

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 Dietary Uses (FSDU)

DISCLAIMER

This guidance document is intended to provide information on Foods for Special Dietary Uses (FSDU) 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. Sections in italic are directly taken from Codex texts.

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 Dietary Uses (FSDU) based on THE GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES — CODEX STAN 146-1985, which establishes 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 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 GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES — CODEX STAN 146-1985.

The brochure can be used as a support for Food Business Manufacturers (e.g. internal trainings programs) or as a background element for discussions with national authorities regarding Foods for Special Dietary Uses.

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

KEY MESSAGES OF THE BROCHURE

- 1)** Foods for Special Dietary Uses are defined at Codex Alimentarius level as *foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such⁽¹⁾. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.*
- 2)** Codex Alimentarius also further defines specific FSDU through different texts that cover among others and in broad terms infant formula, follow-up formula, complementary foods, foods for special medical purposes, meal replacement and total diet replacement, gluten free food, low sodium food.
- 3)** Other FSDU exist and are recognized in some national regulations, but are not necessarily defined at Codex Alimentarius level. One example is the sports food category.
- 4)** FSDU remain food products and should therefore comply with all the relevant Codex texts and requirements established by Codex Alimentarius, unless provided otherwise.

⁽¹⁾ This includes foods for infants and young children.

CONTENT OF THE GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES — CODEX STAN 146-1985

The Standard for the Labelling and Claims for Prepackaged Foods For Special Dietary Uses (FSDU) focuses on the labelling and claims elements in relation to prepackaged foods falling into the category of Foods for Special Dietary Uses.

There are no composition criteria as this Standard focuses on the general principles in relation to labelling and claims for this specific category of products.

The Standard for the Labelling and Claims for Prepackaged Foods For Special Dietary Uses ([CODEX STAN 146-1985](#)) provides for the following elements (further detailed in the following pages of this Guidance document):

1. SCOPE
2. DESCRIPTION
3. GENERAL PRINCIPLES
4. MANDATORY LABELLING OF PREPACKAGED FOODS FOR SPECIAL DIETARY USES
5. ADDITIONAL MANDATORY REQUIREMENTS FOR SPECIFIC FOODS
6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS
7. OPTIONAL LABELLING
8. PRESENTATION OF MANDATORY INFORMATION

CODEX ALIMENTARIUS DEFINITION OF FSDU

The Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses ([CODEX STAN 146-1985](#)), defines in section 2.1 *Foods for Special Dietary Uses as those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such⁽¹⁾. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.*

FSDU

General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses ([CODEX STAN 146-1985](#)) - applies to all FSDU

FSDU COMMODITIES FURTHER DEFINED BY SPECIFIC CODEX ALIMENTARIUS TEXTS

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

Infant Formula	Section A of Infant formula and formulas for special medical purposes intended for infants* (CODEX STAN 72-1981) REV 2007
Follow-up Formula	Follow-up formula (CODEX STAN 156-1987) - under revision
Complementary Foods	<ul style="list-style-type: none"> • Formulated Complementary Foods for Older Infants and Young Children (CODEX CAC/GL 8-1991) REV 2013 • Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981) REV 2006 • Standard for Canned Baby Foods (CODEX STAN 73-1981)
Applicable to all of the above	Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children (CAC/GL 10-1979) REV 2008
Foods for Special Medical Purposes	<ul style="list-style-type: none"> • Standard for Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) • Section B of Infant formula and formulas for special medical purposes intended for infants* (CODEX STAN 72-1981) REV 2007 • Ready to use Therapeutic Food (RUTF) - under development • Formula Foods for Use in Very Low Energy Diets for Weight Reduction* (CODEX STAN 203-1995)
Meal Replacement & Total Diet Replacement	<ul style="list-style-type: none"> • Formula Foods for Use in Weight Control Diets (CODEX STAN 181-1991) • Formula Foods for Use in Very Low Energy Diets for Weight Reduction* (CODEX STAN 203-1995)
Gluten Free Food	Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118-1979) REV 2008
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 ALIMENTARIUS TEXTS

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	FSDU not already falling under the above-mentioned categories

⁽¹⁾ This includes foods for infants and young children.

FSDU IN THE CODEX ALIMENTARIUS FRAMEWORK

Other Codex Standards, Guidelines, and texts (or documents) applicable to FSDU

Many Codex Standards, Guidelines and texts (or document) are applicable to FSDU without prejudice to the specific requirements established in the relevant FSDU Codex Standards and Guidelines.

The graph below is a simplified and non-exhaustive representation of this interaction between various Codex Texts.

FSDU Standards and Guidelines should therefore never be read in isolation and should always be considered in conjunction with other relevant Codex texts.

It is also the responsibility of the Food Business Manufacturer to assess all national/regional and Codex requirements applicable to FSDU before marketing the product.

LABELLING AND CLAIMS

- General Standard for the Labelling and Claims for Prepackaged Foods for Special Dietary Uses ([CODEX STAN 146-1985](#)) & other FSDU specific commodities Standards
- General Standard for the Labelling of Prepackaged Foods ([CODEX STAN 1-1985](#))
- Guidelines on Nutrition Labelling ([CAC/GL 2-1985](#))
- General Guidelines on Claims ([CAC/GL 1-1979](#))
- Guidelines for Use of Nutrition and Health Claims ([CAC/GL 23-1997](#))

FOOD ADDITIVES

- FSDU specific commodities Standards
- Codex General Standard on Food Additives or GSFA ([CODEX STAN 192-1995](#))

CONTAMINANTS

- FSDU specific commodities Standards
- General Standard for Contaminants and Toxins in Food and Feed ([CODEX STAN 193-1995](#))

HYGIENE

- FSDU specific commodities Standards
- General Principles on Food Hygiene ([CAC/RCP 1-1969](#))
- Specific codes of hygienic practice, where appropriate
- Guidelines on microbiological criteria ([CAC/GL 21-1997](#))

ETC.

