codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA
Discussion Paper of the Electronic Drafting Group[1] on the Scope and Text of the Proposed Draft Revised Standard for Infant Formula

The Discussion on the question if foods for special medical purposes should remain in the Scope of the existing Standard for Infant Formula (CODEX STAN 72-1981) started with the Proposed Draft Revised Standard for Infant Formula (CX/NFSDU 96/8) presented to the 20th session of CCNFSDU in 1996 and has not been resolved since.

Introduction

The wording of the Scope of the present Standard was formulated before 1976 and is: *This standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants. It also provides a standard for formulae intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements.*

In the further passages of this standard, formulae intended for infants with special nutritional requirements are mentioned only once under the Section Labelling 9.1.5: *A product intended for infants with special nutritional requirements shall be labelled to show clearly the special requirement for which the formula is to be used and the dietary property or properties on which this is based.*

The scope of the Standard for Infant Formula was not revised for more than 20 years, also not when the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) was adopted in 1991, with the following description: *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 or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolise ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, 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.*

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[1] Australia, Brazil, Canada, Denmark, France, Germany (coordination) India, Kenya, Mexico, The Netherlands, Russian Federation, Romania, South Africa, Switzerland, Tanzania, Thailand, Uruguay, EC, CIAA, ENCA, ISDI, IDACE, IBFAN, IACFO and ESPGHAN.

From this description it appears that foods for special medical purposes:

- have to be specially processed and formulated
- are intended for patients only
- are to be used under medical supervision
- are essential for the dietary management of the disorder of the patient and this dietary management is not possible by other means
- can be complete foods which provide all energy and nutrients or can be incomplete foods which have to be complemented by other foodstuffs to provide the energy and all nutrients necessary.

A typical example for a complete food for special medical purposes is an infant formula substitute which contains free amino acids only instead of intact proteins and, in addition, fats, carbohydrates, minerals and vitamins and which can be given to infants with e.g. cow's milk protein allergy. This product can also be used for partial feeding of allergic older infants in addition to tolerated complementary food.

Other indications for formula for special medical purposes for infants are:

- **intestinal diseases** with malabsorption, that can be inborn, such as glucose-galactose malabsorption, congenital lactase deficiency, microvillus inclusion disease, or acquired, such as short bowel disease, secondary mucosal atrophy;
- **certain liver diseases**, such as extra-hepatic biliary atresia, progressive familial cholestasis, neonatal hepatitis, hepatic shock syndrome, and other forms of chronic cholestasis;
- **certain renal diseases**, such as chronic renal failure;
- **disease conditions**, where **high-energy density formula** is required, such as cardiac disease with limited fluid tolerance and high energy needs;
- **defective exocrine function of the pancreas**, such as cystic fibrosis, Shwachman syndrome;
- **inborn errors of amino acid and organic acid metabolism**, such as phenylketonuria, propionic acidemia;
- **inborn defects of lipid metabolism**, such as fatty acid oxidation defects, a-betalipoproteinemia, lipoprotein lipase deficiency, apoprotein CII-deficiency;

and others.

Formula for special medical purposes is not to be given to healthy infants, because it could be detrimental to health and/or because it would not provide a benefit but be more costly.

Because foods for special medical purposes should not be given to healthy persons, the Codex-Standard 180-1991 provides extensive labelling provisions for foods for special medical purposes in order to prevent the inappropriate use of such products in healthy persons on the one hand and to inform the potential consumer of the product over its properties and indications on the other hand.

The 24th session of CCNFSDU, 2002 agreed that two drafts should be provided to the delegates of the 25th session of CCNFSDU: a) a draft proposal for a standard for infant formula which includes formula for special medical purposes for infants, which will hereafter be named Draft Standard A, and b) a draft proposal for a standard for formula for special medical purposes for infants, hereafter, named Draft Standard B.

The members of the working group came to the conclusion that the mandate included only consideration of such products for special medical purposes for infants equivalent to infant formula in providing the sole source of nutrition during the first months of life.

