

# Foods for Special Dietary Uses & Claims

*Guidance document*

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isdi

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The development of this brochure has been coordinated by Xavier Lavigne, ISDI Board Member and Marian Brestovanski, ISDI Secretariat. Members of the ISDI Working Group on Infant and Young Child Nutrition and of the Working Group on Medical and Adult Nutrition contributed to this work.

## DISCLAIMER

This guidance document is intended to provide information on Foods for Special Dietary Uses (FSDU) and Claims 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 Guidelines 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.**

## 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 claims in relation to Foods for Special Dietary Uses (FSDU) including Foods for Special Medical Purposes (FSMP). For more information on FSDU and FSMP, you can access to the [ISDI BROCHURE ON FOODS FOR SPECIAL DIETARY USES](#) and [ISDI BROCHURE ON FOODS FOR SPECIAL MEDICAL PURPOSES](#) (FSMP).

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 concept of claims in the context of:

- General Standard for the Labelling of Prepackaged Foods - [CODEX STAN 1-1985](#)
- General Guidelines on Claims - [CAC/GL 1-1979](#)
- Guidelines for Use of Nutrition and Health Claims - [CXG 23-1997](#)
- General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (FSDU) - [CODEX STAN 146-1985](#) and all Standards and Guidelines relevant to FSDU, including but not limited to the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (FSMP) - [CODEX STAN 180-1991](#). See ISDI brochure on FSDU for more information.

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 claims and foods for special dietary uses. The brochure does not consider the specific regulations on claims and on FSDU or FSMP in each country and should not be considered in isolation.

At Codex Alimentarius level, among the standardized functional foods and foods that are intrinsically linked to the concept of nutrition and health claims, Food for Special Dietary Uses are central. The definitions and founding standards of these categories have indeed a clear focus on the labelling and claims – reflected in the very title of the Standards:

- General Standard for **the Labelling of and Claims for** Prepackaged Foods for Special Dietary Uses ([CXS 146-1985](#))

The Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses ([CODEX STAN 146-1985](#)), defines Foods for Special Dietary Uses (FSDU) 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<sup>(1)</sup>. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature if such ordinary foods exist. (1) This includes foods for infants and young children.*

However, in the last decades, the increased health conscience and recognition of the importance of nutrition have led general foods to increase the use of nutrition & health claims.

Nevertheless, the capacity to use nutrition and health claims (or information constructed as nutrition and health claims) in FSDU remains key considering the nature & purpose of these categories of products, the very specific nutrition and health claims that are necessary to explain the characteristics of these products to both the consumers and the health care professionals (HCP). The specific HCP audience in addition to the consumer ones is another key aspect that explains the importance for these products to be able to make nutrition and health claims. This allows to distinguish themselves from general food not meeting the definition of FSDU, and in the case of FSMP is also framed within the medical supervision that accompanies the consumption of these products.

As established in the ISDI FSDU brochure, Codex texts should never be read in isolation and should always be considered in conjunction with other relevant Codex texts.

This is also the case in relation to claims, and the purpose of this brochure is to emphasize the articulation between how the Codex Alimentarius framework manages claims and foods for special dietary uses (FSDU).

For more information on FSDU and FSMP, you can access to the [ISDI brochure on Foods for Special Dietary Uses](#) and [ISDI brochure on Foods for Special Medical Purposes \(FSMP\)](#).

## I – GENERAL APPROACH

### STEP 1:

**Horizontal** - elements on claims applicable to all food including FSDU

General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) or GSLPF

General Guidelines on Claims (CAC/GL 1-1979)

Guidelines for Use of Nutrition and Health Claims (CXG 23-1997)



### STEP 2:

**Vertical** – elements on claims specific to FSDU

**FSDU** : General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (FSDU) (CODEX STAN 146-1985)



**FSMP** : Standard for Labelling of and Claims for Foods for Special Medical Purposes (FSMP) (CODEX STAN 180-1991)



In addition, other Standards and Guidelines covering specific FSDU or FSMP (Specific labelling & Claims elements)  
SEE ISDI FSDU BROCHURE



## II - HORIZONTAL ELEMENTS ON CLAIMS

Applicable to all food including FSDU.

