

The logo for the International Special Dietary Foods Industries (ISDI) features the letters 'ISDI' in a white, bold, sans-serif font. The letter 'I' is positioned to the left of the 'S', 'D', and 'I'. The letter 'D' is significantly larger than the other letters and has a vertical line extending upwards from its top, which continues as a thin white line above the 'I'.

International Special
Dietary Foods Industries

Foods For Special Medical Purposes (FSMP)

DISCLAIMER

This guidance document is intended to provide information on Foods for Special Medical Purposes (FSMP) in the context of the Codex Alimentarius. It is for general information purposes only and does not constitute legal or other professional advice. It does not replace the relevant Codex Standards and should be read in conjunction with all the relevant texts at Codex Alimentarius level. The information provided is without prejudice to national regulations and interpretations. A full and updated list of Codex texts ([standards](#), [guidelines](#) and [codes of practice](#)) contained within this document can be found on the Codex website. ***Sections in italic are directly taken from Codex texts.***

The development of this brochure has been coordinated by Xavier Lavigne, ISDI Board Member and Marian Brestovansky, ISDI Secretariat. Members of the ISDI Task Force on FSMPs contributed to this work.

USER GUIDE

TARGET GROUP

The audience for the brochure is food business manufacturers and national authorities.

PURPOSE OF THE BROCHURE

The brochure provides the international background regarding Foods for Special Medical Purposes (FSMP) based on THE STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES – [CODEX STAN 180-1991](#) (FSMP) which defines at international level this category of products.

The [CODEX ALIMENTARIUS](#) international food standards, guidelines and codes of practice contribute to the safety, quality and fairness of international food trade. Codex standards are based on sound science provided by independent international risk assessment bodies or ad hoc consultations organised by FAO and WHO.

The brochure is for general information purpose and aims to facilitate the reading and understanding of:

- THE CODEX STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES – [CODEX STAN 180-1991](#)
- The FSMP section of the CODEX STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS – [CODEX STAN 72-1981](#)
- THE CODEX STANDARD FOR FORMULA FOODS FOR USE IN VERY LOW ENERGY DIETS FOR WEIGHT REDUCTION – [CODEX STAN 203-1995](#)

The brochure can be used as a support for Food Business Manufacturers as an educational material (e.g. internal trainings) or as a background element for discussions with national authorities regarding Foods for Special Dietary Uses (FSDU) and Foods for Special Medical Purposes which are a category of FSDU.

The brochure does not consider the specific regulations of FSDU, FSMP or other specialised nutrition products in each country and should not be considered in isolation.

KEY MESSAGES OF THE BROCHURE

- 1) FSMP are specific FSDU. See the [ISDI brochure on FSDU](#)
- 2) Codex Alimentarius defines general labelling and claims requirements for FSMP and also further defines specific FSMPs through different texts that cover Formulas for special medical purposes intended for infants (iFSMP), very low calorie diet (Formula Foods for Use in Very Low Energy Diets for Weight Reduction), and in future Ready to Use Therapeutic Food (RUTF).
- 3) The approach of a general framework via THE CODEX STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES – [CODEX STAN 180-1991](#) offers the flexibility necessary to formulate a *very diverse range of* FSMPs to meet the nutritional requirements of a wide variety of health conditions.
- 4) FSMP are FSDU at Codex level and therefore remain food products and should comply with all the relevant Codex texts and requirements established by Codex Alimentarius.

BROCHURE ORGANISATION

Foods for Special Medical Purposes in the Codex Alimentarius framework

Standard for the Labelling of and Claims for Foods for Special Medical Purposes

The Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes ([CODEX STAN 180-1991](#)) defines in section 2 (Description) Foods for special medical purposes *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 metabolize 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.*

Formulas for Special Medical Purposes intended for infants (IFSMP)

The Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants provides that *Formula for Special Medical Purposes Intended for Infants means a substitute for human milk or infant formula that complies with Section 2, Description, of the 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* (Section B Section 2.1 Product definition in [CODEX STAN 72-1981](#)).

Formula Foods for Use in Very Low Energy Diets for Weight Reduction

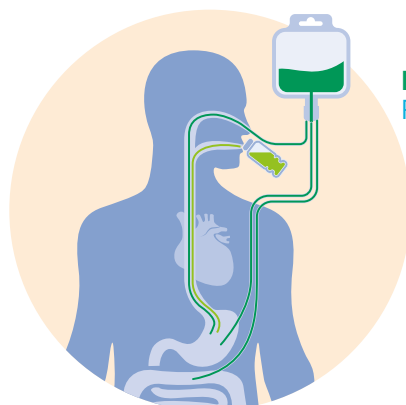
The Codex Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction ([CODEX STAN 203-1995](#)) provides that:

- *A formula food for use in very low energy diets is a food specially prepared to supply a minimum amount of carbohydrates and the daily requirements of the essential nutrients in 450–800 kcal which represents the sole source of energy intake* (Section 2 Definition in [CODEX STAN 203-1995](#)).
- *These foods are defined as foods for special medical purposes and must be used under medical supervision by individuals with moderate or severe obesity. The matter of sale on prescription should be a decision made at national level. This Standard does not apply to prepackaged meals presented in the form of conventional foods* (Section 1 Scope in [CODEX STAN 203-1995](#)).