A discussion paper (Draft C) was also to be provided which should state the advantages and disadvantages of Draft Standards A and B. The CCNFSDU will have to decide on the name of products which are foods for special medical purposes intended for infants and can satisfy by themselves the nutritional requirements of the infant patients for whom they are intended. **The name chosen in the drafts is to be regarded as preliminary.**

I. Draft Standard A (attached as Annex I)

Draft A is based both on the Proposed Draft Revised Standard for Infant Formula (ALINORM 03/26A, Appendix II) and the Codex Standard for the Labelling of and Claims for Special Medical Purposes (CODEX-STAN 180-1991). Change of wording in the Draft Standard relating to infant formula was only done, where necessary. For formula for special medical purposes intended for infants the text provided by CODEX STAN 180-1991 was taken over, wherever possible. Deviations form both these texts in Draft Standard A are indicated in bold.

Para 34 of ALINORM 03/26A indicated that Draft Standard A could contain the provisions for formula for special medical purposes intended for infants either in an Annex or as a separate part of the Standard. Both these options turned out to be difficult with regard to both clarity and repetition. Therefore, at present a format has been chosen which contains text of relevance for **both** infant formula and formula for special medical purposes intended for infants and text for **either** infant formula **or** formula for special medical purposes intended for infants divided into two columns.

The Committee will have to consider the practicability of that approach.

II. Draft Standard B (attached as Annex II)

Draft B is a draft for a Standard for Formula for Special Medical Purposes Intended for Infants. The text of this draft is taken from the Proposed Draft Revised Standard for Infant Formula (ALINORM 03/26A, Appendix II) and from the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991). Wording which is not in either of the documents has been indicated in bold. This draft standard covers only such formula for special medical purposes which can provide the sole source of nutrition during the first months of life to substitute for either breast-milk or infant formula.

The Committee will have to decide:

- on the name of the product, and
- on the usefulness of having a separate standard for these products.

III. Draft Standard C

Two draft proposals for scrutiny by CCNFSDU have been written:

Draft Standard A: Provisional Draft Revised Standard For Infant Formula Including Formula For Special Medical Purposes Intended For Infants;
Draft Standard B: Provisional Draft For Formula For Special Medical Purposes Intended For Infants

The third task of the Working Group was to outline the advantages and disadvantages of the draft Standards A and B each.

Advantage of Draft Standard A:

1. One standard and the provisions in that standard with regard to safety, choice of nutrients, hygiene, contaminants would be valid for all types of formula which can replace breast-milk as the sole source of nutrition during the first months of life of healthy infants and infant patients.
2. The compositional criteria for infant formula are indicated as the basis for the formulation of formula for infant patients. Necessary deviations in the composition of the latter can be identified and indicated.
3. The observation of one standard is potentially easier than of two.

Disadvantage of Draft Standard A:

1. Infant formula would not be regulated in a separate standard to underline its uniqueness and its identity as the only approved breast-milk substitute for healthy infants.

2. The combination in one standard of rules for products with completely different target groups (healthy infants and infant patients) is confusing and can lead to misunderstanding by manufacturers and government authorities.
3. The combination in one standard of rules for products with completely different target groups (healthy infants and infant patients) is not customary in Codex.
4. The inclusion of compositional and labelling requirements for formula for special medical purposes intended for infants into the Standard for infant Formula would be in contrast to the system of horizontal Standards for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985), including the Standards for Infant Formula (CODEX STAN 72-1981), for Canned Baby Foods (CODEX STAN 73-1981), for Processed Cereal Based Foods for Infants and Children (CODEX STAN 74-1981), for Follow-Up Formula (CODEX STAN 156-1987), for Gluten-Free Foods (CODEX STAN 118-1981) and for Formula Foods for Use in Weight Control Diets (CODEX STAN 181-1991). The Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991), which are also foods for special dietary uses, does not contain compositional criteria and consists mainly of a description and exceptions from the labelling according to the CODEX STAN 146-1985 for these very special foods. CODEX STAN 180-1991 could be the horizontal standard and formula for special medical purposes intended for infants could be a vertical standard falling under its scope.
5. The section on essential composition will have to be amended for formula for special medical purposes intended for infants (other/more nutrients; other/more food additives).

Advantage of Draft Standard B:

1. The special characteristics and identity of formula for special medical purposes intended for infants are clearly apparent in a separate standard.