- FSDU**
- Infant Formula
- Follow-up Formula
- Complementary Foods
- Foods for Special Medical Purposes
- Meal Replacement & Total Diet Replacement
- Gluten Free Food
- Low Sodium Food
- Sports Food
- Other FSDU

SPECIFIC REQUIREMENTS FROM THE CODEX GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES ([CODEX STAN 1-1985](#))

General Principles	
FSDU presentation	<i>FSDU shall not be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous</i>
Advice from a qualified person	<i>Nothing in the labelling and advertising of FSDU shall imply that advice from a qualified person is not needed.</i>

Mandatory labelling of prepackaged FSDU	
Name of the FSDU	<p><i>In addition to the declaration of the name of the food in accordance with Section 4.1 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985) the following provisions apply:</i></p> <ul style="list-style-type: none"> • <i>The designation “special dietary”, “special dietetic” or an appropriate equivalent term, may be used in conjunction with the name only where the product corresponds to the definition of an FSDU.</i> • <i>The characterizing essential feature, but not the condition for which the food is intended, shall be stated in appropriate descriptive terms in close proximity to the name of the food.</i>
List of ingredients	<p><i>The declaration of the list of ingredients shall be in accordance with Section 4.2 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985).</i></p>
Nutrition Labelling	<p><i>In addition to the provisions established by the Guidelines on Nutrition Labelling (CAC/GL 2-1985), the FSDU Standard (CODEX STAN 146-1985) provides that the Nutrition labelling of an FSDU shall include the following:</i></p> <ol style="list-style-type: none"> <i>1. The amount of energy per 100 grammes or 100 ml of the food as sold and where appropriate per specified quantity of the food as suggested for consumption, expressed in kilocalories (kcal) and kilojoules (kJ).</i> <i>2. The number of grammes of protein, available carbohydrate and fat per 100 grammes or 100 ml of the food as sold and where appropriate per specified quantity of the food as suggested for consumption.</i> <i>3. The total quantity of those specific nutrients or other components which provide the characterizing essential feature for the special dietary use for which the food is intended per 100 grammes or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as suggested for consumption.</i>
Net contents and drained weight	<p><i>The declaration of net contents and drained weight shall be in accordance with Section 4.3 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985).</i></p>

Mandatory labelling of prepackaged FSDU

Name and address	<i>The name and address shall be declared in accordance with Section 4.4 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985).</i>
Country of origin	<i>The country of origin shall be declared in accordance with Section 4.5 of the Codex General Standard for the labelling of pre-packaged foods (CODEX STAN 1-1985).</i>
Lot indication	<i>The lot identification shall be declared in accordance with Section 4.6 of the Codex General Standard for the labelling of pre-packaged foods (CODEX STAN 1-1985).</i>
Date marking and storage instructions	<p><i>In addition to the declaration of date marking and storage instructions in accordance with Section 4.7 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985) the following provisions apply:</i></p> <ul style="list-style-type: none"> • <i>Storage of opened food</i> • <i>Storage instructions of opened packages of a Foods for Special Dietary Uses shall be included on the label if necessary to en-sure that the opened product 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>

SPECIFIC REQUIREMENTS FROM THE CODEX GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES (CODEX STAN 1-1985)

Additional mandatory requirements for specific foods	
Quantitative labelling of ingredients	<i>The quantitative labelling of ingredients shall be in accordance with Section 5.1 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985).</i>
Claims	<i>Any claims made for the foods covered by this standard shall be in accordance with the General Guidelines for Claims elaborated by the Codex Alimentarius Commission (CAC/GL 1-1979).</i>
Suitable for "special dietary uses"	<i>Where a claim is made that the food is suitable for "special dietary uses" that food shall comply with all provisions of this standard except as otherwise provided in a specific Codex Standard for FSDU.</i>
"This food is by its nature "X"	<i>A food which has not been modified in accordance with Section 2.1 but is suitable for use in a particular dietary regimen because of its natural composition, shall not be designated "special dietary" or "special dietetic" or any other equivalent term. However, such a food may bear a statement on the label that "this food is by its nature "X" ("X" refers to the essential distinguishing characteristic), provided that such statement does not mislead the consumer.</i>
Prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition	<p><i>Claims as to the suitability of a food defined in Section 2.1 for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition are prohibited unless they are:</i></p> <ol style="list-style-type: none"> <i>1. in accordance with the provisions of Codex standards or guidelines for foods for special dietary uses, and follow the principles set forth in such standards or guidelines; or</i> <i>2. in the absence of an applicable Codex standard or guideline, permitted under the laws of the country in which the food is distributed.</i>
Irradiated foods	<i>Irradiated foods for special dietary uses shall be labelled in accordance with Section 5.2 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985).</i>
Additional or different provisions in a Codex standard for a food for special dietary use	<i>Nothing in the FSDU Codex Standard (CODEX STAN 146-1985) shall preclude the adoption of additional or different provisions in a Codex standard for a food for special dietary use, in respect of labelling, where the circumstances of a particular food would justify their incorporation in that standard.</i>
Exemptions from mandatory labelling requirements	<i>Exemptions from mandatory labelling requirements shall be in accordance with Section 6 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985).</i>
Optional labelling	<i>Optional labelling of foods for special dietary uses shall be in accordance with Section 7 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985).</i>
Presentation of mandatory information	<i>The presentation of the mandatory information shall be in accordance with Section 8 of the General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985).</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/>