Ready to Use Therapeutic Food (RUTF)

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is developing a Guideline for another specific FSMP, the Ready to Use Therapeutic Foods (RUTF), category intended for older infants and children with severe acute malnutrition. Please note that this ISDI brochure is not covering this category in a specific section as it is not yet finalized.

FSMP MODE OF ADMINISTRATION



ENTERAL NUTRITION (EN)
FSMP

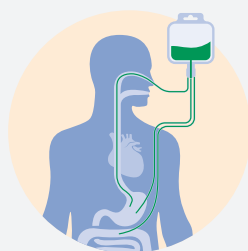
ORAL NUTRITIONAL (ON)
FSMP

FOODS FOR SPECIAL MEDICAL PURPOSES (FSMP)



ORAL NUTRITION (ON)

Oral Nutrition refers to nutrients taken by mouth. It is designed to meet the specialized nutritional needs of a variety of patients who can take nutrition by mouth. Oral Nutrition provides macronutrients and micronutrients and is designed to be consumed orally, thus taste and format are important considerations. ON is available as ready-to-drink liquids or powders that can be prepared as drinks (also called 'sip feeds'). They may be suitable as a sole source of nutrition, to help maintain nutrition status or as a supplement to normal foods. ON is an effective and non-invasive solution to tackle Disease Related Malnutrition (DRM). ON can be effective in a large number of diseases, medical conditions and their dietary management – including cancer, stroke/cerebrovascular accident (CVA), neurological and gastrointestinal conditions, and surgery.



ENTERAL NUTRITION (EN)

Enteral Nutrition (EN) is defined in this brochure as nutrition provided through the gastrointestinal tract via a tube, catheter, or stomach that delivers nutrients distal to the oral cavity. EN is required when a patient is unable to consume sufficient nutrition via the oral route. Examples include severe cystic fibrosis, cerebral palsy, after a stroke/cerebrovascular accident (CVA), or major surgery, head and neck trauma and critical illness (e.g. burns). EN can be supplementary to oral intake or parenteral nutrition, or can be the sole source of nutrition

PARENTERAL NUTRITION (PN) IS NOT AN FSMP

Parenteral Nutrition – also known as 'intravenous feeding' – is primarily utilised when the gastrointestinal tract does not provide the necessary nutrition support. Individuals are fed directly via peripheral or central vein into the bloodstream. It is generally regulated as a pharmaceutical product. Parenteral Nutrition is not covered by the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991), which clearly specifies that the statement "The product is not to be used for parenteral administration" shall appear on the label of FSMP.

EXAMPLES OF PRODUCT USE AND TARGET POPULATIONS

You will find below a non-exhaustive list of examples of FSMP considering the purpose of the FSMP or the target patient group:

FSMP for infants (IFSMP)

Covered by the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants ([CODEX STAN 72-1981](#)), IFSMP are Infant Formula products designed for the dietary management of infants with specific disorders, diseases or medical conditions such as prematurity, low birthweight, cow milk protein allergy, severe food allergy, gastrointestinal disorders, disorders of fat metabolism, and rare genetic metabolic disorders such as galactosemia.

FSMP for children

These FSMP are for a child with a disease, disorder or medical condition. They are meant for children that are unable to meet their nutritional needs via the normal diet due to disease, feeding difficulties, etc. Children need nutrients to support rapid growth and development in the early years of life. Around the world, children with feeding difficulties present a significant problem. The consequences of inadequate nutrition in childhood can be serious. Children who do not get complete and balanced nutrition for extended periods may experience nutrient deficits, growth deficiencies and impaired cognitive development, as well as compromised immune function with increased risk for infectious diseases.

FSMP for inborn errors of metabolism

Infants, children and adults with inborn errors of metabolism lack the ability to utilize specific nutrients, such as amino acids, and thus require very precisely controlled nutrient intakes to manage their condition. These FSMP ensure growth in children and health in adults. These products are specially designed to provide carefully controlled intakes of specific amino acids or other specific nutrients. Inborn errors of metabolism cover conditions such as tyrosinaemia, homocystinuria, phenylketonuria (PKU), maple syrup urine disease (MSUD), etc.