Disadvantage of Draft Standard B:

1. Having a separate standard for formula for special medical purposes intended for infants gives too much weight to a comparatively small number of products.
2. A standard for special medical purposes intended for infants covers only a very small section of all foods for special medical purposes, which remain unregulated.
3. The labelling of formula for special medical purposes intended for infants and equivalent to infant formula is covered by a separate standard from that covering foods for special medical purposes intended for other age groups. This could create the problem that different provisions could develop during the revision or the development of the different standards. In particular, formula for special medical purposes equivalent to infant formula would be covered by a different standard than other foods for special medical purposes intended for infants.
4. The begin of the use of a formula for special medical purposes in an infant patient depends on the age at diagnosis of the disease. In many cases the need for a formula for special medical purposes will continue after the age of 12 months. Formula/food for special medical purposes intended for older children with a diagnosis necessitating the use of foods for special medical purposes will not be covered by this standard.
5. This draft standard covers only formula for special medical purposes intended for infants and suitable for exclusive feeding. The much more numerous formulae for partial feeding are outside the scope.

An alternative to both Standard A and B would be another draft standard developed from CODEX STAN 180-1991 with cross-reference, where necessary, to the Codex Standard for Infant Formula. A member of the working group has developed such a draft standard. This draft is outside the task of the working group as defined in Para 34 of ALINORM 03/26A.

However, as this had already been proposed in the discussion paper prepared by Germany for the 24th session of CCNFSDU 2002 (CRD 12) and might be proposed again during the 25th session, this draft (draft Standard D) has also been attached as Annex III.

Annex I

DRAFT STANDARD A (changes to ALINORM 03/26A Appendix II and to CODEX STAN 180-1991 in bold)

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA Including Nutritionally Complete Formula for Special Medical Purposes intended for Infants

Preamble: *This standard is a revision of the CODEX STANDARD FOR INFANT FORMULA, CODEX-STAN 72-1981, and incorporates relevant provisions adapted for infants from the CODEX STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES, CODEX STAN 180-1991.*

1. SCOPE

1.1 This standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants.

The provisions in this standard also **apply to formula for** special **medical purposes intended for infants, except for certain compositional deviations necessary to meet the special nutritional requirements deriving from the disorder, disease or medical condition for whose dietary management the formula is formulated, labelled and presented.**

1.2 The standard contains compositional, quality and safety requirements to ensure a safe and nutritionally adequate product.

1.3 The application of the Standard should take into account the recommendations given to countries under the International Code of Marketing of Breast-milk Substitutes and the World Health Assembly resolution WHA54.2 (2001).

2. DESCRIPTION

2.1 PRODUCT DEFINITIONS

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

2.1.2 Formula for special medical purposes intended for infants is a product that fulfils the definition of food for special medical purposes as defined in Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is intended to satisfy by itself the particular nutritional requirements of infant patients during the first months of life.

2.1.**3** When in liquid form **products defined in 2.1.1 and 2.1.2 may** be used either directly or prepared with safe, and previously boiled water before feeding according to directions for use. In powdered form, **both types of product** also require safe, and previously boiled water for preparation.

2.1.**4** **Products defined in 2.1.1 and 2.1.2 are** so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 Other Definitions

The term ***infant*** means a person not more than 12 months of age.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1 **Infant formula** is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding.	**3.2.1 Formula for special medical purposes intended for infants are based on ingredients of animal and/or plant origin or on synthetic compounds suitable for human consumption.**