### 3 Key texts in Codex:

- General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) => GSLPF
- General Guidelines on Claims (CAC/GL 1-1979)
- Guidelines for Use of Nutrition and Health Claims (CXG 23-1997)

### STEP 1:

**Horizontal** - elements on claims applicable to all food including FSDU

General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) or **GSLPF**

General Guidelines on Claims (CAC/GL 1-1979)

Guidelines for Use of Nutrition and Health Claims (CXG 23-1997)

### 1

## GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (GSLPF) GENERAL REQUIREMENTS & DEFINITION

**Definition:** "Claim" means any representation which states, suggests or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality.

ISDI notes that in Codex Alimentarius the voluntary or mandatory nature of claims is not included in the definition. This point could differ in the regulations at local/regional levels.

This represents a key element to understand the claims framework at Codex level and in relation to FSDU. For general food, claims in the Codex system are always voluntary, whereas for FSDU, claims can be voluntary or mandatory in nature.

**General Principle:** *Prepackaged food 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.***<sup>1</sup>

**1:** *Examples of descriptions or presentations to which these General Principles refer are given in the Codex General Guidelines on Claims.*

This general principle applies to claims and to all food, including FSDU.

## 2 GENERAL GUIDELINES ON CLAIMS - CAC/GL 1-1979

**Definition:** Same general definition for claim as in GSLPF

*A claim means any representation which states, suggests or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality.*

### Other definitions:

The General Guidelines on Claims also define 3 types of claim made for a food, irrespective of whether or not the food is covered by an individual Codex Standard:

1. Defines prohibited claims
2. Defines **potentially** misleading claims
3. Defines conditional claims

### Prohibited claims

- Claims stating that any given food will provide an **adequate source of all essential nutrients**, except in the case of well defined products for which a Codex standard regulates such claims as admissible claims or where appropriate authorities have accepted the product to be an adequate source of all essential nutrients.
- Claims implying that a **balanced diet** or ordinary foods cannot supply adequate amounts of all nutrients.
- Claims which cannot be **substantiated**.
- Claims as to the **suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition** unless they are:

**A-** in accordance with the provisions of Codex standards or guidelines for foods as developed by the CCNFSDU and follow the principles set forth in these guidelines. or

**B-** in the absence of an applicable Codex standard or guideline, permitted under the laws of the country in which the food is distributed.

Claims which could give rise to doubt about the **safety of similar food** or which could arouse or **exploit fear** in the consumer.

ISDI notes that there are no provisions in any Codex Standard that would allow an FSDU to make a claim on prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition. Therefore, these claims are strictly prohibited at Codex Alimentarius for all food, including FSDU.

Codex also provides the possibility for the law of a country to allow such a claim, and to ISDI knowledge no country allows such claims for food, including FSDU.

ISDI strongly supports this principle established by the Codex Alimentarius.

### Misleading claims

- **Meaningless claims** including incomplete comparatives and superlatives.
- **Claims as to good hygienic practice**, such as “wholesome”, “healthful”, “sound”

This general principle applies to claims and to all food, including FSDU.

### Conditional claims

Claims permitted subject to the particular condition attached to each:

**(i)** An indication that a food has obtained an **increased or special nutritive value by means of the addition of nutrients**, such as vitamins, minerals and amino acids may be given only if such an addition has been made on the basis of nutritional considerations according to the Codex General Principles for the Addition of Essential Nutrients to Foods. This kind of indication should be subject to legislation by the appropriate authorities.

**(ii)** An indication that the food has **special nutritional qualities by the reduction or omission of a nutrient** should be on the basis of nutritional considerations and subject to legislation by the appropriate authorities.

**(iii)** Terms such as “**natural**”, “**pure**”, “**fresh**”, “**home made**”, “**organically grown**” and “**biologically grown**” when they are used, should be in accordance with the national practices in the country where the food is sold. The use of these terms should be consistent with the prohibitions set out in Section 3.

