codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 **CX/NFSDU 01/5-Add. 1**
November 2001

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-third Session
Berlin, Germany, 26 - 30 November 2001

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA

DISCUSSION PAPER : FOODS FOR SPECIAL MEDICAL PURPOSES REGULATED IN THE STANDARD FOR INFANT FORMULA

(prepared by Germany)

Introduction

At the 22-nd session of the **Codex Committee on Nutrition and Foods for Special Dietary Uses the Proposed Draft Revised Standard for Infant Formula** (Alinorm 99/26, Appendix V) was discussed. Agreement on the wording of section 1.1 of the scope could not be reached.

Whereas some delegations were of the opinion that a standard for infant formula should cover only those products intended and suitable for satisfying the nutritional needs of healthy infants who are not breast-milk fed, other delegations were of the opinion that this standard should continue to apply to products intended and suitable for infants with special nutritional needs resulting from a medical disorder or disease. This category of foods is called foods for special medical purposes. Examples of disorders are metabolic defects such as phenylketonuria, maple syrup urine disease and many others.

Section 1.3 of the proposed draft revised standard states, that the recommendations of the International Code of Marketing of Breast-milk Substitutes should be observed. This led to a discussion in the session on whether foods for special medical purposes (FSMPs) for infants are breast-milk substitutes in the sense of the Code or not. The representatives of both WHO and UNICEF indicated, that the Code covered all types of formula used as a replacement for breast milk, including those intended for infants with special nutritional or medical needs.

The delegation of Germany was asked to prepare, in co-operation with several delegations and observers, proposals to address the issue of infant formula for special medical purposes as related to the current standard (for infant formula) or other relevant standards, as necessary, for consideration at the next session (**Alinorm 01/26, para 63**).

The following delegations and observers have contributed to preparing the discussion paper: Germany, Canada, WHO, European Commission and ISDI.

The paper consists of three parts:

I. A table of similarities and dissimilarities of infant formula and foods for special medical purposes intended for infants

II. Options for regulating foods for special medical purposes intended for infants

III. Background information to help in decision making

I. Table of dissimilarities and similarities between infant formula and foods for special medical purposes intended for infants

	Infant formula	**Foods for special medical purposes**
Nutritional aim	Adapted to normal requirements of infancy	Adapted to special nutritional requirements of patients
Intended for	Healthy infants; can in some instances be used for patients	Patients only
Suitable for exclusive feeding in first months of life	Yes	Yes, for nutritionally complete No, for nutritionally incomplete products
Use	On advice of health worker	Under medical supervision
Contraindication	Possible in special disorder	Healthy infants
Advertising to the general public	Prohibited (International Code of Marketing of Breast-milk Substitutes)	Prohibited (Codex Stan 180-1991)
Possible substitute	Breast milk	None; health and development of the patient dependent on product
Requirements for quality and purity of ingredients	Codex-Stan 72-1981	Should be identical to infant formula
Requirements for contaminants, hygiene	Codex-Stan 72-1981	Should be identical to infant formula
Requirements for composition	Substitute for the nutritional role of breast-milk in general	Specific and dependent on requirements of the patient´s disorder
Breast-milk substitute ?	Yes	Yes, for nutritionally complete products. Partially, for nutritionally incomplete products
Labelling provisions	According to **Codex Stan 1-1985 (Rev. 1-1991)** Name Nutrition labelling — Protein source "*Use on advice of health worker*" — — — Instructions for use and storage Feeding instructions —	According to **Codex Stan 180-1991 and 146-1985** Name Complete nutrition labelling Osmolality Protein source "*Use under medical supervision*" Health hazards to persons who do not have the disease etc. the product is intended for "*For the dietary management of ....*" Precautions, side effects, contraindications, product-drug interactions Instructions for use and storage Feeding instructions Rationale for use and description of properties

II Options for regulating foods for special medical purposes intended for infants

The following three options for regulating FSMPs intended for infants have been formulated.

OPTION A: Revise the standard for foods for special medical purposes to include compositional requirements for foods for special medical purposes for infants. Eliminate foods for special medical purposes for infants from the Scope of the present Codex Standard for Infant Formula for healthy infants.

The existing Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (Codex Stan 180-1991) could be revised to make the compositional requirements for infant formula applicable to FSMPs intended for infants, as appropriate, by reference to the Codex Standard for Infant Formula. A possible text could be:

"*Where this is not contrary to the requirements dictated by the intended use, foods for special medical purposes intended specifically for infants shall comply with the provisions relating to nutrients applicable to infant formula laid down in Codex Stan 72-1981"*

In addition, criteria for quality and purity of ingredients, contaminants, hygiene and packaging for foods for special medical purposes could be included by reference to the Codex Standard on Infant Formula.