	3.2.2 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 scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the infants for whom they are intended.
3.1.2. "Infant formula shall contain per 100 kilocalories (or 100 kilojoules) of intake the following minimum and maximum levels of vitamins, minerals in an available form, choline, protein, fat and fatty acids, carbohydrates and energy: ... (left out to save space)	3.2.3 The nutrient composition of formula for special medical purposes intended for infants shall be based on the requirements for infant formula as given in section 3.1.2, **except for certain 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 formulated, labelled and presented.**
3.3 OPTIONAL INGREDIENTS	
3.**3.**1 In addition to the compositional requirements listed under 3.**1**, other [nutrients/ingredients] may be added in order to provide [nutrients/substances] ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant **or for the dietary management of the disease(s), disorder(s) or medical condition(s) for which a formula for special medical purposes intended for infants is formulated.**	
3.**3**.2 [The usefulness/suitability/beneficial effect] for the particular nutritional uses of infants and safety of these nutrients shall be scientifically demonstrated].	
3.**3**.3 When any of these nutrients is added, the formula shall contain sufficient amounts of these nutrients to achieve the intended effect based on levels in human milk.	
3.**3**.4 Only L(+) producing lactic acid cultures may be used**.**	
3.4 VITAMIN COMPOUNDS AND MINERAL SALTS	
Vitamins and minerals added in accordance with Section 3.1.2 (a, b, c) and **3.3.1** should be selected from the **revised** Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).	
3.5 CONSISTENCY AND PARTICLE SIZE	
When prepared according to the label directions for use, the product shall be free of lumps and of large coarse particles and suitable for adequate feeding of young infants.	
3.6 PURITY REQUIREMENTS	
All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.	
3.7 SPECIFIC PROHIBITION	
The product and its components shall not have been treated by ionizing radiation.	
4. FOOD ADDITIVES	
The following additives are permitted in the preparation of Infant Formula, as described in Section 1 of this Standard, and with the restrictions stated below: *(list left out)*	
4.6 For formula for special medical purposes intended for infants described in Section 1 of this Standard the following additional food additives are permitted when required: (*-to be determined)	
4.**7** Carry-over of Food Additives	
No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:	
(a) of the food additives listed under Sections 4.1 to 4.4 (or 4.5) of this standard within the limits of the maximum levels stipulated in this standard; and	

(b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.
5. CONTAMINANTS
5.1 PESTICIDE RESIDUES
The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.
5.2 Other Contaminants
Infant formula **and formula for special medical purposes intended for infants** shall not contain contaminants or undesirable substances (e.g. biologically active substances) in amounts which may represent a hazard to the health of the infant.
The product**s** covered by the provisions of the Standard shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission.
Maximum level Lead 0.02 mg/kg (in the ready-to-use product)
6. HYGIENE
6.1 It is recommended that the product**s** covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1 1969, Rev. 3- 1997), and other relevant Codex texts such as the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).
6.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).
7. PACKAGING
7.1 The product**s** shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the products shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.
7.2 The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.
8. FILL OF CONTAINER
In the case of products in ready-to-eat form, the fill of container shall be:
(i) not less than 80% v/v for products weighing less than 150 g (5 oz.);
(ii) not less than 85% v/v for products in the weight range 150-250 g (5-8 oz.); and
(iii) not less than 90% v/v for products weighing more than 250 g (8 oz.)
of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20° C which the sealed container will hold completely filled.
9. LABELLING
The text of the label and all other information accompanying the products shall be written in the appropriate language.

Labelling of Infant Formula	**Labelling of Formula for Special Medical Purposes Intended for Infants**
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:	Formula for Special Medical Purposes Intended for Infants shall be labelled in accordance with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX-STAN 146-1985 except that a) Sections 4.3, 5.1, 5.2.2, 5.2.3 and 6 [] do not apply to the Labelling of **these products**; and b) the following specific provisions apply:
9.1 The name of the Food:	
9.1.1**.1** The name of the product shall be either "Infant Formula" or any appropriate designation indicating the true nature of the product, in accordance with national usage.	**9.1.2.1 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.**
9.1.**1.2** The sources of protein in the product shall be clearly shown on the label.	**9.1.2.2** Information on the nature of the animal or plant proteins or protein hydrolysates should be provided.
9.1.**1.3** If cow's milk is the only source of protein, the product may be labelled "Infant Formula Based on Cow's Milk".	**9.1.2.3 Formula** for special medical purposes **intended for infants** in which the essential characteristic involves a specific modification of the content or the nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the amino acid, fatty acid or carbohydrate profile, when necessary.
9.1.**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.	**9.1.2.4** Information on osmolality or osmolarity and/or acid-base balance shall be given when appropriate.
9.1.**1.5** [Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labelled "Infant Formula with added Iron"].	**9.1.2.5** A statement specifying the nutrient(s) which have been reduced, deleted, increased, or otherwise modified, relative to normal requirements, and the rationale for the reduction, deletion, increase or other modification.
or	
[Products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]	
9.**3** LIST OF INGREDIENTS	
9.**3.**1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.	
9.**3.**2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.	
9.**4** DECLARATION OF NUTRITIVE VALUE **for infant formula**	9.**5** Nutrition Labelling **for formula for special medical purposes intended for infants**
The declaration of nutrition information shall contain the following information in the following order:	**Formula** for special medical purposes **intended for infants** shall be labelled with complete nutrition labelling as follows:

(a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label.	**a**) The declaration of nutrient content shall be numerical. However, the use of additional means of presentation should not be excluded
(b) the total quantity of each vitamin, mineral, choline as listed in paragraph **3.1.2** and any other ingredient as listed in paragraph **3.3.1** of this Standard per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label.	**b**) Information on energy value shall be expressed in KJ and kcal per 100 g or per 100 ml as sold as well as per specified quantity of the food as suggested for consumption.
(c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.	**c**) Information on the amounts of protein, carbohydrate and fat in the **formula** shall be expressed in g per 100 g or per 100 ml as sold, as well as per specified quantity of the food suggested for consumption. Information on the amounts of essential and non-essential amino acids and/or essential fatty acids may be expressed similarly in metric units as appropriate.
	d) Information on the amounts of vitamins and essential minerals shall be expressed in metric units per 100 g or per 100 ml as sold as well as per specified quantity of the food as suggested for consumption.
	e) In addition, where it is appropriate the quantity of nutrients may be expressed in terms of percentages of the relevant internationally recognised recommended daily allowances.
	[f) In countries where serving sizes are normally used, the information described in b) to d) may be given only per serving as quantified on the label or per portion provided that the number of servings of portions contained in the package is stated.**]**
9.**6** **DATE MARKING AND STORAGE INSTRUCTIONS**	
9.**6**.1 The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer.	
In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.	
9.**6**.2 In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon.	
Where practicable, storage instructions shall be in close proximity to the date marking.	
9.**7** **INFORMATION FOR USE**	
9.**7**.1 Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet.	

9.**8** **ADDITIONAL LABELLING REQUIREMENTS FOR INFANT FORMULA**	**9.9 ADDITIONAL LABELLING REQUIREMENTS FOR FORMULA FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS**
9.**8**.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:	**9.9.1** A prominent statement "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from other written, printed or graphic information.
a) the words "important notice" or their equivalent;	**9.9.2** An additional prominent warning statement consisting of an explanatory statement shall appear on the label in bold letters in an area separated from other written, printed or graphic information if the **formula** for special medical purposes **intended for infants** poses a health hazard when consumed by **infants** who do not have the disease(s), disorder(s) or medical condition(s) for which the **product** is intended.
b) [a statement of the superiority of breastfeeding or breast-milk, for example the statement: Breast-milk is the best food for your baby, it protects against diarrhea and other illnesses];	9.9.3 A statement that the product is not to be used for parenteral administration shall appear on the label.
or	9.9.4 A prominent statement indicating **that** the product is intended as the sole source of nutrition shall appear on the label.
b) [The statement "Breastfeeding is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk.]	**9.9.5 Labels 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.**
c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use;	**9.9.6 The product shall be labelled in such a way as to preclude any confusion with other foods for special dietary uses for infants, especially infant formula and follow-up formula.**
d) instructions for appropriate preparation;	**9.9.7** The statement "For the dietary management of ... " with the blank to be filled in with the specific disease(s), disorder(s) or medical condition(s) for which the product is intended, and for which it has been shown to be effective.
e) a warning against the health hazards of inappropriate preparation; and a warning that formula remaining after each feeding should be discarded.	**9.9.8** A complete statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable.
9.**8**.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula. The label shall have graphics illustrating the method of preparation of the product and methods of feeding.	**9.9.9** A statement of the rationale for the use of the product and a description of the properties and characteristics that make it useful.
9.**8**.3 The terms "humanized", "maternalized" or other similar terms shall not be used.	**9.9.10** A statement specifying the nutrient(s) which have been reduced, deleted, increased, or otherwise modified, relative to normal requirements, and the rationale for the reduction, deletion, increase or other modification.

9.**8**.4 Information shall appear on the label to the effect that infants should receive **complementary** foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.	**9.9.11** Feeding instructions, including the method of administration and serving size, if applicable.
9.**8**.5 [The products shall be labelled in such a way as to avoid any risk of confusion between infant formula and follow-up formula.]	**9.9.12** The information according to sections **9.97** to **9.9.11** may be provided separately from the package.