FSMP for patients with diabetes

These FSMP also called Diabetes-specific formulas (DSF) are a safe, efficacious and cost-effective strategy to support the management of patients with or at risk for poor glucose control. Dietary management and behavioural guidance that help manage glycaemic levels and support metabolic control can provide tremendous support to individuals who must manage diabetes and its complications. Proper nutrition is essential for patients with diabetes to minimize glycaemic spikes and improve Hemoglobin A1C (HbA1c).

FSMP for re-hydration purposes

These products are intended to maximize intestinal absorption of fluid and electrolytes, especially those due to losses from diarrhoea and excessive vomiting.

FSMP for disease related malnutrition

Many conditions can impact the ability to ingest, digest, metabolize, and excrete nutrients which can lead to malnutrition. These products are specifically designed to accommodate the altered nutritional needs caused by different diseases conditions by modifying the types, levels, and forms of nutrients. Diseases or medical conditions can be for example Stroke/Cerebrovascular Accident (CVA), Dementia, Dysphagia, Renal Failure, Cancer, Surgery, Cystic Fibrosis, AIDS, Crohn's Disease, etc.

FSMP IN THE CODEX ALIMENTARIUS FRAMEWORK FOR FSDU

FSDU	General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) – Applies to all FSDU including FSMP
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FSDU COMMODITIES

The following FSDU commodities have standards established by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU):

Infant Formula and <i>IFSMP</i>	Infant formula and <i>formulas for special medical purposes intended for infants*</i> (CODEX STAN 72-1981) Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children (CAC/GL 10-1979)
Follow Up Formula	Follow up formula (CODEX STAN 156-1987) Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children (CAC/GL 10-1979)
Baby Food	Formulated Complementary Foods for Older Infants and Young Children (CODEX CAC/GL 8-1991) Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981) Standard for Canned Baby Foods (CODEX STAN 73-1981)
<i>Food for Special Medical Purpose (FSMP)</i>	<i>Standard for Labelling of and Claims for Foods for Special Medical Purposes*</i> (CODEX STAN 180-1991) <i>Formulas for special medical purposes intended for infants*</i> (CODEX STAN 72-1981) <i>Ready to use Therapeutic Food (RUTF) – under development*</i>
Formula foods for use in weight control diets	Formula Foods for Use in Weight Control Diets (CODEX STAN 181-1991)
<i>Formula foods for use in very low energy diets for weight reduction</i>	<i>Formula Foods for Use in Very Low Energy Diets for Weight Reduction*</i> (CODEX STAN 203-1995)
Gluten Free Food	Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118-1979)
Low Sodium Food	Standard for Special Dietary Foods with Low-Sodium Content (Including Salt Substitutes) (CODEX STAN 53-1981)

OTHER EXAMPLE OF FSDU CATEGORIES NOT SPECIFICALLY DEFINED BY CODEX

Sports Food	Sports food : FSDU specifically designed, formulated and marketed in relation to physical activity, physical performance and/or post-exercise recovery & bearing nutrition and/or health claim(s)
Other FSDU	Other products meeting the definition of FSDU but not already falling under the above mentioned categories.