Advantages: The revision of the existing Codex Stan 180-1991 to include infant formula for special medical purposes would have the advantage of setting out specific compositional and labelling requirements for these foods and/or specific principles for their development. Specific requirements would aid in the manufacture of such products. A clear discrimination between foods intended for patients only (FSMPs) and foods intended for healthy persons would be achieved. Especially in the case of healthy infants, who are not breastfed, confusion between infant formula and FSMP intended for infants should be avoided, because the latter are contraindicated in healthy infants. By regulating both infant formula and FSMPs intended for infants in one standard, there is a risk that these completely different kinds of food will be confused.

Disadvantages: The need to revise the existing Codex Stan 180-1991 to include compositional criteria could be regarded as a disadvantage. Moreover, such a compositional standard may be difficult to establish in detail and would probably have to consist of general principles only. In the case of FSMPs for infants, reference to the compositional criteria for infant formula, according to Codex Stan 72-1981, and guidance for their modification to meet the special nutritional requirements dictated by the intended use will have to suffice.

OPTION B: Do not develop a separate compositional standard for FSMPs (e.g. by revising the existing Codex Stan 180-1991), including FSMPs intended for infants, but eliminate FSMPs intended for infants from the Codex Standard on Infant Formula (Codex Stan 72-1981).

The mention of foods for special medical purposes would have to be deleted from the existing Codex standard (Codex Stan 72-1981) and from the Proposed Draft revised Standard for Infant Formula (Alinorm 99/26, Appendix V) in sections 1 and 9.1.5.

Advantages: The Codex Standard for Infant Formula would clearly exclude formula for special medical purposes**.** The risk of confusing the two categories would be reduced. Labelling requirements would be different and product-specific. For infant formula labelling would follow the provisions in Codex Stan 72-1981 or its revision. For FSMPs for infants labelling would follow the provisions established in Codex Stan 180-1991.

Disadvantages: Apart from the description, general principles and labelling rules of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (Codex Stan 180-1991) there would be no other rules for FSMPs. There would be no criteria for composition, quality and purity of ingredients, contaminants, hygiene and packaging other than those for foods for special dietary uses or food in general and no controls on use of food additives. There would be no safety and nutritional quality standards for these products at the international level. The potential risk of nutritionally inadequate FSMPs would be significant.

OPTION C: Keep foods for special medical purposes intended for infants in the standard for infant formula.

If this option were chosen the following changes on the proposed/amended standard for infant formula would be necessary and are indicated:

"1. *Scope*

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

1.2. **(new)** *The provisions in this standard are also intended for foods for special medical purposes (formulated according to the description and general principles of Codex Stan 180-191) for infants except for certain compositional provisions which must be modified to meet the special nutritional requirements of the disease, disorder or medical condition for whose dietary management the food is formulated*".

Section 4 would need to be amended to provide for additional food additives necessary for the production of formulas for special medical purposes.

The labelling of infant formula and foods for special medical purposes for infants should be regulated in two separate sections to clearly demonstrate the differences:

"9. *Labelling of infant formula"*

Text as is except for the elimination of section 9.1.5

"10. (new) Labelling of foods for special medical purposes for infants

10.1 Foods for special medical purposes for infants shall be labelled in accordance with the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (Codex Stand 180-1991)".

(It will have to be decided, if it is advisable to add further sections - as Canada proposes-, which give the essence of sections 4.4 and 4.5 of Codex Stan 180-1991).

Advantages: All criteria for quality and purity of ingredients, for contaminants, hygiene and packaging and controls on food additives set out for infant formulas would also apply to foods for special medical purposes for infants.

Disadvantages: The choice of this option would mean that, whereas The Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (Codex Stan 180-1991) defines these products and regulates their labelling and claims, for the subgroup of foods for special medical purposes for infants additional regulations would be found in the Codex Standard for Infant Formula.

By regulating both infant formula and FSMPs for infants in one standard, with regard to composition, quality and purity of ingredients, contaminants, hygiene, packaging and food additives, there is a risk that these completely different kinds of food would be confused.

In some instances the compositional criteria of section 3 of the Codex Standard for Infant Formula would not be relevant in the formulation of complete or incomplete foods for special medical purposes for infants. This issue may, however, be addressed either by incorporating into the Standard for Infant Formula specific exemptions, specific requirements or general principles to guide the modification of the composition of infant formulas.