Annex II

DRAFT STANDARD B
PROPOSED DRAFT FOR FORMULA FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

(Wording which is neither in the Proposed Draft Revised Standard for Infant Formula (ALINORM 03/26A, Appendix II) nor in the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) is indicated in bold.)

1. SCOPE

1.1 This standard applies to **formula for special medical purposes intended for infants**

1.2 The standard contains compositional, quality, safety and labelling requirements for **formula for special medical purposes intended for infants as defined in Section 2 below, and presented as such.**

1.3 The application of this standard should take into account the recommendations given to countries under the International Code of Marketing of Breast-milk Substitutes where applicable and of World Health Assembly resolution WHA 54.2, 2001).

2. DESCRIPTION

2.1 PRODUCT DEFINITION

2.1.1 Formula for special medical purposes intended for infants is a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of **infant** patients and may be used only under medical supervision. They are intended for the exclusive feeding of infant patients with limited or impaired capacity to take, digest, absorb or metabolise **breast-milk or** [ordinary] **infant formula** or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal **infant** diet, by other foods for special dietary uses, or by a combination of the two, during the first months of life up to the introduction of appropriate complementary feeding.

2.1.2 When in liquid form **formula for special medical purposes intended for infants** may be used either directly or be prepared with safe and previously boiled water before feeding, according to directions for use. In powdered form **formula for special medical purposes intended for infants** requires safe, and previously boiled water for preparation.

2.1.3 Formula for special medical purposes intended for infants is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 OTHER DEFINITIONS

The term infant means a person not more than 12 months of age.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 GENERAL PRINCIPLES

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 scientific evidence, to be safe and beneficial in meeting the nutritional requirements for the **infant patients** for whom they are intended.

3.2 NUTRIENT COMPOSITION

The nutrient composition of **formula for special medical purposes intended for infants, except for provisions necessitated by special nutritional requirements deriving from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is formulated, should be based on the nutrient composition of infant formula, where applicable** (CODEX STAN 72-1981, revised section 3.1).

3.3 INGREDIENTS

The ingredients used should be appropriate for the disease(s), disorder(s) or medical condition(s) for which the product is formulated.

3.4 VITAMIN COMPOUNDS AND MINERAL SALTS

Vitamins and minerals added in accordance with section 3.2 and 3.3 should be selected from the **[revised]** Advisory List of [Nutrient compounds] for Use in Foods for [Special Dietary Uses for] Infants and Children.

3.5 PURITY REQUIREMENTS

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.6 SPECIFIC PROHIBITION

The product and its components shall not have been treated by ionising radiation.

4. FOOD ADDITIVES

To be developed

5. CONTAMINANTS

5.1 PESTICIDE RESIDUES

The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

5.2 OTHER CONTAMINANTS

Formula for special medical purposes intended for infants shall not contain contaminants or undesirable substances (e.g. biologically active substances) in amounts which may represent a hazard to the health of the infant.

The products covered by the provision of the Standard shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission.

6. HYGIENE

6.1 It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1 1969, Rev. 3-1997), and other relevant Codex texts such as the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

6.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

7. PACKAGING

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packaging media.

7.2 The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

8. LABELLING

Formula for special medical purposes intended for infants shall be labelled in accordance with the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) except that.

a) Sections 4.3, 5.1, 5.2.2, 5.2.3 and 6 of **that** Standard do not apply to the Labelling of **Formula for Special Medical Purposes intended for infants**; and

b) the following specific provisions apply.

8.1 NAME OF THE FOOD

The name of the product shall be "**Formula for Special Medical Purposes intended for Infants**".

8.2 NUTRITION LABELLING

Formula for special medical purposes intended for infants shall be labelled with complete nutrition labelling as follows:

8.2.1 The declaration of nutrient content shall be numerical.

8.2.2 Information on energy value shall be expressed in kilojoules (kJ) and kilocalories (kcal) per 100 g or per 100 ml as sold as well as per specified quantity of the food as suggested for consumption.

8.2.3 Information on the amount of protein, carbohydrate and fat in the food shall be expressed in g per 100 g or per 100 ml as sold, as well as per specified quantity of the food suggested for consumption.
Information on the amounts of essential and non-essential amino acids and/or essential fatty acids may be expressed similarly in metric units as appropriate.

8.2.4 Information on the total contents of vitamins and essential minerals shall be expressed in metric units per 100 g or per 100 ml as sold as well as per specified quantity of the foods as suggested for consumption.

