

A9.1.5 A product which contains neither milk or any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

Comment: These provisions from Section A are not in square brackets and are applicable to Section B. We propose their addition.

9.5 Information for Use

Comment: The previous draft included section 9.5, Information for Use. Why was Section 9.5 omitted from this draft?

9.6 Additional Labelling Requirements

[9.6.4 Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended.

9.6.5 The product shall be labelled in such a way as to avoid any confusion between formula for special medical purposes intended for infants, infant formula and follow-up formula.]

Comment: We suggest removal of square brackets on 9.6.4 and 9.6.5.

VENEZUELA

PROPOSED CHANGES TO ALINORM 05/28/26 **Appendix IV (B)**	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 B: FORMULAS FOR SPECIAL DIETARY PURPOSES INTENDED FOR INFANTS **This comment applies to the whole text of the document**. [An alternative would be to substitute "DIETARY USES" for "Medical purposes".]	Substitute the preposition "**de**" for "**para**". (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. [] This wording implies the compliance with certain principles, which are necessary in order to provide a sufficient, complete, balanced and adequate nutrition.
1. **SCOPE**	
1.1 This section of the standard applies to Formula for Special ~~Medical~~ Purposes Intended for Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk [or infant formula] in meeting the special nutritional requirements arising from the disorder, ~~disease~~ or medical condition for whose dietary management the product has been formulated. It would read: This section of the standard applies to Formula for Special **Dietary** Purposes Intended for **Healthy** Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk or infant formula in	Substitute one of the following options for "Medical Purposes": ...Special **Dietary** Purposes..., Special **Dietary Uses,** or Special **Dietary Regimes**... Specify "**healthy** infants" Delete [] Add...**physiological** disorder**...** Delete the word **"disease"**. Substitute **"**dietary **use**" **for** "dietary **management**". Insert "...**se** haya". (Applies to Spanish version only. Translator's note)

meeting the special nutritional requirements arising from the **physiological** disorder or medical condition for whose dietary management the product has been formulated. **This comment applies to the whole text of the document.**	
2. DESCRIPCIÓN	
2.1 Formula for Special Medical Purposes Intended for Infants means a breast-milk substitute that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.	Insert the word "**six**" between "**first**" and "**months**" … Add ", **at its due time,**" after "introduction". Complement the word "appropriate" using one of the following options: ..."complementary feeding appropriate **for their age"** **... "**appropriate complementary feeding **in order to progressively change over to a healthy diet"** **or** delete the word **"appropriate"** and replace it with "**... in order to ensure an adequate nutrition".**
2.1.2 The reference is wrong, because there is no Section A 2.1.3.	
3. ESSENTIAL COMPOSITION AND QUALITY FACTORS.	
3.1 Essential Composition	
3.1.1 Formula for Special Medical Purposes Intended for Infants is a product based on ingredients of animal and/or plant origin or on synthetic compounds suitable for human consumption. All ingredients and food additives shall be gluten-free.	Add "**and**/or on synthetic compounds …" after "plant origin". Substitute ... (Applies to Spanish version only. Translator's note)
3.2 Optional Ingredients	
3.2.3 ~~[~~Only L(+) producing lactic acid cultures may be used in formulas for special medical purposes for infants~~ if shown to be safe and appropriate for use in these vulnerable populations.]~~	Delete [] as well as the last part of this section. Explanation: This is already covered by section 3.2.2.

ENCA - European Network of Childbirth Associations

1. Scope

1.1 Delete the brackets and the text in square brackets. This text is superfluous as infant formula is a substitute of human milk.

Delete the word disorder.

Rationale: It is unclear and vague and may open the door to products that are not medically indicated but are only created to exploit parents concerns about infant behaviors like spitting, crying or sleeping disorders.

