

Foods for Special Dietary Uses (FSDU) and Front of Pack Nutrition Labelling (FOPNL)

*Annex II of the Codex Alimentarius Guidelines on
Nutrition Labelling (CXG 2-1985)*

October 2022

The logo for International Special Dietary Foods Industries (ISDI) features the lowercase letters 'isdi' in a white, sans-serif font on a teal square background. The 'i' is notably taller than the other letters.

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International Special
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DISCLAIMER

This guidance document is intended to provide information on Foods for Special Dietary Uses (FSDU) and Front of Pack Nutrition Labelling (FOPNL) 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 Front of Pack Nutrition labelling (FOPNL) 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 Annex II of the Guidelines on Nutrition Labelling ([CXG 2-1985](#))

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 Front of pack Nutrition Labelling (FOPNL) 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.



KEY MESSAGES OF THE BROCHURE

1 Specific consideration should be given to Food for Special Dietary Uses (FSDU) including Foods for Special Medical Purposes (FSMP) when establishing FOPNL as FSDU are tailored to meet the particular nutritional needs of the targeted group.

2 FOPNL established for adult general healthy population are not suitable for infants and young children. Products specifically formulated for this target population should be excluded from FOPNL.

3 For FSDU products, a proportionate risk management approach should be considered, taking into account the specificity of the FSDU categories vs. the relevance of the FOPNL and nutrient profiling system.

4 The Codex Guidelines (Annex 2 of Guidelines on Nutrition Labelling ([CXG 2-1985](#)) directly excludes the following product categories:

- Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants ([CXS 72-1981](#))
- Standard for Follow-up formula ([CXS 156-1987](#))
- Standard for Labelling of and Claims for Foods for Special Medical Purposes ([CXS 180-1991](#)). FSMPs include formula foods for use in very low energy diets for weight reduction ([CXS 203-1995](#))

5 Additionally, the Codex Guidelines authorise for the consideration of other exclusions of FSDU dependent on the type of FOPNL. The following foods should be excluded from FOPNL:

- Canned Baby Foods as included in the Standard for Canned Baby Foods ([CXS 73-1981](#))
- Processed Cereal-Based Foods for Infants and Young Children as stipulated in the Standard for Processed Cereal-Based Foods for Infants and Young Children ([CXS 74-1981](#)),
- Formula Foods for Use in Weight Control Diets as included in the Standard for Formula Foods for Use in Weight Control Diets ([CXS 181-1991](#)),
- Guidelines on Formulated Complementary Foods for Older Infants and Young Children ([CXG 8-1991](#)).

CODEX GUIDELINES ON FOPNL

The Codex Guidelines (Annex 2 of Guidelines on Nutrition Labelling ([CXG 2-1985](#))) exclude the following texts:

- *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants ([CXS 72-1981](#))*
- *Standard for Follow-up formula ([CXS 156-1987](#))*
- *Standard for Labelling of and Claims for Foods for Special Medical Purposes ([CXS 180-1991](#)).*

ISDI notes that Foods for Special Medical Purposes (FSMPs) include formula foods for use in very low energy diets for weight reduction ([CXS 203-1995](#))

As referred to in Annex 2 of the Guidelines on Nutrition Labelling [CXG 2-1985](#):

In addition, other foods may be considered for exclusion at a national level dependent on the type of FOPNL being developed, such as alcoholic beverages and other foods for special dietary uses. FOPNL should not be used to promote the consumption of alcohol.

As such, ISDI proposes that National and regional authorities shall additionally exclude the following foods from FOPNL:

- **Canned Baby Foods as included in the Standard for Canned Baby Foods ([CXS 73-1981](#)),**
- **Processed Cereal-Based Foods for Infants and Young Children as stipulated in the Standard for Processed Cereal-Based Foods for Infants and Young Children ([CXS 74-1981](#)),**
- **Formula Foods for Use in Weight Control Diets as included in the Standard for Formula Foods for Use in Weight Control Diets ([CXS 181-1991](#)),**
- **Guidelines on Formulated Complementary Foods for Older Infants and Young Children ([CXG 8-1991](#)).**

As the association representing Foods for Special Dietary Uses (FSDU) industry at international level, ISDI considers essential to provide further guidelines on FOPNL on FSDU.

FSDU EXCLUSIONS

ISDI reemphasizes that the nutritional compositional requirements of FSDU are tailored to meet the particular nutritional needs of the targeted group and are based on science including the dietary recommendations of recognised authoritative scientific bodies (RASBs) (e.g. energy contribution from macronutrients, the contribution of micronutrients to recommended daily intake, etc.).