* *FSMP*

OTHER CODEX STANDARDS, GUIDANCE, AND CODES APPLICABLE TO FSMP

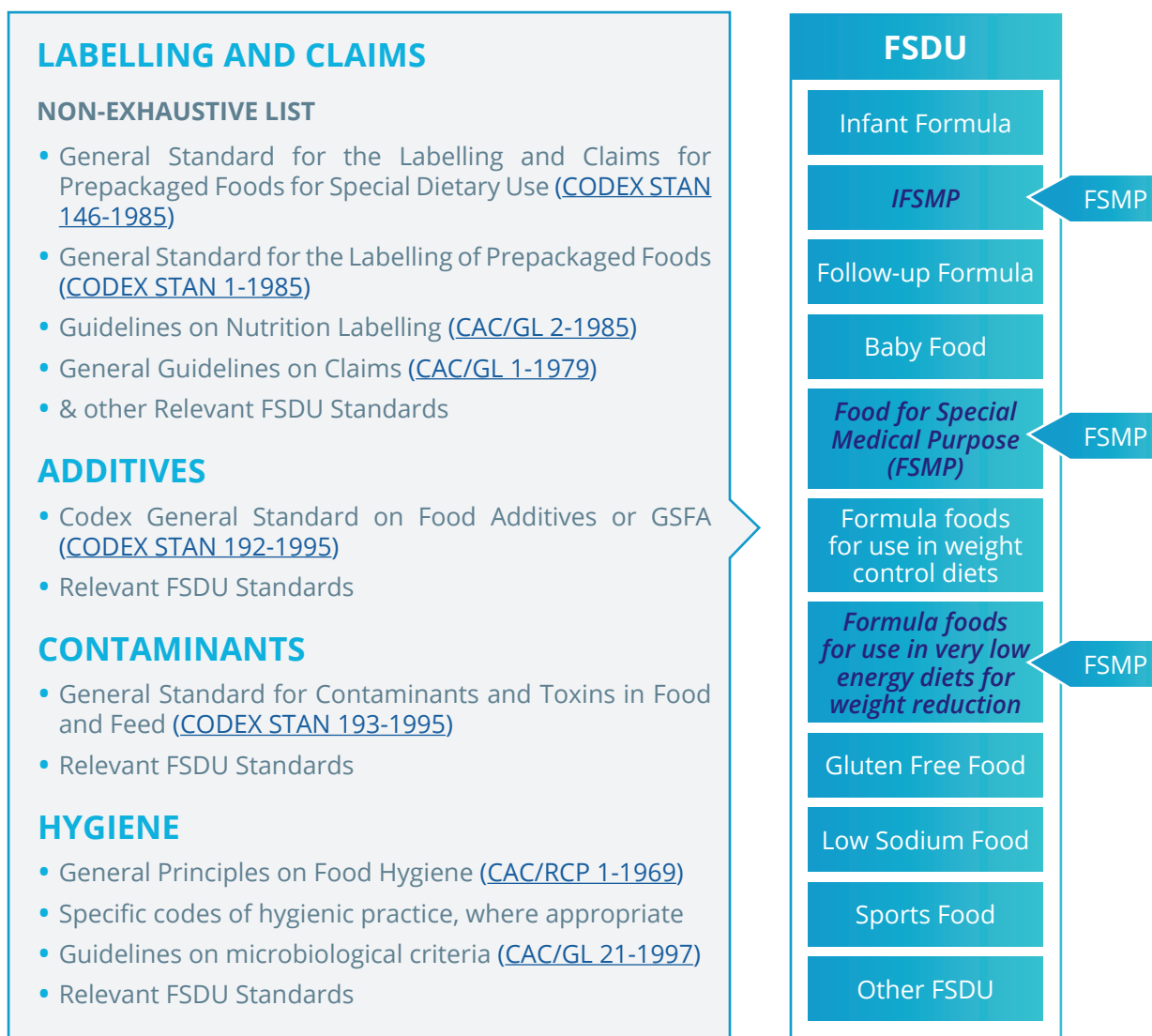
Specific requirements applying to FSMP from the FSDU codex standard

[SEE ISDI BROCHURE ON FSDU](#)

Requirements applicable to Food for Special Dietary Use (FSDU) as defined in the General Standard for the labelling of and claims for prepackaged Foods for Special Dietary Use ([CODEX STAN 146-1985](#)) are applicable to FSMP unless specific provisions are included in the Standard for the labelling of and claims for Foods for Special Medical Purpose ([CODEX STAN 180-1991](#)).

In addition to the FSDU requirements applicable to FSMP, many other Codex Standards, Guidance and Codes are applicable to FSMP. The graph below is a simplified and non-exhaustive representation of this interaction between various Codex Texts.

The FSMP Standard should therefore never be read in isolation and should always be considered in conjunction with other relevant Codex texts. It is the responsibility of the Food Business Manufacturer to assess all the relevant Codex and national/regional requirements applicable to FSMP before marketing the product.



CONTENT OF THE STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES – [CODEX STAN 180-1991](#)

This section covers specific requirements for the labelling of and claims for foods for special medical purposes ([CODEX STAN 180-1991](#)).

The Standard for the labelling of and claims for Foods for Special Medical Purpose (FSMP) focuses on the labelling and claims elements in relation to foods falling into the category of Foods for Special Medical Purpose.

It is worth noting that contrary to other Codex Standards, there are no composition criteria as this Standard focuses on the general principles in relation with the labelling and claims for this specific category of products. This approach allows for flexibility in composition of FSMP intended for a wide variety of health conditions while ensuring that FSMP meet the conditions and general principles established by the FSMP Standard ([CODEX STAN 180-1991](#)). Composition criteria for 3 specific categories of FSMP are however defined by CODEX standards/texts: Formulas for special medical purposes intended for infants, Very Low calorie Diets (VLCD) and in the future Ready to Use Therapeutic Foods (RUTF).

The Standard for the Labelling of and Claims for Foods for Special Medical Purpose ([CODEX STAN 180-1991](#)) provides for the following elements (further detailed in the following pages of this Guidance document):

1	SCOPE	Provides the scope of the Standard
2	DESCRIPTION	Provides the description
3	GENERAL PRINCIPLES	Provides the general principles
4	LABELLING	Provides the labelling requirements

Scope

This standard applies to the labelling of and claims for foods for special medical purposes as defined in Section 2 (Description), and presented as such.