III. Background information to help in decision making.

The following items will be considered:

A. Aim of the International Code of Marketing of Breast-milk Substitutes

B. Definition of breast milk-substitute in the Code

C. Labelling of breast-milk substitutes in the Code

D. Definition of infant formula

E. Labelling of infant formula

F. Definition of foods for special medical purposes (FSMP)

G. Labelling provisions for FSMP in Codex Alimentarius

H. Suitability of Code labelling provisions for FSMP intended for infants

I. Suitability of compositional, quality and safety provisions of the standard for infant formula for FSMP intended for infants.

J. Conclusions

A. Aim of the International Code of Marketing of Breast-milk Substitutes

Article 1 of the Code states: *"The aim of this Code is to contribute to the provision of safe and adequate nutrition of infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution".*

As noted in the **preamble** to the Code:

- breastfeeding provides the ideal food for the healthy growth and development of infants;
- breastfeeding should, therefore, be protected and promoted by governments, health care systems, educational and other social services and also by manufacturers and distributors of breast-milk substitutes;
- there is a legitimate market for infant formula (and for suitable ingredients form which to prepare it), which should be made accessible to those who need them, but in ways that do not interfere with the protection and promotion of breastfeeding;
- infants should receive appropriate complementary foods when nutritionally required but these foods should not be used as breast-milk substitutes.

In the Guidelines Concerning the Main Health and Socioeconomic Circumstances in which Infants have to be fed on Breast-milk Substitutes, reviewed by the 39th World Health Assembly in 1986 (see document WHA39/1986/REC/1, Annex 6, paragraph 10), three situations have been identified, where infants cannot, or should not be breastfed:

a) "Infants who cannot be fed at the breast, for example those with sucking difficulties, but for whom breastmilk remains the food of choice". For this group *"expressed breastmilk provided by their own mothers would be best, followed by breast milk from a wet-nurse or a breast-milk bank".*

b) "Infants who should not receive breast milk, or any other milk, including the usual breast-milk substitutes, for example those with rare metabolic disorders". For this small group *"special preparations are required to replace breast milk or the usual milk-based breast-milk substitutes".*

c) "Infants for whom breast milk is not available for whatever reasons". For these infants *"the appropriate use of commercially-produced infant formula represents an important nutritional advance".*

Fortunately, infants who should not be fed human milk because it could be detrimental to their health, growth and/or development are few in number relative to the world´s total infant population and the problem of infant malnutrition. Taking into account all known metabolic disorders for which breast-milk

feeding is contraindicated, or has to be restricted and (partially) replaced by FSMPs, the estimated total incidence is 1 in 5000 newborns.

Therefore:

- Breastfeeding is the ideal food for most infants, however, for some infants it is contraindicated and can lead to (irreversible) adverse effects on their health and development.
- Infants, who are not breastfed for non-medical or maternal reasons need a breast-milk substitute that corresponds to the nutritional needs of a healthy infant.
- Infants who should not be breastfed for medical reasons need specially formulated foods which are not suitable for the healthy infant. Recognition of their special nutritional needs does not constitute an interference with the protection and promotion of breastfeeding.

B. Definition of breast-milk substitutes in the Code

The Code defines breast-milk substitutes as *"any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose"*.

Article 2 of the Code names the foods included in this definition: infant formula, as well as other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable for use as a partial or total replacement of breast milk.

Together this means **(1)** that infant formula is a breast-milk substitute that is nutritionally adequate to promote normal growth and development (when used in accordance with its directions for use), and **(2)** that for all other products it is the marketing or representation as a breast-milk substitute - suitable or not for that purpose - that brings them under the scope of the Code.

Foods for special medical purposes (FSMP), will not be marketed or represented as breast-milk substitutes for healthy infants, although they substitute for it for infants who are not healthy (see section F below). Instead, according to Codex Stan 180-1991, their labels have to declare their special composition, which makes them suitable for the dietary management of the named disorder(s).

C. Labelling of breast-milk substitutes according to the Code.

For all breast-milk substitutes as defined by article 2 of the Code the recommendations of the Code apply, i.e., those on educating and informing the public and especially mothers (**Articles 4, 5 , 6, 7, 8**) as well as those on quality (**Article 10**) and implementation and monitoring of the Code (**Article 11**).

Article 9.1 of the Code states that breast-milk substitutes (and other non-food products mentioned in the scope of the Code) should carry on their labels appropriate instructions for their use and should not discourage breastfeeding.

Food products, which are not infant formula, but which can be modified to be suitable for infant feeding, should carry warnings that they should not be the sole source of nourishment in their unmodified form (**Article 9.3**).

The labelling provisions in **Article 9.4** are standard provisions in the Codex Alimentarius for prepackaged foods.