Add the following the sentence at the end: the product has to be used under medical supervision

1.3 Because the numbering in Section A has changed after the last meeting (see our comments to section A) (1.2 was split into 1.2 and 1.3 in the version circulated actually in Alinorm 05/28/26) the former paragraph 1.3 on the International Code went to 1.4 in section A. This means that in section B the reference needs to get changed accordingly to 1.4 to correctly reflect the renumbering in section A, if the old numbering has not been reinstaured yet.

It is of critical importance that infants with special medical needs are not needlessly formula fed. Thus the necessity for compliance with the International Code is even more important to protect this specific population.
See our comments in 1.4 to section A for rewording

2. Description
2.1 Product Definition
2.1.1 Delete the word disorder (see 1.1) and add this sentence at the end. The product shall only been used when medically indicated under medical supervision of the infant".
2.1.2 A reference is given here to 2.1.3 in section A, as this section doesn't exist we guess that the reference has to be to 2.1.2

3. Essential Composition and Quality Factors
3.1 Essential Composition
3.1.1 ENCA's comment to section A are to be applied here. Reword the first sentence to read:
"Formula for Special Medical Purposes Intended for Infants is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, and/or only when necessary on synthetic compounds, suitable for infant feeding."
Synthetic compounds should only be used when naturally occurring compounds are contraindicated for the disease or the medical condition of the infant.
NOTE: The use of soy as a major ingredient should be reviewed. See our comments to section A
3.1.2 Add after scientific evidence"free from conflict of interest"
3.1.3 Delete the word "disorder" following our rationale developed in 1.1
3.2 Optional Ingredients
See our comments submitted for section A.
3.2.1 Delete the word "disorder" following our rationale developed in 1.1
Add the following sentence already proposed by ENCA for section A:
Optional ingredients are mentioned in the ingredients list and give no right to make claims or use them in a promotional way.
3.2.2 Add the following after: scientifically demonstrated by research free from commercial interest.
3.2.3 ENCA wants to underline that case reports exist where lactobacillus bacteremia occurred in vulnerable infants.
Two cases of lactobacillus bacteremia during probiotic treatment of short gut syndrome Kunz A.N, Noel J.M et al J Pediatr Gastroenterol Nutr, Vol 38, No 4, 2004
3.4 See our comments in section A
3.5 Purity Requirements
Add after clean. free from chemical and microbiological contamination,
3.6 Specific Prohibition
See ENCA's comments to section A

4. FOOD ADDITIVES
Food additives should have only a very reduced use here when they are absolutely necessary for the product and where this cannot be achieved by other means These non-nutritive chemicals expose infants to needless risks and may be even more harmful to infants who have special medical conditions.

5. CONTAMINANTS
5.1 our comments to section A are to be applied here: 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.
This is in accordance with the European legislation.
5.2 Same comments as for section A.

6. HYGIENE

COMMENTS AS PROVIDED FOR SECTION A

6.1 Replace "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 poisonous or deleterious substances

6.3 Add a new paragraph to reflect the outcome of the Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganism in powdered infant formula, see our comments to section A

9. LABELLING

9.1 The Name of the Food

See our comments to section A

Para 9.1.1 of section A should be included or referenced here.

The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.5. Information for use

This chapter is still missing in section B. A reference to section A could be introduced between section 9.4 and 9.6 in section B

See our comments to section A

9.6 Additional Labelling Requirements

We would favour a text presentation of section 9.6. similar to section A with the specific labelling requirements for formulas for special medical purposes to be added at the end.

If there is no agreement on this proposal we want at least to have 9.6.1.c, 9.6.2 and 9.6.3 and 9.6.4 and 9.6.6 of section A repeated here.

Reinsert text 9.6.1.c of section A here:

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.

Reinsert text 9.6.2 of section A here:

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

Reinsert text 9.6.3 of section A here:

The terms "humanized", "maternalized" or similar terms shall not be used

Reinsert text 9.6.4 of section A reworded in accordance to our comments in section A, here:

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.

