

The logo for the International Special Dietary Foods Industries (ISDI) is displayed in white text on a blue rectangular background. The letters 'ISDI' are in a bold, sans-serif font, with the 'I' and 'D' being significantly taller than the 'S' and the second 'I'.

International Special
Dietary Foods Industries

Foods For Special Dietary Uses (FSDU)

SEPTEMBER 2018,
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Guidance Document

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. 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 Working Groups on Medical and Adult Dietetic Nutrition & Infant and Young Child Nutrition 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 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 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 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 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).

The brochure does not consider the specific situation of FSDU or other 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	Provides the scope of the Standard
2	DESCRIPTION	Provides the description
3	GENERAL PRINCIPLES	Provides the general principles
4	MANDATORY LABELLING OF PREPACKAGED FOODS FOR SPECIAL DIETARY USES	Defines the mandatory labelling requirements
5	ADDITIONAL MANDATORY REQUIREMENTS FOR SPECIFIC FOODS	Defines the additional mandatory labelling requirements
6	EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS	Provides the exemptions from the mandatory labelling requirements
7	OPTIONAL LABELLING	Provides the optional labelling requirements
8	PRESENTATION OF MANDATORY INFORMATION	Describes the 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
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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⁽²⁾</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⁽²⁾</i> (CODEX STAN 180-1991) <i>Formulas for special medical purposes intended for infants⁽²⁾</i> (CODEX STAN 72-1981) <i>Ready to use Therapeutic Food (RUTF) – under development⁽²⁾</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⁽²⁾</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.

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

⁽²⁾ FSMP.

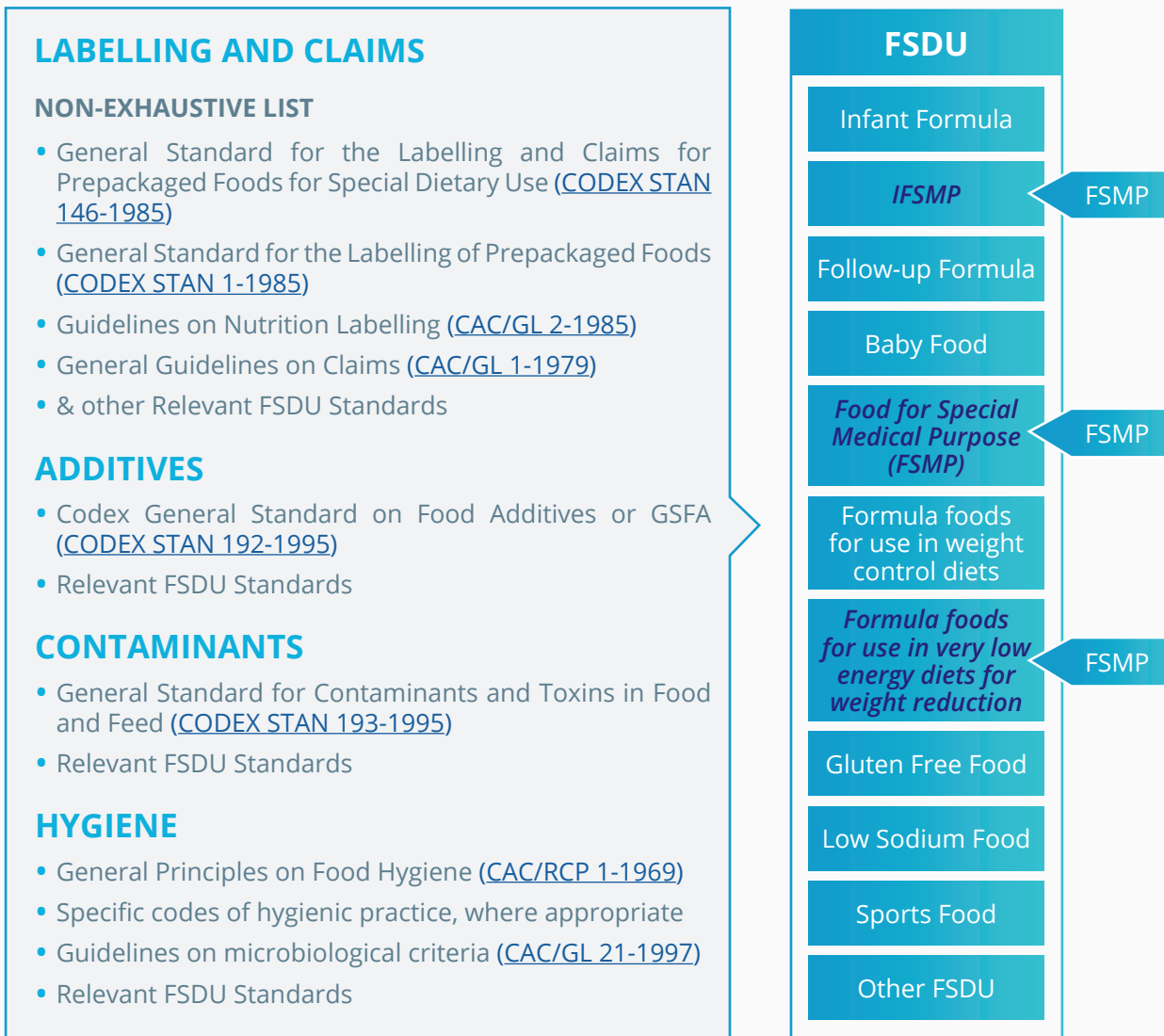
FSDU IN THE CODEX ALIMENTARIUS FRAMEWORK

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

Requirements applicable to Food for Special Dietary Use (FSDU) are defined in the General Standard for the labelling of and claims for prepackaged Foods for Special Dietary Use ([CODEX STAN 146-1985](#)).

Many other Codex Standards, Guidances and Codes are applicable to FSDU. The graph below is a simplified and non-exhaustive representation of this interaction between various Codex Texts.

The FSDU 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 FSDU before marketing the product.



For further details on Foods for Special Medical Purposes (FSMP), see the [ISDI Brochure on FSMP](#). For additional reading on Gluten Free Food, see the [ISDI Brochure on Gluten Free Food](#).

SPECIFIC REQUIREMENTS FROM THE CODEX GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES

General Principles

FSDU presentation	<i>FSDU shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.</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

The label of all prepackaged Foods for Special Dietary Uses shall bear the below mandatory information as applicable to the food being labelled, except to the extent otherwise expressly provided in a specific FSDU Codex Standard.

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	<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>

Mandatory labelling of prepackaged FSDU

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>
Name and address	<p><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></p>
Country of origin	<p><i>The country of origin shall be declared in accordance with Section 4.5 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985).</i></p>
Lot indication	<p><i>The lot identification shall be declared in accordance with Section 4.6 of the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985).</i></p>
Date marking Storage instructions Storage of open food	<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> <p><i>Storage of opened food.</i></p> <p><i>Storage instructions of opened packages of a Foods for Special Dietary Uses shall be included on the label if necessary to ensure 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></p>

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” “X” = essential distinguishing characteristic	<i>A food which has not been modified in accordance with the FSDU definition 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 an FSDU 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>

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International Special
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