Description of FSMP

1

A category of foods for special dietary uses (FSDU), as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (Section 2, Description in [CODEX STAN 146-1985](#)).

2

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 metabolize 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 (Section 2, Description, in [CODEX STAN 180-1991](#)).

General principles from the FSMP codex alimentarius standard

General Principles of the Standard for the labelling of and claims for Foods for Special Medical Purpose ([CODEX STAN 180-1991](#)) are listed in Section 3.

1

The formulation of foods for special medical purposes should be based on sound medical and nutritional principles.

2

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.

3

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.

4

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.

Labelling requirements applying to FSMP from the FSDU codex standard

Labelling of the Standard for the labelling of and claims for Foods for Special Medical Purpose ([CODEX STAN 180-1991](#)) is listed in Section 4.

FSMP 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:

- *Section 4.3: Nutrition Labelling*
- *Section 5.1: Quantitative labelling of ingredients*
- *Section 5.2.2 and :5.2.3 : Claims*
- *Section 6 : Exemptions from mandatory labelling requirements*

of the General Standard for the Labelling of and Claims for Prepackaged FSDU do not apply to the Labelling of FSMP.

Nutrition Labelling

Nutrition Labelling of the Standard for the labelling of and claims for Foods for Special Medical Purpose ([CODEX STAN 180-1991](#)) is listed in section 4.2.

Declaration of nutrient content	<i>Shall be numerical. However, the use of additional means of presentation should not be excluded.</i>
Energy value	<i>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.</i>
Amounts of protein, carbohydrate and fat	<i>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.</i>
Amounts of vitamins and essential minerals	<i>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.</i>
Quantity of nutrients	<i>May be expressed in terms of percentages of the relevant internationally recognized recommended daily allowances.</i>
Osmolality or osmolarity and/or on acidbase balance	<i>Shall be given when appropriate.</i>
Serving sizes	<i>In countries where serving sizes are normally used, the information described for energy value or the amounts of vitamins and essential minerals 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.</i>
Protein nature	<i>Information on the nature of the animal or plant proteins or protein hydrolysates should be provided.</i>
Modification of the content or the nature of the proteins, fats or carbohydrates	<i>FSMPs 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.</i>

Date Marking

Date Marking of the Standard for the labelling of and claims for Foods for Special Medical Purpose ([CODEX STAN 180-1991](#)) is provided in Section 4.3.

Date Marking	<i>The date of minimum durability as provided for in Section 4.7 (Date marking and storage instructions) of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) shall be declared.</i>
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Additional Information

Additional Labelling Information of the Standard for the labelling of and claims for Foods for Special Medical Purpose ([CODEX STAN 180-1991](#)) is provided in Section 4.4.

Medical Supervision	<i>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.</i>
Preparation	<i>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.</i>
Warning statement in case of Health Hazard when consumed by individuals who do not have the disease(s)	<i>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.</i>
Parenteral Nutrition	<i>A statement that the product is not to be used for parenteral administration shall appear on the label.</i>
Source of Nutrition	<i>A prominent statement indicating whether the product is or is not intended as the sole source of nutrition shall appear on the label.</i>

Information to be included in the Labelling

Information to be included in the Labelling of the Standard for the labelling of and claims for Foods for Special Medical Purpose ([CODEX STAN 180-1991](#)) is listed in Section 4.5.

The information below may be provided separately from the package.

For the dietary management of	<i>A 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.</i>
Precautions, Side effects, Contraindications, and Product-drug interactions	<i>A complete statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable.</i>
Rationale for the use	<i>A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.</i>
Specific age group	<i>If the product has been formulated for a specific age group, it should carry a prominent statement to this effect.</i>
Nutritional modifications	<i>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.</i>
Feeding instructions	<i>Feeding instructions, including the method of administration and serving size, if applicable.</i>

CONTENT OF THE STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSE INTENDED FOR INFANTS (IFSMP)

CODEX STAN 72-1981

This section covers specific requirements for formulas for special medical purpose intended for infants (IFSMP) ([CODEX STAN 72-1981](#)).