Reinsert text 9.6.6of section A, where the square brackets have been deleted and the text retained to read:

No nutrition and health claims shall be made regarding the dietary properties of the product.

This product for special medical purposes should not bear health claims, this would be misleading or bear the danger that the product is used by infants who don't have the disease or medical condition for whose dietary management the product has been formulated. 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.

9.6.2 This may unnecessarily restrict the use of the product as for some disease the feeding of the product will continue together with adequate complementary food adapted to the disease or medical condition.

9.6.4 Delete square brackets and keep the text

Add to 9.6.4"completely" before contraindicated as for some metabolic disease (for example some forms of PKU) partial breastfeeding is possible and should be recommended and supported.

9.6.5 Delete square brackets and keep the text

IACFO - International Association of Consumer Food Organisations

IACFO supports all the comments by IBFAN on this standard

IBFAN - International Baby Food Action Network

1.Scope
1.1 REWORD to read:
This section of the standard applies to Formulas for Special Medical Purposes Intended for Infants, in liquid or powdered form, intended, where necessary, and only when human milk is unavailable or cannot be utilized, ***in meeting the nutritional requirements of infants when medically indicated and to be used only under continuing medical care.***
Rationale:
The terms ***disorder, disease or medical condition*** are vague and undefined. The term ***when medically indicated*** is simpler and helps to protect against needless use of these products. Special needs infants have the most to gain from breastmilk and this must be protected wherever this is feasible.
The term ***when medically indicated*** is also in conformity with the WHO/UNICEF Baby-Friendly Hospital Initiative.
1.2 REWORD to read:
This section ***of the standard*** *contains compositional, quality, labelling and safety requirements for Formulas for Special Medical Purposes Intended for Infants.*
1.3 DELETE **normal healthy** 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.
1.4 ADD as in SECTION A and CHANGE 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: It is of critical importance that infants with special medical needs are not needlessly formula fed. The necessity for compliance with the International Code and relevant resolutions of the WHA is even more important for this high needs population than for full term healthy infants.

2. DESCRIPTION
2.1 Product Definition
2.1.1 REWORD to read: *Formula for Special Medical Purposes Intended for Infants means a breastmilk substitute that complies with section 2, Description, of the Codex Standard for the Labelling of and Claims for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the* ~~***special***~~ *nutritional requirements of infants* ***when medically indicated*** ~~***with specific disorders, diseases or medical conditions***~~ *during the first* ***six*** *months of life up to the introduction of complementary feeding.*
2.1.2 See 2.1.2 of Section A and change 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.*
Rationale:
The safety and hygienic properties of formulas for infants with special medical needs are vital, especially since high needs infants who are formula fed infants are immunologically compromised.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS
3.1 Essential Composition
3.1.1 DELETE the phrase **synthetic compounds suitable for human consumption** and ADD **through independently funded and systematically reviewed research to be suitable for infant feeding** to read:
Formula for Special Medical Purposes Intended for Infants 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. All ingredients and food additives used shall be gluten-free*

Rationale: Synthetic compounds increases the risk for allergies, inflammatory disease or autoimmune responses. Infants medically and/or immunologically compromised will be more vulnerable to these potential side effects.
The wording in the previous draft noting all possible ingredient sources should be retained. This is more informative for consumers. To omit this information could be deceptive for consumers.
The use of soy as a core ingredient should be reviewed. SEE APPENDIX A.