The question of discouraging breastfeeding on labels of FSMP does not arise. Breastfeeding in the instances where FSMP are needed is prohibited or restricted on medical advice. FSMP are to be prescribed by a medical doctor and to be used under medical supervision only (see sections F and G below).

D. Definition of infant formula

According to **Article 3** of the Code infant formula means *a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age, and adapted to their physiological characteristics. Infant formula may also be prepared at home, in which case it is described as "home-prepared"*.

The existing **Codex Standard for Infant Formula** (Codex Stan 72-1981, amended 1983, 1985, 1987) 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 formula intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements*" (**section 1, scope**).

Section 2.1.2 requires in addition: *"The product shall be nutritionally adequate to promote normal growth and development when used in accordance with its directions for use".*

The proposed draft revised standard for infant formula (**Alinorm 01/26, Appendix V**) differs from the existing Codex Standard for Infant Formula (Codex Stan 72-1981) by naming healthy infants in section 1.1 first sentence, by putting the second sentence into square brackets, and by adding a half sentence in square brackets to section 2.1.2 *[and to satisfy by itself the nutritional requirements of infants during the first four to six months of life]*.

This means that infant formula, used directly or prepared with water, should be suitable to be used as exclusive food for infants for the same period as breast milk and, like breast milk, thereafter together with suitable complementary food, when breast milk or infant formula alone *"become insufficient to satisfy the nutritional requirements of the infant"* (**Article 3 of the Code**).

As will be seen in **Section F** below this definition of infant formula as a food suitable for exclusive feeding of an infant does not coincide with all the various types of FSMPs.

The existing and the proposed revised standard for infant formula contain detailed requirements with regard to **composition** (energy, protein, fat, carbohydrates, vitamins, minerals, trace elements and other nutrients), **quality and purity of ingredients, food additives, contaminants, hygiene** and **packaging**. Inclusion of FSMPs into the scope of this standard would, therefore, mean that all requirements for quality, purity, safety of ingredients and food additives, contaminants and hygiene would apply, whereas the composition of nutrients could vary according to the special nutritional needs. The desirability of identical quality and safety requirements for FSMPs intended for infants as for infant formula is evident, as is the idea that FSMPs for infants should be nutritionally appropriate for infants. However, the possible and necessary deviations from the compositional requirements for infant formula are numerous. They will mostly concern the macronutrients protein, fat and carbohydrates and micronutrient density.

A standard for infant formula is meant to cover the nutritional requirements of the majority of infants who are not breastfed. Like breast milk, infant formula can be contraindicated or will have to be restricted in use in some disorders that can be treated with a special diet.

E. Labelling of infant formula

Article 9.2 of the Code contains instructions for the labelling of infant formula. It requests a statement on the superiority of breastfeeding (over infant formula feeding), a statement that infant formula should be used only on the advice of a health worker, instructions for appropriate preparation and a warning against the health hazards of inappropriate preparation. It prohibits pictures of infants and texts idealizing the use of infant formula as well as certain terms. Similar provisions are contained in the proposed revised Codex Standard for Infant Formula.

A mandatory statement on the superiority of breastfeeding on the labels of FSMP intended for infants, who cannot be breastfed for medical reasons, is inappropriate, because for this minority of infants breast milk is not superior to the prescribed diet. Such a statement is liable to undermine the confidence of the parents in the special diet necessary for their infant.

F. Definition of foods for special medical purposes

The **Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes** (Codex Stan 180-1991) describes foods for special medical purposes in **section 2** as *"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 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".

This definition has been the basis of national legislation for foods for special medical purposes. An example is the directive 1999/21/EC on dietary foods for special medical purposes of the European Community.

This definition permits the classification of FSMPs in two major categories**:** nutritionally complete foods which can be used as the sole source of nourishment and nutritionally incomplete foods, which are not suitable to be used as the sole source of nourishment, but have to be complemented by other food products to cover all nutritional requirements of a patient.

The Codex Standard for the Labelling of and Claim for Foods for Special Medical Purposes (Codex Stan 180-1991) does not provide compositional criteria for FSMPs, however, in **section 3 General Principles** are stated: *"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 for special medical purposes should provide sufficient information on the nature and purposes 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*".

In the European Community the requirements for infant formula with regard to vitamins, minerals, and trace elements are the guiding principle for both nutritionally complete and incomplete foods for special medical purposes, with, however, important modifications being possible to meet the specific nutritional needs of the patients for whom the product is intended.

The Codex Standard for Infant Formula is not intended for nutritionally incomplete products, i.e. those which cannot be used for exclusive feeding for the first months of life. It does not provide guidance for the composition of nutritionally incomplete foods for special medical purposes with regard to micronutrients. However, these incomplete foods for special medical purposes, are numerous.