The Standard for Infant Formula and Formulas for Special Medical Purpose Intended for Infants ([CODEX STAN 72-1981](#)) provides for the following elements regarding Infant Formula for Special Medical Purpose (IFSMP) in its section B:

1	SCOPE	Provides the scope of the Standard
2	DESCRIPTION	Provides the product definition
3	ESSENTIAL COMPOSITION AND QUALITY FACTORS	To be noted sections on : <ul style="list-style-type: none"> • Vitamin Compounds and Mineral Salts • Consistency and Particle Size • Purity Requirements • Specific Prohibitions Refer to section A of the Standard for Infant Formula and Formulas for Special Medical Purpose Intended for Infants (CODEX STAN 72-1981) covering Infant Formula.
4	FOOD ADDITIVES	Refers to section A of the Standard (CODEX STAN 72-1981) covering Infant Formula.
5	CONTAMINANTS	Refers to section A of the Standard (CODEX STAN 72-1981) covering Infant Formula.
6	HYGIENE	Refers to section A of the Standard (CODEX STAN 72-1981) covering Infant Formula.
7	PACKAGING	Refers to section A of the Standard (CODEX STAN 72-1981) covering Infant Formula.
8	FILL OF CONTAINER	Refers to section A of the Standard (CODEX STAN 72-1981) covering Infant Formula.
9	LABELLING	To be noted sections on : <ul style="list-style-type: none"> • List of Ingredients • Date Marking and Storage Instructions • Information for Use Refer to section A of the Standard (CODEX STAN 72-1981) covering Infant Formula.
10	METHODS OF ANALYSIS	Refers to section A of the Standard (CODEX STAN 72-1981) covering Infant Formula.

This section only covers specific requirements for **Formulas for Special Medical Purposes Intended for Infants (IFSMP)** provided by Section B of the Standard for Infant Formula and Formulas for Special Medical Purpose Intended for Infants ([CODEX STAN 72-1981](#)). Elements from section A concerning Infant Formula in general are not covered by this guidance.

Description of IFSMP

Product definition	<i>Formula for Special Medical Purposes Intended for Infants means a substitute for human milk or infant formula that complies with Section 2, Description, of the 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.</i>
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Essential composition and quality factors of IFSMP

Ingredients	<i>Formula for Special Medical Purposes intended for Infants is a product based on ingredients based of animal, plant and/or synthetic origin suitable for human consumption.</i>
Gluten free	<i>All ingredients and food additives shall be gluten-free.</i>
Scientific evidence	<i>The composition of Formula for Special Medical Purposes Intended for Infants shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the formula shall be scientifically demonstrated to support growth and development in the infants for whom it is intended, as appropriate for the specific products and indications. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.</i>
Energy and nutrient composition	<i>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 of the Standard for Infant Formula and Formulas for Special Medical Purpose Intended for Infants (CODEX STAN 72-1981), 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 specifically formulated, labelled and presented.</i>

In addition the following requirements shall also be taken into account, where appropriate:

	Unit	Minimum	Maximum	GUL
Chromium	µg/100 Kcal	1.5	-	10
	µg/100 KJ	0.4	-	2.4
Molybdenum	µg/100 Kcal	1.5	-	10
	µg/100 KJ	0.4	-	2.4

Optional ingredients

Addition of other ingredients	<i>Other ingredients may be added in order to provide substances ordinarily found in human milk or required to ensure that the formulation is suitable as the sole source of nutrition for the infant and for the dietary management of his/her disease, disorder or medical condition.</i>
Suitability	<i>The suitability for the intended special medical purpose, the suitability 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.</i>
L(+)-lactic acid producing cultures	<i>Only L(+)-lactic acid producing 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.</i>

Labelling of IFSPM

Name of the food	<i>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</i>
Cow's milk as sole source of protein	<i>If cows' milk is the only source of protein, the product may be labelled "Formula for Special Medical Purposes Intended for Infants Based on Cows' Milk".</i>
Declaration of Nutritive Value	<i>Formula for Special Medical Purposes Intended for Infants shall be labelled with complete nutrition labelling according to Section 4.2 (Nutrition Labelling) of Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).</i>

Additional Labelling Requirements for IFSMP	
Medical Supervision	<i>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.</i>
Warning statement in case of Health Hazard when consumed by individuals who do not have the disease(s)	<i>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.</i>
Parenteral Nutrition	<i>A statement that the product is not to be used for parenteral administration shall appear on the label.</i>
For the dietary management of	<i>A 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.</i>
Nutritional modifications	<i>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.</i>
Sole source of nutrition	<i>A prominent statement indicating that the product is intended as the sole source of nutrition shall appear on the label.</i>
Precautions, Side effects, Contraindications, and Product-drug interactions	<i>A complete statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable</i>
Rationale for the use	<i>A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.</i>
Feeding instructions	<i>Feeding instructions, including the method of administration and serving size, if applicable.</i>
Breastfeeding	<i>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.</i>

CONTENT OF THE STANDARD FOR FORMULA FOODS FOR USE IN VERY LOW ENERGY DIETS FOR WEIGHT REDUCTION (VLCD)

[CODEX STAN 203-1995](#)

This section covers specific requirements for Formula Foods for Use in Very Low Energy Diets for Weight Reduction ([CODEX STAN 203-1995](#)).