3.1.2 REWORD to read:
The formulation of Formula for Special Medical Purposes Intended for Infants should be based on sound medical and nutritional principles. Their use should have been demonstrated ***by independently-funded and systematically-reviewed scientific research,*** *to be safe and beneficial in meeting the nutritional needs of infants for whom they are intended.*
3.1.3 DELETE the phrase **deriving from disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specially formulated, labelled and presented.**
REWORD to read:
The energy content and nutrient composition of Formula for Special Medical Purposes Intended for Infants shall be based on the requirements for infant formula as given in Sections A 3.1.2 and A 3.1.3 except for the compositional provisions which must be modified to meet special nutritional requirements ***when medically indicated.***
3.2 Optional Ingredients
3.2.1 CHANGE text to read: *In addition to the compositional requirements listed under 3.1.3, ingredients may be added* ***only if demonstrated by independently-funded and verifiable research to be safe and essential for infant health and when medically indicated. ~~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: Additional/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, essential and efficatious 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 standard should be revised at the earliest opportunity to list all ingredients added.
Section A seems to permit the presence of numerous optional ingredients. This calls into question the need for a separate SECTION B of the standard. If any and all ingredients are to be allowed any modifications required for medically indicated uses could be made within the range of ingredients permitted.
All infants who are artificially fed should be assured the safest and most nutritious substitute possible. Optional ingredients also increase the likelihood of manufacturers using claims to promote different types of formulae in competition with breastmilk.
3.2.2 REWORD the text to read:
The suitability ***of ingredients that may be added*** *for the particular nutritional use of* ***infants as medically indicated, must be demonstrated through independently-funded and systematically reviewed research to be bio-available, safe, to have no unintended side effects and to have the ability to achieve the intended effect, taking into account the levels present in human milk as appropriate.***
3.5 Purity Requirements
SEE IBFAN COMMENTS ON 3.5 SECTION A.
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 to READ:
Food additives for infants with special medical needs should be kept to a minimum.
Rationale: Thickening agents, emulsifiers and antioxidants are not needed in infant formulas. These non-nutritive chemicals expose infants to further needless risks in addition to the large number of foreign substances known to be present in infant formulas. As well formula fed infants are in an immunologically deprived status and less able to handle unnecessary foreign chemicals. Additional additives - often added

for cosmetic purposes - may be even more harmful to infants who have special medical needs than to healthy infants. Cosmetic ingredients are frequently used to please the parents rather than providing for the infant's needs.
No ingredient should be added unless it has been demonstrated to be safe, by means of independently funded scientific research.

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 the European legislation.

5.2 Other Contaminants

DELETE the 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 for medical purposes 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 needs to 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….*
6.3 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
The 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 understandable warning of possible contamination, stressing preparation instructions to minimize the risk of harm related to the lack of sterility.
Labels must highlight the need to prepare correctly just before feeding; 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 multiplication of microbial contaminants present in the product (cf. Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganism in powdered infant formula).
The report of the 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

9.2 The Name of the Food
9.2.1 INSERT the following text:
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 sold.***
9.2.2 Add the sentence:
The name of the product 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 **Hypo-allergenic** (indicating possible reduction of allergy risk**), AR, Staydown**, (indicating anti-reflux properties), **Organic, Prebiotic, Probiotic** or **Humana**. All these descriptive terms indicate claims that promote the product as having certain properties. These should be considered health and nutritional function claims and therefore should not be permitted. Particular

properties of products are more safely conveyed through clear nutrition labelling, or independent certification stamps, alongside clear instructions that 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. (See Appendix B: Allergenicity Claims)

9.1.3 INSERT the following text:

Formulas for Special Medical Purposes Intended for Infants shall indicate the nature of the protein, fat, carbohydrate and other ingredients for the purpose of compositional modification, including food 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.

9.5 Information for use.

This section must have been inadvertently omitted and should be reinserted.

Insert the text to be the same as Section A with the following change:

9.5.1 Remove the text in brackets ***or in the accompanying leaflet*** and the ADD the following paragraphs *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.

This information is of vital importance to parents of infants with medical needs.