**(iv) Religious or Ritual Preparation** (e.g. Halal, Kosher) of a food may be claimed provided that the food conforms to the requirements of the appropriate religious or ritual authorities (see also the General Guidelines for the Use of the Term “Halal”, CAC/GL 24-1997).

**v)** Claims that a food **has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.**

**(vi)** Claims which highlight the **absence or non-addition of particular substances** to food may be used provided that they are not misleading and provided that the substance:

- a)** is not subject to specific requirements in any Codex Standard or Guideline;
- b)** is one which consumers would normally expect to find in the food;
- c)** has not been substituted by another giving the food equivalent characteristics unless the nature of the substitution is clearly stated with equal prominence; and
- d)** is one whose presence or addition is permitted in the food.

**(vii)** Claims which highlight the **absence or non-addition of one or more nutrients** should be regarded as nutrition claims and therefore should invoke **mandatory nutrient declaration** in accordance with the Codex Guidelines on Nutrition Labelling.

This general principle applies to claims and to all food, including FSDU.



## 3

**GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS - CAC/GL 23-1997****Preamble of the Guidelines for Use of Nutrition and Health Claims - [CAC/GL 23-1997](#):**

Nutrition claims should be **consistent with national nutrition policy** and support that policy. Only nutrition claims that support national nutrition policy should be allowed.

Health claims should be **consistent with national health policy**, including nutrition policy, and support such policies where applicable. Health claims should be **supported by a sound and sufficient body of scientific evidence to substantiate the claim**, *provide truthful and non-misleading information* to aid consumers in choosing healthful diets and be supported by specific consumer education.

The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities.

*Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.*

*Elements in bold are interesting elements of guidance provided by Codex Alimentarius, noting elements in purple are redundant with the previous Codex Guidelines.*

Claims of the type described in section 3.4 of the Codex General Guidelines on Claims [CAC/GL 1-1979](#) are :

Claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition unless they are:

*(a) in accordance with the provisions of Codex standards or guidelines for foods as developed by the Committee on Nutrition and Foods for Special Dietary Uses and follow the principles set forth in these guidelines. or,*

*(b) in the absence of an applicable Codex standard or guideline, permitted under the laws of the country in which the food is distributed.*

**KEY CONCEPTS IN RELATION TO FSDU****Apply without prejudice...**

Section 1.2 of the Guidelines for Use of Nutrition and Health Claims stipulates:

*These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes.*

The term "without prejudice" clearly establishes that the provisions and requirements of these guidelines apply to FSDU an FSMP, unless specific provisions and requirements are established in the FSDU and FSMP standards that would deviate from the provisions and requirements established in the guidelines.

**Foods for infants and young children**

Section 1.4 of the Guidelines for Use of Nutrition and Health Claims stipulates:

*Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.*

Foods for infants and young children are all FSDU in the Codex Framework (see above mentioned definition of FSDU). This prohibition is specifically reiterated in the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS [CXS 72-1981](#), but not in the other standards or at least not in the same way (See in this Brochure the relevant section below on “Focus on Claims and FSDU for Infants and Young Children”).

With this sentence, nutrition and health claims can be authorized through specific Codex Standards and / or more importantly at national level. Flexibility is indeed given for Foods for infants and young children to use nutrition and health claims, in case this will be specifically permitted by the corresponding local/regional regulation.

## RUTF

### No Nutrition and Health Claims

The Labelling section (Section 12) of the Codex Guidelines for Ready to Use Therapeutic Foods (RUTF) stipulates: *Nutrition and health claims shall not be permitted for RUTF.*

Ready to Use Therapeutic Foods (RUTF) are foods for special medical purposes.

ISDI notes that Codex does not provide the flexibility of specific decision at national level, as it is the case for foods for infants and young children. However, in line with the section 12.3 of this Guidelines for RUTF, it is essential to note that mandatory information on the characteristics of the products have to be provided and that such information are actually mandatory information that can be constructed like, but should not be confused with, voluntary claims for general food or other FSDU.