8.2.5 In addition, the declaration of nutrients in 8.2.3 and 8.2.4 per 100 kilocalories (or per 100 kilojoules) is permitted.

8.2.6 In addition, where it is appropriate the quantity of nutrients may be expressed in terms of percentages of the relevant internationally recognised recommended daily allowances.

8.2.7 Information on osmolality or osmolarity and/or on acid-base balance shall be given when appropriate.

8.2.8 In addition, information on the nature of the animal or plant proteins or protein hydrolysates should be provided.

8.2.9 Formula for special medical purposes intended for infants in which the essential characteristic involves a specific modification of the content or the nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the amino acid, fatty acid or carbohydrate profile, when necessary.

8.3 DATE MARKING AND STORAGE INSTRUCTIONS

The date of minimum durability as provided for in section 4.7 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991)) shall be declared.

8.4 ADDITIONAL INFORMATION

8.4.1 A prominent statement "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from other written, printed or graphic information.

8.4.2 Adequate information for the preparation including the requirement to add **water**, for the use of the **formula** and for its storage and keeping after the container has been opened, shall be included on the label.

8.4.3 An additional prominent warning statement consisting of an explanatory statement shall appear on the label in bold letters in an area separated from other written, printed or graphic information if the **formula for special medical purposes intended for infants** poses a health hazard when consumed by **infants** who do not have the disease(s), disorder(s) or medical condition(s) for which the **formula** is intended.

8.4.4 A statement that the product is not to be used for parenteral administration shall appear on the label.

8.4.5 A prominent statement indicating that the **formula** is intended as the sole source of nutrition for infant patients up to the introduction of appropriate complementary feeding.

8.4.6 Labels 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.**

8.4.7 The product shall be labelled in such a way to avoid any risk of confusion **with normal foods for special dietary uses for infants, especially infant and follow-up formula.**

8.5 INFORMATION TO BE INCLUDED IN THE LABELLING[2]

8.5.1 The statement "For the dietary management of ..." with the blank to be filled in with the specific disease(s), disorder(s) or medical condition(s) for which the product is intended, and for which it has been shown to be effective.

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

8.5.3 A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.

8.5.4 A statement specifying the nutrient(s) which have been reduced, deleted, increased, or otherwise modified, relative to normal requirements, and the rationale for the reduction, deletion, increase or other modification.

8.5.5 Feeding instructions, including the method of administration and serving size, if applicable.

[2] This information may be provided separately from the package.

Annex III

DRAFT STANDARD D
PROPOSED DRAFT REVISED
CODEX STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES AND THE ESSENTIAL COMPOSITION OF FOODS FOR SPECIAL MEDICAL PURPOSES INTENDED AS THE SOLE SOURCE OF NUTRITION FOR INFANT PATIENTS (CODEX STAN 180-1991)

(Additions to the current standard are indicated in bold)

1. SCOPE

This standard applies to the labelling of and claims for foods for special medical purposes as defined in Section 2 below, and presented as such. **In the case of foods for special medical purposes that are intended as the sole source of nutrition for infant patients the requirements regarding essential composition and additional labelling are specified.**

2. DESCRIPTION

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 or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolise ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, 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.

Food for special medical purposes intended as the sole source of nutrition for infant patients **is a food for special medical purposes intended to satisfy by itself the particular nutritional requirements of infant patients during the first months of life.**

3. GENERAL PRINCIPLES

The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended. The labels, accompanying leaflets and/or other labelling and advertising of all types of foods for special medical purposes should provide sufficient information on the nature and purpose of the food as well as detailed instructions and precautions for their use.

The advertising of these products to the general public should be prohibited. The format of the information given should be appropriate for the person for whom it is intended.

4. LABELLING

4.1 Foods for Special Medical Purposes shall be labelled in accordance with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985)1[3] except that:

(a) Sections 4.3, 5.1, 5.2.2, 5.2.3 and 6 of the General Standard do not apply to the Labelling of Foods for Special Medical Purposes; and

[3] Hereafter referred to as "General Standard".

(b) the following specific provisions apply:

4.2 Nutrition Labelling

Foods for special medical purposes shall be labelled with complete nutrition labelling as follows:

4.2.1 The declaration of nutrient content shall be numerical. However the use of additional means of presentation should not be excluded.