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 Delete and REPLACE with the following text:

Labels (except where specifically medically indicated such as for PKU, where the need for breastmilk is carefully monitored, or Galactosemia, where breastfeeding is contraindicated) shall not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

- ***a) the words "important notice" or their equivalent;***
- ***b) the statement "Breastfeeding provides the best food for your baby" or a similar statement as to the superiority of breastfeeding and breastmilk;***
- ***c) a prominent statement that the products should only be used on the advice of a health worker, independent of commercial interest, as to the need for its use and the proper method of use, such as, "Use only when medically indicated and only under medical supervision";***
- ***d) instructions for appropriate preparation;***
  a warning about the health hazards of inappropriate use
  a warning that powdered infant formulas may be contaminated with harmful microorganisms during manufacturing, or they 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.
- ***e) product labels must clearly distinguish the product as suitable for infants with medical needs where breastmilk needs to be limited or is contraindicated.***

f) ***A statement that the product must be ONLY be used when medically indicated and under continuing medical supervision for the feeding of infants with… who cannot be breastfed.***

Rationale: The statement should not make a health or disease risk reduction claim. The product simply needs to say what it contains, its purpose and how it can be used safely. Since these products are to be administered only under medical supervision there is no need to provide a rationale for their use.

9.6.2 INSERT the following text to READ:

The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula. The terms "humanized", "maternalized" or similar terms shall not be used;

9.6.3 DELETE the references to *4.5.3 and 4.5.5 of the Codex Standard 180-1991 and retain 4.5.2 to read:*

A complete statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable.

9.6.4 RE-INSERT the following text with changes as in Section A 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****.*

9.6.5 Retain as is

9.6.6 RE-INSERT the following text:

The label shall have no nutrition, health or comparative claims, nor any symbols, pictures of infants and women or other pictures or text, which idealizes artificial feeding or implies a health advantage. The term "humanized", "maternalized", or other similar terms shall not be used.

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 nutrition labelling. The products must not carry any symbols or logos which imply special health advantages.

Rationale: ***Given the nature of breastmilk substitutes there is a potential for any claim to suggest superiority over breastfeeding. (Product promotions and labels are using graphics on foods – for example a brain or a battery – to symbolize intelligence, energy etc.)***

The market for specialized infant formulae has expanded in recent years, fueled by unsubstantiated health claims and various promotional devices. The claims are invariably supported by industry-funded research and exploit parental concerns by suggesting that certain infant behaviours or normal feeding occurrences which are classified as* "ill health" *or* 'symptoms of illness' *(regurgitation, colic, sleep disorders, intolerance, etc) can be addressed by these products [1]. Specialized formulae are often presented as the first option for care in these cases. There is evidence from the USA, where restrictions on marketing are minimal, that 40% of mothers switch to specialized formulas even though published evidence indicates that only 2-7% should need them. This increases the proportion of babies fed soy formula (in the USA 26% of babies are fed on soy formulas) and encourage parents to believe that their babies are allergic or otherwise abnormal[2].

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 baby formula that it sent to Israel with 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.

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1 SMA High Energy is a food for special medical purposes not suitable for normal healthy babies. A promotion for this infant formula to health visitors in Wales, contained 20 health claims, no breastfeeding is best notice and an offer of winning £39 worth of play equipment. April 2004.

2 Polack FP et al. *Changing partners : the dance of infant formula changes*. Clinical Pediatrics, Vol 38, no 12, December 1999, pp 703-708

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[3].

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[4].*** 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.

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.[5]