Those are mandatory indications for RUTF as the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (FSMP) - [CODEX STAN 180-1991](#) provides in section 4.5.3 that *A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful is a mandatory indication on FSMP labels.*

**The Guidelines for Use of Nutrition and Health Claims - [CAC/GL 23-1997](#) is also a key Codex text, as it defines:**

**Nutrition claim:** *Any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.*

*The following do not constitute nutrition claims:*

- *The mention of substances in the list of ingredients;*
- *The mention of nutrients as a mandatory part of nutrition labelling;*
- *Quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.*

**Nutrient content claim:** *A nutrition claim that describes the level of a nutrient contained in a food. (Examples: “source of calcium”; “high in fibre and low in fat”).*

COMPONENT	CLAIM	CONDITIONS (not more than)
Energy	Low	40 kcal (170kJ) per 100 g (solids) or 20 kcal (80kJ) per 100 ml (liquids)
	Free	4 kcal per 100 ml (liquids)
Fat	Low	3 g per 100 g (solids) 1.5 g per 100 ml (liquids)
	Free	0.5 g per 100 g (solids) or 100 ml (liquids)
Saturated Fat <sup>2</sup>	Low	1.5 g per 100 g (solids) 0.75 g per 100 ml (liquids) and 10% of energy from saturated fat
	Free	0.1 g per 100 g (solids) 0.1 g per 100 ml (liquids)
Cholesterol <sup>2</sup>	Low	0.02 g per 100 g (solids) 0.01 g per 100 ml (liquids)
	Free	0.05 g per 100 g (solids) 0.05 g per 100 ml (liquids) and, for both claims, less than: 1.5 g saturated fat per 100 g (solids)  0.75 g saturated fat per 100 ml (liquids) and 10% of energy from saturated fat
Sugars	Free	0.5 g per 100 g (solids) 0.5 g per 100 ml (liquids)
Sodium	Low	0.12 g per 100 g
	Very Low	0.04 g per 100 g
	Free	0.005 g per 100 g
Protein	Source	10% of NVR per 100 g (solids) 5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ)
	High	2 times the values for "source"
Vitamins and Minerals	Source	15% of NVR per 100 g (solids) 7.5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 15% of NRV per serving.
	High	2 times the values for "source"
Dietary Fibre	Source	3 g per 100 g <sup>3</sup> or 1.5 g per 100 kcal or 10% of daily reference value per serving <sup>4</sup>
	High	6 g per 100 g <sup>3</sup> or 3 g per 100 kcal or 20% of daily reference value per serving <sup>4</sup>

ISDI notes that these conditions for nutrient content claims are established for general food.

These conditions can represent a relevant reference for FSDU, however depending on the role and characteristic of the FSDU (purpose and population targeted by the FSDU) these references may need to be adapted or disregarded, based on relevant scientific justifications and because FSDUs are intended for people with specific dietary needs that differ from those of the general population.

**Nutrient comparative claim:** A claim that compares the nutrient levels and/or energy value of two or more foods. (Examples: “reduced”; “less than”; “fewer”; “increased”; “more than”.)

**Non-addition claim:** Any claim that an ingredient has not been added to a food, either directly or indirectly. The ingredient is one whose presence or addition is permitted in the food and which consumers would normally expect to find in the food. (example: “no added sugars”...)

**Health claim:** Any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

— **Nutrient function claims:** A nutrition claim that **describes the physiological role of the nutrient in growth, development and normal functions of the body. a**

Example => Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development).  
Food X is a source of/ high in nutrient A.”

— **Other function claims:** These claims concern **specific beneficial effects** of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a **positive contribution to health or to the improvement of a function or to modifying or preserving health.**

Examples => “Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health).”

— **Reduction of disease risk claims:** Claims relating the consumption of a food or food constituent, in the context of the total diet, to the **reduced risk of developing a disease or health-related condition.** Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims. Examples:

“A healthful diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A.”

“A healthful diet rich in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A.”