The Standard for for Formula Foods for Use in Very Low Energy Diets for Weight Reduction ([CODEX STAN 203-1995](#)) provides for the following elements regarding VLCD :

1	SCOPE	Provides the scope of the Standard
2	DESCRIPTION	Provides the product definition
3	ESSENTIAL COMPOSITION AND QUALITY FACTORS	To be noted sections on : <ul style="list-style-type: none"> • Energy content • Nutrients Contents: <ul style="list-style-type: none"> * Protein * Fats * Carbohydrates * Vitamins and minerals * Ingredients
4	FOOD ADDITIVES	Authorized food additives
5	CONTAMINANTS	Pesticide residues
6	HYGIENE	Hygiene requirements
7	PACKAGING	Packaging requirements
8	FILL OF CONTAINER	Fill of container requirements
9	LABELLING	<ul style="list-style-type: none"> • List of Ingredients • Declaration of Nutritive Value • Date Marking • Storage Instructions: <ul style="list-style-type: none"> * Unopened Food * Information for Utilization • Additional provisions

Description of VLCD products

<p>Scope of the Standard</p>	<p>The Codex Standard for Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction (CODEX STAN 203-1995) provides <i>that this standard applies to formula foods for use in very low energy diets for weight reduction as defined in Section 2. These foods are defined as foods for special medical purposes and must be used under medical supervision by individuals with moderate or severe obesity. The matter of sale on prescription should be a decision made at national level. It does not apply to prepackaged meals presented in the form of conventional foods. (Section 1 Scope in CODEX STAN 203-1995).</i></p>
<p>Definition</p>	<p>The Codex Standard for Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction (CODEX STAN 203-1995) provides that a formula food for use in very low energy diets is a food specially prepared to supply a minimum amount of carbohydrates and the daily requirements of the essential nutrients in 450–800 kcal which represents the sole source of energy intake (Section 2 Definition in CODEX STAN 203-1995).</p>

Essential composition and quality factors

The product as sold should comply with the following composition and quality factors:

<p>Energy Content 450 < E < 800 kcal per day</p>	<p>A formula food for very low energy diets shall provide when prepared according to instructions a daily energy intake of 450–800 kcal as the only source of energy.</p>
<p>Nutrients Contents</p>	
<p>Protein</p>	<ul style="list-style-type: none"> • Not less than 50 g protein with a nutritional quality (1) equivalent to a protein-digestibility-corrected amino acid score of 1 shall be present in the recommended daily intake of energy. • Essential amino acids may be added to improve protein quality only in amounts necessary for this purpose. Only L-forms of amino acids shall be used, except that DL-methionine may be used.
<p>Fats</p>	<p>(1) Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Bethesda, MD USA, 4–8 December 1989, FAO Food and Nutrition Paper No. 51, 1991, Rome, p. 23.</p> <p>Very low energy diets shall provide not less than 3 g of linoleic acid and less than 0.5 g α-linolenic acid in the recommended daily intake with the linoleic acid/α-linolenic acid ratio between 5 and 15.</p>

Carbohydrates

Very low energy diets shall provide not less than 50 g of available carbohydrates in the recommended daily intake of energy.

Vitamins and Minerals

Very low energy diets shall provide 100% of the recommended daily intakes for vitamins and minerals. Other essential nutrients not specified below may also be included.

These lists should be reviewed when new FAO/WHO recommendations become available.

Vitamins

Vitamin A	600 µg
Vitamin D	2.5 µg
Vitamin E	10 mg
Vitamin C	30 mg
Thiamin	0.8 mg
Riboflavin	1.2 mg
Niacin	11 mg
Vitamin B6	2 mg
Vitamin B12	1 µg
Folic Acid (as monoglutamate)	200 µg

Minerals

Calcium	500 mg
Phosphorus	500 mg
Iron	16 mg
Iodine	140 µg
Magnesium	350 mg
Copper	1.5 mg
Zinc	6 mg
Potassium	1.6 g
Sodium	1.6 g

* The value of 15 µg is based on minimal sunlight exposure throughout the year. Competent national and/or regional authorities should determine an appropriate NRV-R that best accounts for population sunlight exposure and other relevant factors.

Essential composition and quality factors

The product as sold should comply with the following composition and quality factors:

Ingredients	<i>Very low energy diets shall be prepared from protein constituents of animal and/or plant which have been proved suitable for human consumption and from other suitable ingredients necessary to achieve the essential composition of the product as set out in Sections 3.1 (Energy Content) and 3.2 (Nutrients Contents) above.</i>
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Food Additives

Food additives cleared by the Joint FAO/WHO Expert Committee on Food Additives shall be permitted at levels endorsed by the Codex Committee on Food Additives and Contaminants.