These products are standardized by Codex and **must follow stricter food composition and safety requirements in comparison with foods for the general population.**

Applying FOPNL schemes and nutrient profiles developed for the adult healthy population on these products would mislead consumers and prevent them from making informed choices adapted to their nutritional needs. It would unjustifiably discriminate against these categories and undermine the purpose of the products.

ISDI considers that this is also in line with the recommendation from WHO in the scope section of *"WHO Guiding principles and framework manual for front-of-pack labelling for promoting healthy diet"* where the rationale for excluding standardized foods for infants and young children is that they have "strict compositional criteria; hence, promoting reformulated products is not appropriate".



CODEX ALIMENTARIUS & FOOD FOR SPECIAL DIETARY USE (FSDU)

Codex Standard on 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.*

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



KEY PRINCIPLES IN RELATION TO FOOD FOR SPECIAL DIETARY USE (FSDU)

ISDI supports initiatives that aim to improve public health by promoting a healthy nutrition and welcomes labelling policy initiatives that could help consumers to easily understand nutrition labelling and make informed decisions and participate to fight against obesity and NCDs.

FSDU are regulated with specific requirements on composition (macro and micro-nutrients), food additives, labelling, hygiene, packaging etc. The nutritional compositional requirements are tailored to meet the particular nutritional needs of the targeted group, and are based on science including the dietary recommendations of recognised authoritative scientific bodies (e.g. energy contribution from macronutrients, contribution of micronutrients to recommended daily intake etc.)

ISDI considers that whenever the use of Nutrient Profiles for General Food or the addition of supplementary nutrition information, including Front of Pack labelling is discussed, **FSDU should be considered for exclusion because supplementary nutritional information (including Front of Pack labelling) and Nutrient Profiles established for General Food are not appropriate for FSDU**, or that the following principles should apply for FSDU:

PRINCIPLE 1:

Specific consideration should be given to FSDU when establishing FOPNL. FSDU are specially processed or formulated to satisfy particular dietary needs and nutritional composition requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such.

PRINCIPLE 2:

FSDU are globally traded more than General Food. They are lower in volume in market terms and are more complex to manufacture. Their higher trade dependency means that their availability in markets is intrinsically linked to those markets being compliant with international trade standards, including Codex Alimentarius. Therefore, in terms of labelling, it is imperative that these products:

- comply with Codex requirements
- are not subject FOPNL requirements at national level which could create barriers to trade.

PRINCIPLE 3:

For FSDU products, a proportionate risk management approach should be considered, taking into account the specificity of the FSDU categories vs. the relevance of the FOPNL and Nutrient profiles that are established for general adult population.

PRINCIPLE 4:

FOPNL established for adult general healthy population are not suitable for infants and young children nor for FSMPs that are intended for patients. Products specifically formulated for these target populations and other specific target populations (e.g. formulated products for population following a restricted calorie intake diet) should be excluded.

FSDU VS. FOPNL & NUTRIENT PROFILES FOR GENERAL FOOD AND ADULT POPULATION

For FSDU products, a proportionate risk management approach should be considered, taking into account the specificity of the FSDU categories vs. the relevance of the FOPNL and Nutrient profiles that are established for general adult population.

Any nutrient profiling or FOPNL systems, should establish a specific framework for FSDU and establish where necessary, exclusions for the relevant FSDU food categories.

As stated in the Codex Guidelines on Nutrition Labelling ([CAC/GL 2-1985, PARAGRAPH 3.2.7](#)), nutrition labelling should take into account the specific labelling requirements established by certain Codex standards:

In the case where a product is subject to labelling requirements of a Codex standard, the provisions for nutrient declaration set out in that standard should take precedence over but not conflict with the provisions of Sections 3.2.1 to 3.2.6 of these Guidelines.'

It is important to stress that the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses ([CODEX STAN 146-1985](#)) and the other specific FSDU commodity standards highlighted in the table below have specific nutritional labelling requirements that do apply notwithstanding the provisions established in Codex Guidelines on Nutrition Labelling [CAC/GL 2-1985](#).

In addition, the formulation of FSDU products are based on local regulations and/or Codex standards and/or scientific requirements for the specific target group. Those FSDU products are required to meet mandatory macro- and micronutrient levels, along with other conditions of use. FSDU are also more strictly or specifically regulated in terms

of contaminants, residues, food additives, labelling, hygiene, packaging, composition, appropriate texture and safety, etc. Failure to take into consideration this specific situation creates an unfair and discriminatory situation for FSDU products in comparison with General Food.