**The Guidelines for Use of Nutrition and Health Claims - [CAC/GL 23-1997](#) is also a key Codex text because it emphasizes MANDATORY Nutrition Labelling when a Nutrition or Health claim is made**

The use of a Nutrition or Health Claims implies Mandatory nutrition labelling: *Any food for which a nutrition or health claim is made should be labelled with a nutrient declaration in accordance with Section 3 of the Codex Guidelines on Nutrition Labelling.*

*To be noted that, for FSDU, nutrition labelling is already mandatory – with or without Nutrition or Health claim. However, it is important to note that if the claim is about a nutrient that is not mandatory for the corresponding FSDU category, this nutrient needs to be added to the mandatory nutrition labelling in alignment with Codex GSLPF (example, in case of claim about vitamin B6 in a baby food, this vitamin needs to be included in the nutritional table).*

See: *GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES — [CODEX STAN 146-1985](#)*

## SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS

**Several important elements are stated in the core text of the guidelines:**

*Health claims must be **based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognized by generally accepted scientific review of the data** and the scientific substantiation should be reviewed as new knowledge becomes available.*

*The health claim must consist of two parts:*

1. Information on the physiological role of the nutrient or on an accepted diet-health relationship; followed by
2. Information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food.

## ANNEX: RECOMMENDATIONS ON THE SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS

*Scientific substantiation of health claims:*

- **Process for the substantiation of health claims**
- **Criteria for the substantiation of health claims**
- **Consideration of the evidence**

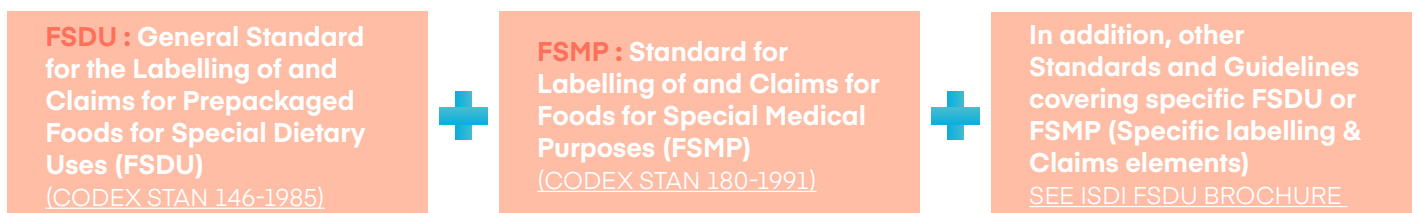
*Specific safety concerns*

*Re-evaluation*

## II – VERTICAL ELEMENTS - CLAIMS & FSDU IN THE CODEX FRAMEWORK

### STEP 2:

**Vertical** – elements on claims specific to FSDU



In the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (FSDU) - [CODEX STAN 146-1985](#) section 5.2 stipulates the following:

**Claims:** 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](#))

ISDI notes that the general requirements on claims apply to FSDU without prejudice of specific provisions in relation to claims in the FSDU Standard and the other relevant FSDU standards and guidelines (vertical). [SEE ISDI BROCHURE ON FSDU](#).

As there are no specific provisions in relation to claims in the FSDU Standard, it is understood that claims are generally allowed for FSDU products.

This is also in line with the very titles of the Codex related Standards for FSDU:

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

This is in particular linked to the fact that the claims definition at Codex Alimentarius does not purposefully include in the definition of claims the concept of voluntary vs. mandatory, as claims are always voluntary for general foods, but can be either voluntary or mandatory for FSDU.

This is also linked to the original idea that FSDU, as the archetype of functional foods, are more entitled to make claims than general food. The exponential development of claims in the general food area, has led to the essential distinction between mandatory and voluntary claims/information that has been established in some local/regional regulatory framework.

## FOCUS ON CLAIMS AND FSDU FOR INFANTS AND YOUNG CHILDREN

The General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (FSDU) - [CODEX STAN 146-1985](#) defines all foods for infants and young children (i.e. below 36 months) as FSDU.

As previously mentioned, the Codex Guidelines for Use of Nutrition and Health Claims - [CAC/GL 23-1997](#) stipulates that:

*Nutrition and health claims shall not be permitted for foods for infants and young children except **where specifically provided for in relevant Codex standards or national legislation.***

This prohibition is specifically reiterated in the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS [CXS 72-1981](#), but not in the other standards or at least not in the same way. Indeed, in the STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN [CXS 74-1981](#), it is clearly indicated that:

*'8.1.2 Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, nutrition claims may be **permitted** under national legislation for the foods that are the subject of the standard **provided that they have been demonstrated in rigorous studies with adequate scientific standards.***

As a consequence: National authorities can authorize nutrition and health claims for foods for Infant and young children.