G. Labelling of foods for special medical purposes.

The labelling of FSMP is regulated in the **Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes** (Codex-Stan 180-1991). In addition to the rules laid down in the **Codex Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses** (Codex Stan 146-1985), nutrition labelling of energy, protein, carbohydrates, fat, vitamins and minerals is required, and the declaration of the amounts of essential and nonessential amino acids and/or individual fatty acids is permitted. Specific modifications of the content or nature of the macronutrients should be described and detailed profiles given. Products must bear a statement "*Use under medical supervision*" and, if appropriate, statements on potential hazards to the health of consumers for whom the product is not intended. Products should be clearly marked as intended or not intended as the sole source of nutrition. The label should bear a statement "*For the dietary management of ...*" naming the disease, disorder or medical condition the product is intended for, and name adequate precautions, side effects, contraindications and product-drug interactions. The label should explain the rationale for the composition and use of the product and describe its properties.

These labelling provisions differ, by necessity, essentially from those given in the Codex standard for Infant Formula and from those in the International Code of Marketing of Breast-milk Substitutes, both for breast-milk substitutes generally and infant formula specifically.

H. Suitability of the labelling provisions in the International Code of Marketing of Breast-milk Substitutes for foods for special medical purposes intended for infants

The Code's labelling provisions for breast-milk substitutes, including infant formula, have been described above in sections C and E. The provisions of **articles 9.1, 9.2, 9.3 and 9.4** are applicable. A description of

the characteristics of an FSMP, which make it suitable for and efficient in the dietary management of a disease, cannot be considered as discouraging breastfeeding.

However, the mandatory statement on labels for infant formula (**article 9.2 of the Code**) on the superiority of breastfeeding must be regarded as misplaced on the label of an FSMP intended for infants, that has to be given for medical reasons. The draft proposal for a revised standard for infant formula, which at present includes FSMP, does not sufficiently differentiate between the labelling of infant formula and that for FSMP intended for infants. There is not even a reference to Codex Stan 180-1991, neither are necessary exemptions from section 9.6 for the labelling of FSMP for infants considered.

I. Suitability of the infant formula standard's compositional, quality and safety provisions for foods for special medical purposes intended for infants.

The Codex Standard for Infant Formula aims to provide a product which can substitute for breast milk in that it meets the normal nutritional requirements of infants without disease, disorder or medical condition, i.e., the majority of infants who are not breastfed.

If an infant has special nutritional requirements because of a disease, disorder or medical condition, the composition of or the ingredients in infant formula (or breast milk) can become hazardous for the health of the infant and will have to be adapted or changed accordingly. As a rule, the resulting product for special medical purposes will no longer be suitable for the healthy infant.

Section 3 of the Standard for Infant Formula not only deals with the general nutritional needs of an infant, but also with the choice, quality and purity of ingredients used. The rules for the latter are applicable to FSMP as well, as are the rules in **Sections 5 to 8**. However, with regard to food additives in **section 4**, it is to be expected that different food additives will be needed for some FSMP.

FSMP that are nutritionally complete, i.e. suitable for the exclusive feeding of an infant patient, should contain all indispensable nutrients. The present **section 3.1.2 b** does not cover all indispensable trace elements. This is acceptable in the case of infant formulas, which, as a rule, are made from natural ingredients and, can be expected to contain the necessary amounts of these trace elements. In the case of FSMP made from modified natural or synthetic ingredients, which cannot be guaranteed to contain these trace elements, it is not.

J. Conclusions

- Some FSMPs intended for infants can be regarded as breast-milk substitutes suitable as a partial or total replacement of breast milk for feeding the minority of infants who need them for medical reasons
- Some FSMPs intended for infants cannot completely substitute for breast milk.
- FSMPs, however, should not be marketed as breast-milk substitutes intended for all infants.
- FSMPs are contraindicated for healthy infants.
- The marketing and presentation of FSMP should be directed at the dietary management of the disease, disorder or medical condition for which they have been formulated and for which they have been shown to be effective.
- The necessary labelling provisions for FSMPs intended for infants differ essentially from those for infant formula.
- The requirements for the quality and safety of the ingredients, for contaminants, hygiene and packaging and the control of food additives for FSMPs intended for infants should be (at least) as stringent as those for infant formula.
- Advertising and promotion of infant formula to the general public are restricted by Article 5 of the International Code of Marketing of Breast-milk Substitutes. Similar restrictions are contained in the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes and apply to foods for special medical purposes for infants.