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."*

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

4 British Journal of Midwifery, July 2004

5 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,

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

Proposed text	**ISDI comments and justification**
1. Scope 1.1 This section of the standard applies to Formula for Special Medical Purposes Intended for Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk ~~[~~or infant formula~~]~~ in meeting the special nutritional requirements deriving from the disorder, disease or medical condition for whose dietary management the product has been formulated.	Remove [ ] Rational: infant formula as in some cases neither breast milk nor infant formula is suitable for feeding the infant.
1.3 See section ~~A1.3~~ A1.4 i.e. The application of this section of the Standard should take into account, **as far as appropriate for FSMPs for infants**, the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001).	Add "as far as appropriate for FSMPs for infants". Rational: FSMPs for infants are breast-milk substitutes but are not infant formula. FSMP for infants come within the Scope of the Code of Marketing of Breast Milk Substitutes. However several of the provisions within the Code are NOT appropriate. Indeed, FSMPs for infants: i) are not recommended as alternatives to breastfeeding or infant formulae but are used where these means of feeding are no longer appropriate, or even contra-indicated; ii) are (usually) prescribed after the first few weeks of life, not from birth, thus do not influence the choice of the mother iii) are required in response to a clinically / medically identified problem that requires dietary intervention. iv) are not mis-used as their use is always on recommendation of a healthcare worker / medical professional. Therefore the following provisions from the Code are not applicable: - *Art 4: Information & Education* *4.2 Important notice about the superiority of breastfeeding, etc.* In many situations, breast milk or infant formula, is **NOT** the most appropriate food for an infant requiring an FSMP. Such statements would be misleading, confusing and may even be

	distressing. - *Art 6: Health Care System* *6.1 Appropriate measures to encourage and protect breastfeeding should be taken* In some cases, the use of an FSMP for infant is in conjunction with breastfeeding/formula. In others, breastfeeding would be contra-indicated.
2. DESCRIPTION **2.1 Product definition** 2.1.1 Formula for Special Medical Purposes Intended for Infants means **where necessary a substitute for human milk or infant formula** ~~a breast-milk substitute~~ that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.	Add "where necessary a substitute for human milk or infant formula" Rational: the wording is more in line with section 1.1.
2.2 Other Definitions see Section A 2.2 i.e. The term ***infant*** means a person not more than 12 months of age. **The term *Foods for special medical purposes* are a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements.**	Add the definition of Foods for special medical purposes intended for infants Rational the proposed definition is based on the definition of Foods for special medical purposes described in Codex Standard for the labelling of and claims for Foods for Special Medical Purposes (CODEX STAN 180-1991). Since this standard covers complete formula, the last part of the last sentence of the definition of FSMPs should not be included (this part reads: "whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two").
3.1 Essential Composition 3.1.1 Formula for Special Medical Purposes Intended for Infants is a product based on ingredients of animal and/or plant origin **and/**or on synthetic compounds suitable for human consumption. [All ingredients and food additives shall be gluten-free].	English, add "and/" Remove [ ].
3.1.2 The **composition** ~~formulation~~ of Formula for Special Medical Purposes Intended for Infants should be based on sound medical and nutritional principles**,** ~~. Their use should have been~~	Reword "formulation" into "composition Delete part of the second sentence

~~demonstrated by scientific evidence, to~~ be safe and beneficial in meeting the nutritional requirements of infants for whom they are intended.	Rational: it is redundant.
3.1.3 The energy content and nutrient composition of Formula**s** for Special Medical Purposes Intended for Infants shall be based on the requirements for infant formula as given in Sections A 3.1.2 and A 3.1.3, except for the compositional provisions which must be modified to meet the special nutritional requirements deriving from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specially formulated, labelled and presented.	ISDI has provided extensive comments on section A 3.1 and will therefore reserve its comment on section B 3.1.3 until the discussion on Section A 3. 1 is finalised.
3.2 Optional Ingredients 3.2.2 The suitability **and safety of the substance**, for the special medical purpose intended for the particular nutritional use of infants ~~and the safety of these substances~~ shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect. ~~3.2.3~~ ~~[Only L(+) producing lactic acid cultures may be used in formulas for special medical purposes for infants if shown to be safe and appropriate for use in these vulnerable populations].~~	Reword for clarity Delete Rational: it is redundant with section 3.2.2
4. Food Additives see Section A 4. The following additional food additives are permitted in the preparation of Formula for Special Medical Purposes Intended for Infants (**to be filled in**).	ISDI detailed comments on this section have been provided to Switzerland in charge of reviewing this section and can be found in ISDI document reference 03/163.