## RATIONALE IN SUPPORT OF FLEXIBILITY FOR NUTRITION AND HEALTH CLAIMS FOR FSDU FOR INFANTS AND YOUNG CHILDREN - IN LINE WITH CODEX ALIMENTARIUS

As previously indicated, the Codex Alimentarius provides for the possibility to allow claims in specific standards or guidelines relevant for that population or at national level.

ISDI notes that some claims for these FSDU products are allowed or mandatory based on the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses ([CXS 146-1985](#)):

- *The designation "special dietary", "special dietetic" or an appropriate equivalent term may be used in conjunction with the name [of the product]*
- *The characterizing essential feature*

A prohibition without allowing for the intended flexibility provided by the Codex Alimentarius framework would have a significant impact on the sector of FSDU for Infants and Young Children, both from a consumer perspective as well as from a market standpoint.

Limiting consumer communication can lead consumers to believe that other products with health claims (such as dairy products for the general population) are superior to products specifically designed to fulfill infant and young children's nutritional needs. This could lead to consumers buying other products with health claims that are not adapted for infant and young children's needs. Health claims are typically related to added value and innovation. Limiting communication could discourage manufacturers from adding the newest developments in FSDU for Infants and Young Children and limiting the access to these innovations.

There is a real risk that restricting the use of nutrition and health claims would be a disincentive to R&D in the future. The ability to inform consumers about the positive health and nutrition impact of past scientific breakthroughs is critical for innovation. Removing this incentive, makes it less likely that breakthroughs will be made that could provide real benefits to the

nutrition of young children in key areas that support growth and development (e.g., the bioavailability of nutrients, development of healthy gut microbiome, brain development and development of the musculoskeletal system) which are all modifiable through diet. Furthermore, the inability to talk about Nutritional improvements, such as sugar reduction or fortification will make voluntary reformulations less likely.

Prohibiting nutrition and health claims without flexibility for allowing relevant nutrition and health claims limit consumers from accessing information about the nutritional benefits of specifically designed products. Consumers are not aware of the particular nutritional compositional criteria of foods designed to cover the specific nutritional needs of infants and young children.

This means that a restriction of nutritional and health claims without the intended flexibility would restrict consumers from making informed nutritional choices and would be in contradiction with the principle of ensuring a high level of consumer protection and information.

In addition, prohibiting nutrition and health claims for all infants and young children products from 6 months of age could direct consumer choices towards foods that can use claims and could therefore be seen as more appealing, but which are not manufactured according to the strict compositional criteria and safety rules applicable for foods for infants and young children. This could lead to an increase in the proportion of infants and young children fed with general foods which do not adequately address their very specific needs from a nutritional aspect as well as from a food safety standpoint.

Such a prohibition would unfairly disadvantage the manufacturers of FSDU for infants and young children.

FSDU for infants and young children are specifically designed for this sensitive target population and follow different regulations for their composition but as well from a food safety point of view. Infants and young children are not little adults; their nutrient requirements are specific and evolve as they transition to the family diet. Foods for infants and young children are formulated and produced in line with international standards such as Codex Alimentarius and national food-based dietary guidelines. They meet safety and quality standards, which are the strictest in the world. Nutrition and Health claims should be permitted in these products.

## III SPECIFIC LABELLING REQUIREMENTS IN FSDU

The General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (FSDU) - [CODEX STAN 146-1985](#) - in section 3 and 4 - establishes the following:

### FSDU PRESENTATION

**Misleading:** *Not presented in a manner that is false, misleading or deceptive etc. => redundant with general principles established by the General Standard for the Labelling of Prepackaged Foods [CODEX STAN 1-1985](#) (see above).*

**Special dietary:** *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.*

**Products’ characteristic:** *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.***



**FSDU Claim:** *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.*

The definition of claims at Codex Alimentarius is:

*“Claim” means any representation which states, suggests or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality*

As previously highlighted the concept of voluntary vs. mandatory claim is not included – purposefully – in this definition.