4.2.2 Information on energy value shall be expressed in kJ and kcal per 100 g or per 100 ml as sold as well as per specified quantity of the food as suggested for consumption.

4.2.3 Information on the amounts of protein, carbohydrate and fat in the food shall be expressed in g per 100 g or per 100 ml as sold, as well as per specified quantity of the food suggested for consumption. Information on the amounts of essential and non-essential amino acids and/or essential fatty acids may be expressed similarly in metric units as appropriate.

4.2.4 Information on the amounts of vitamins and essential minerals shall be expressed in metric units per 100 g or per 100 ml as sold as well as per specified quantity of the foods as suggested for consumption.

4.2.5 In addition, where it is appropriate the quantity of nutrients may be expressed in terms of percentages of the relevant internationally recognised recommended daily allowances.

4.2.6 Information on osmolality or osmolarity and/or on acid-base balance shall be given when appropriate.

4.2.7 In countries where serving sizes are normally used, the information described in Sections 4.2.2 to 4.2.4 may be given only per serving as quantified on the label or per portion provided that the number of servings or portions contained in the package is stated.

4.2.8 In addition, information on the nature of the animal or plant proteins or protein hydrolysates should be provided.

4.2.9 Foods for special medical purposes in which the essential characteristic involves a specific modification of the content or the nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the amino acid, fatty acid or carbohydrate profile, when necessary.

4.3 Date Marking

The date of minimum durability as provided for in Section 4.7 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev.1-1991), Codex Alimentarius Volume 1) shall be declared.

4.4 Additional Information

4.4.1 A prominent statement "**USE UNDER MEDICAL SUPERVISION**" shall appear on the label in bold letters in an area separated from other written, printed, or graphic information.

4.4.2 Adequate directions for the preparation including the requirement to add other ingredients, for the use of the food and for its storage and keeping after the container has been opened, shall be included on the label.

4.4.3 An additional prominent warning statement consisting of an explanatory statement shall appear on the label in bold letters in an area separated from other written, printed or graphic information if the food for special medical purpose poses a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.

4.4.4 A statement that the product is not to be used for parenteral administration shall appear on the label.

4.4.5 A prominent statement indicating whether the product is or is not intended as the sole source of nutrition shall appear on the label.

4.5 Information to be Included in the Labelling [4]

4.5.1 The statement "For the dietary management of ....." with the blank to be filled in with the specific disease(s), disorder(s) or medical condition(s) for which the product is intended, and for which it has been shown to be effective.

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

4.5.3 A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.

4.5.4 If the product has been formulated for a specific age group, it should carry a prominent statement to this effect.

4.5.5 A statement specifying the nutrient(s) which have been reduced, deleted, increased or otherwise modified, relative to normal requirements, and the rationale for the reduction, deletion, increase or other modification.

4.5.6 Feeding instructions, including the method of administration and serving size, if applicable.

5. Additional Labelling Requirements for Foods for Special Medical Purposes Intended as the Sole Source of Nutrition for Infant Patients

5.1 The name of the product shall be ….

5.2 Labels 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.

5.3 The product shall be labelled in such a way to preclude any confusion with normal foods for special dietary uses for infants, especially infant formula and follow-on formula.

6. Essential Composition of Foods for Special Medical Purposes Intended as the Sole Source of Nutrition for Infant Patients

6.1 Foods for special medical purposes intended as the sole source of nutrition for infant patients shall comply with the provisions relating to the essential composition with regard to energy and nutrients applicable to infant formula as laid down in [section 3.1.2] CODEX STAN 72-1981, rev ... except in cases where disease related nutritional needs necessitate appropriate modification in composition.

6.2 Vitamins and minerals added in accordance with section 5.1 should be selected from the advisory lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

6.3 In addition to the foods additives listed in section 4 of CODEX STAN 72-1981, rev ... the following additives may be used in foods for special medical purposes intended as the sole source of nutrition for infant patients.

6.4 The provisions in CODEX STAN 72-1981, rev ... concerning the purity requirements (section 3.5), specific prohibitions (section 3.6), contaminants (section 5), hygiene (section 6) and packaging (section 7) shall apply to foods for special medical purposes intended as the sole source of nutrition for infant patients.

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[4] This information may be provided separately from the package.