Contaminants

Pesticide Residues	<i>The product shall be prepared with special care under good manufacturing practices, so that no residues of pesticides, which may be required in the production, storage or processing of the raw materials or the finished food ingredient, remain in the product, or, if technically unavoidable, are reduced to the maximum extent possible, and shall comply with those maximum residue limits established by the Codex Committee on Pesticide Residues for this commodity.</i>
Other Contaminants	<i>The product shall be free from residues of hormones and antibiotics, as determined by means of agreed methods of analysis, and practically free from other contaminants especially pharmacologically active substances</i>

Hygiene

GMP	<i>To the extent possible in good manufacturing practices, the product shall be free from objectionable matter.</i>
Tests	<i>When tested by appropriate methods of sampling and examination, the product: (a) Shall be free from pathogenic microorganisms; (b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and (c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.</i>

Packaging

- The product shall be packed in containers which will safeguard hygienic and other qualities of the foods. When in liquid form, the product shall be thermally processed and packed in hermetically sealed containers to ensure sterility; nitrogen and carbon dioxide may be used as packing media.*
- 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 substances, used as packaging materials, that standard shall apply.*

Fill of container

In the case of products in ready-to-eat form, the fill of the container shall be:

- (a) Not less than 80% v/v for products weighing less than 150 g (5 oz);*
- (b) not less than 85% v/v for products in the weight range of 150–250 g (5–8 oz); and*
- (c) 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 when completely filled.*

Labelling

In addition to the appropriate Sections of the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) and the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991), the following specific provisions apply:

Name of the food	<i>The name of the food shall be “Formula Food for Use in Very Low Energy Diets”.</i>
List of Ingredients	<i>A complete list of ingredients shall be declared in accordance with Section 4.2 (List of ingredients) of the General Standard.</i>
Declaration of Nutritive Value	<ul style="list-style-type: none"><i>• The nutritive value shall be declared on the label per 100 grammes or 100 ml of the food as sold and, where appropriate, for a specified quantity of the food as suggested for consumption:<ul style="list-style-type: none"><i>(a) The amount of energy expressed in kilocalories (kcal) and kilojoules (kJ);</i><i>(b) the amounts of protein, available carbohydrates and fat expressed in grammes;</i><i>(c) the amounts of vitamins and minerals in Section 3.2.4 (Vitamins and Minerals) expressed in metric units;</i><i>(d) the amounts of other nutrients may also be declared.</i></i><i>• If the fatty acid composition is declared on the label, it should be done in accordance with the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985).</i><i>• In addition, the quantity of nutrients may be expressed in terms of percentages of internationally acceptable recommended daily nutrient standards.</i>
Date Marking	<ul style="list-style-type: none"><i>• The date of minimum durability shall be declared in accordance with Section 4.7.1 (Date marking and storage instructions) of the General Standard.</i>

Unopened food	<i>Any special conditions for the storage of the food shall be declared on the label if the validity of the date depends thereon. Storage instructions of opened packages of the food shall be included on the label to ensure that the opened food maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.</i>
Information for Utilization	<i>In addition to the appropriate sections of the Codex Standard on the Labelling of and Claims for Foods for Special Medical Purposes, the following directions should be provided:</i>
Obesity	<ul style="list-style-type: none"> • <i>The statement “for the dietary management of obesity” shall be declared on the label, in close proximity to the name of the food.</i>
Fluid	<ul style="list-style-type: none"> • <i>Reference to the importance of maintaining adequate daily fluid intake.</i>
Population for whom the product is not indicated	<ul style="list-style-type: none"> • <i>A statement that the product should not be used by pregnant, nursing and lactating women or by infants, children, adolescents and elderly, except when medically indicated.</i>
Additional provisions	
Additional mandatory statement	<i>A statement that the product may not be recommended for use for purposes other than the dietary management of obesity.</i>
Position of the Name of the food and indication of use	<i>The statements with respect to the name of the food and the indications for use as given in Sections 9.1 (Formula Food for Use in Very Low Energy Diets) and 9.6 (Information for Utilization) shall appear on the label of the package and/or sachet for use by the consumer.</i>
Position of the other mandatory statements	<i>Other statements, as required under Section 9.6 (Information for Utilization) above and Section 4.5 (Information to be Included in the Labelling) of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (See page 9 of this brochure), may appear on an accompanying leaflet in which case reference shall be made to this fact on the label of the package and/or sachet.</i>



International Special
Dietary Foods Industries

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

Legal seat: 3200 Windy Hill Road, Marietta GA 30339, Atlanta, USA

Operating office: Avenue de Tervueren, 188A, Postbox 4, 1150 Brussels, Belgium

Tel.: +32 (0)2 761 16 80 – Email: secretariat@isdi.org

Web: <http://www.isdi.org/>