ISDI notes that the information that a food is suitable for “special dietary uses” qualifies as a “claim” in the context of this Standard. However, this information is not to be provided on a mandatory basis, but on a voluntary basis.

More importantly, it is important to stress that “characterizing essential feature” is a mandatory statement that must be provided. ISDI notes that in many cases such mandatory statement/claim will be constructed in a similar way as a voluntary claim, even if they will not be considered as such .

**Prevention, alleviation, treatment or cure:** *Prohibited unless they are:*

- *In accordance with specific provisions at Codex*
- *Permitted under the laws of the country*

ISDI notes that there are no provisions in Codex Alimentarius that is allowing an FSDU, including FSMP, to claim for prevention, alleviation, treatment or cure. Although Codex Alimentarius foresees some flexibility based on specific provisions to be established at Codex, such claims are de facto strictly prohibited at Codex Alimentarius for all food, including FSDU and FSMP.

ISDI also notes that to its knowledge, this prohibition is commonly in place at country level, as this is a key element distinguishing food (including FSDU and FSMP) from pharmaceuticals/drugs.

## FSMP PRESENTATION

In addition to the requirements established for all FSDU, FSMP - as a specific category under the FSDU framework - have additional mandatory requirements established by section 4.5 of the Standard for Labelling of and Claims for Foods for Special Medical Purposes ([CXS 180-1991](#)).

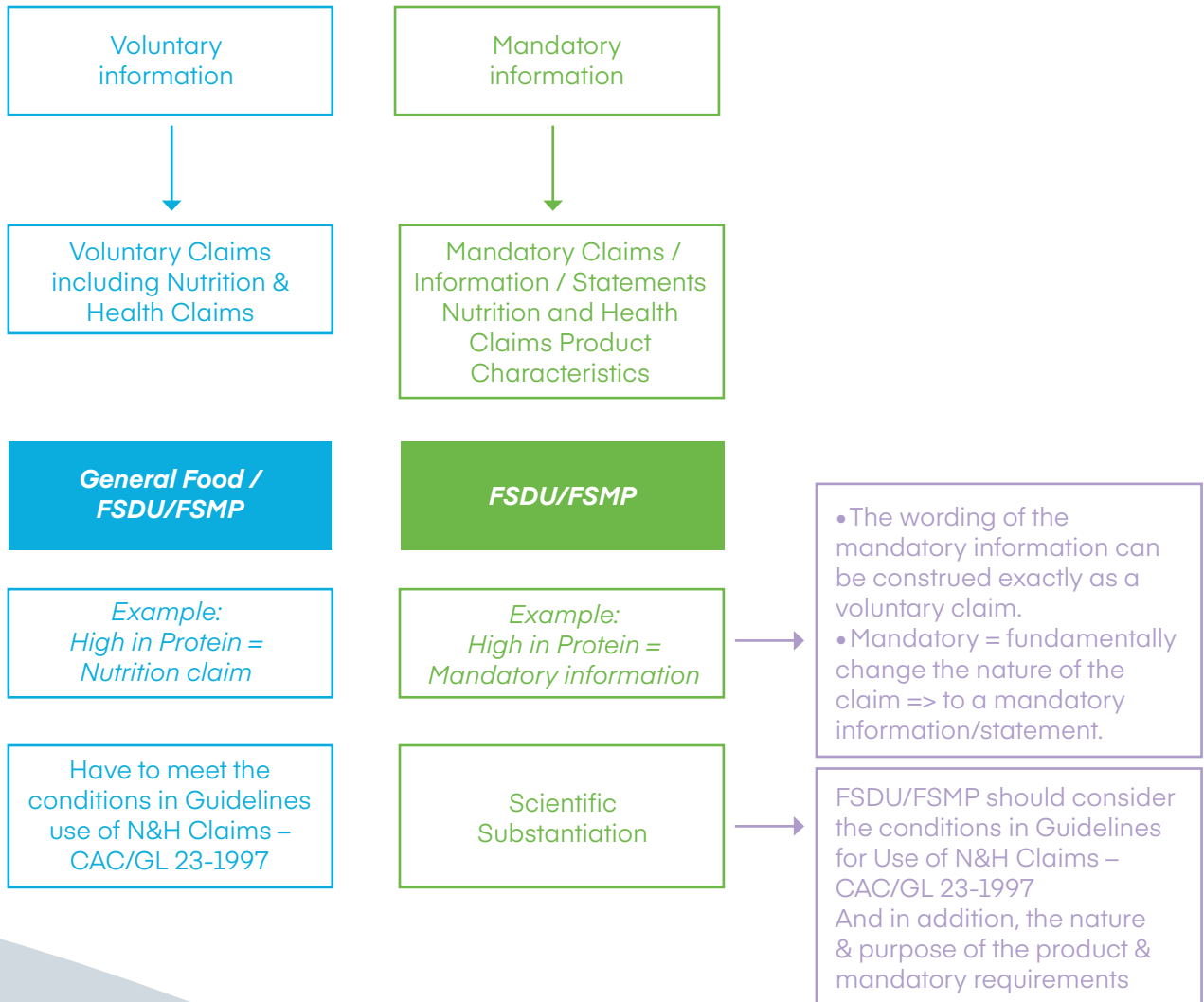
**“Dietary management of”:** *Statement “For the dietary management of .....” / specific disease(s), disorder(s) or medical condition(s)*

**Rationale for use and usefulness:** *A statement of the **rationale for the use** of the product and a description of the **properties or characteristics** that make it useful*

**Rationale on product formulation:** *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.*

ISDI notes that in many cases the above information will be constructed in a similar way as a voluntary claim, but will not be considered as such, as it corresponds to a mandatory information.

# IV CLAIMS: A VOLUNTARY INFORMATION TO BE OPPOSED TO MANDATORY INFORMATION



## NUTRITION IS ONE SCIENCE

ISDI notes therefore that nutrition and health claims justified for healthy population can be of relevance for FSDU e.g., protein builds muscle mass. It remains however essential to consider the nature and the purpose of the product. FSDU also have to provide mandatory information to characterize the products => mandatory nutrition and health claims or information constructed as nutrition and health claims are essential to explain the nature and purpose of the product.

In the example above,

the expression “High in protein” is a nutrition claim

or the expression “Protein contributes to a growth in muscle mass” a health claim

- A general food would have to meet certain criteria to be authorized to bear the nutrition and/or the health claim
- An FSDU could have to provide this information as characterizing the product. This therefore is not a voluntary claim anymore, but a mandatory claim that must be provided.

Semantically, the voluntary claim and the mandatory claim will be similarly constructed.

In relation to the conditions of use, ISDI notes that it is always interesting to consider nutrition and health claims and their conditions of use for general food to inform the discussion around mandatory claims & information on FSDU and FSMP that can be constructed like the voluntary claims for general food.

However, these considerations have then to integrate the perspective of the specific purpose of the FSDU and FSMP product, including the target population. So, the scientific rationale to support the mandatory information on FSDU and FSMP could eventually be very different from the one used to support the condition for the claims for general food and general population.

Therefore, ISDI considers essential to:

- allow for claims on FSDU, as foreseen in the Codex Alimentarius framework
- allow for the mandatory claims to be provided on FSDU, including FSMP, to be constructed similarly to relevant voluntary claims and to take into consideration the conditions of use of the claim for general food and general population, when such conditions of use are established and relevant to the intended population of the FSDU (as one of many elements to be considered when building the rationale in relation to information on the characteristics of the FSDU/FSMP product).

The Codex Standard for Labelling of and Claims for FSMP ([CXS 180-1991](#)) recalls in section 3 that these products shall be based on sound medical and nutritional principles. FSDU and FSMP must be science based, just like nutrition and health claims.

# ISDI

International Special  
Dietary Foods Industries



## INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

Avenue des Arts 46, 1000 Brussels, Belgium

Tel.: +32 2 732 70 40 - Email: [secretariat@isdi.org](mailto:secretariat@isdi.org) -  [@isdi\\_org](https://twitter.com/isdi_org)

**WWW.ISDI.ORG**