These specific requirements should be recognized by the nutritional labelling regulatory framework.

If not, FSDU products will be subject to undue discrimination by a regulatory framework created for and applicable to General Food only, that mandates use of either nutrient profile and/or FOPNL that will contradict the very purpose of an FSDU.

ISDI has also major concerns that the application of FOPNL developed for General Food to FSDU could mislead consumers and eventually represent a health risk. For example, one of the key risks is that consumers/parents/care-givers (according to the FSDU sub categories considered) will be misled in considering that the FSDU is not adapted to its very purpose and will not follow the instructions of use. This could lead to increased nutrient inadequacies for the targeted group and lastly, will bring confusion between fortified products (which are General Food) and FSDU.

In the case of Infants and Young children, ISDI also believes essential to consider the advice of the World Health Organisation (WHO) in the scope section of "[WHO Guiding principles and framework manual for front-of-pack labelling for promoting healthy diet](#)" where the rationale for excluding standardized foods for infants and young children is that they have "strict compositional criteria; hence, promoting reformulated products is not appropriate"

ANNEX I

GENERAL CONSIDERATIONS FOR FSDU & FSDU SUBCATEGORIES IN THE CODEX CONTEXT

FSDU

Codex Standard on 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 *specialy 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.***

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

On the basis of this definition, ISDI considers that FSDU should generally be excluded from FOPNL established for General Food; all of which do not take into account the specificity of the FSDU categories.

Foods for Infants and Young Children

General

Infants and young children have different nutritional needs than older children and adults. Food products for infants and young children are designed to meet these specific nutritional needs to ensure healthy growth and development. For example, infants and young children need to eat proportionally more fat than adults, as fat helps develop their immune systems and absorb vitamins. A general FOPNL scheme based on adults' nutritional needs would give the perception that infant nutrition products are high in fat and would mislead parents and lead them to choose inappropriate or unhealthy alternatives.

Therefore, FOPNL schemes and nutrient profiles established for general adult population that aim to guide consumer behaviour towards healthier alternatives are not appropriate in this framework.

In addition, if these FSDU products were not excluded from FOPNL, it would encourage parents and caregivers to compare infant and young children products that are tailor made for this population (in terms of nutrition and food safety requirements) with general food products that appear similar but that are in reality not adapted to that population.

For example, infant formulas and follow up formulas cannot be substituted by common milks or vegetable drinks which are not adapted to the nutritional needs of infants and young children, and the consumption of which could lead to a nutritional imbalance. Similarly, canned baby foods or processed cereal-based foods for infants and young children cannot be substituted by common cereals, biscuits or purées, or any general food products that could look similar, but do not meet the proper nutritional or food safety requirements of FSDU.

ISDI considers that this is also in line with the recommendation from WHO in the scope section of "[WHO Guiding principles and framework manual for front-of-pack labelling for promoting healthy diet](#)" where the rationale for excluding standardized foods for infants and young children is that they have "strict compositional criteria; hence, promoting reformulated products is not appropriate"

Infant Formula

Codex

Codex Standard on Infant formula (IF) and formulas for special medical purposes (IFSMP) intended for infants ([CODEX STAN 72-1981](#)) define IF as a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding and IFSMP as 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.

ISDI considers that IF and IFSMP should generally be excluded from FOPNL established for General Food; all of which do not take into account the specificity of the Infant Formula category. This is in alignment with Annex 2 (Guidelines on Front-Of-Pack Nutrition Labelling) of the Guidelines on Nutrition Labelling [CXG 2-1985](#).

Follow Up Formula

Codex

La Norma del Codex para Codex Standard for Follow up formula ([CODEX STAN 156-1987](#)) defines follow-up formula as *a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.*

2.2 *Follow-up formula is a food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the 6th month on and for young children.*

2.3 *Follow-up formula is a food processed by physical means only so as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.*

2.4 *Follow-up formula, when in liquid form, is suitable for use either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation. **The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use.***

Follow up formula for both older infants (6-12m) and young children (12-36m) are regulated with specific requirements on composition (macro and micro-nutrients), food additives, labelling, hygiene, packaging etc. The nutritional compositional requirements are tailored to meet the particular nutritional needs of older infant and young children and are based on science including the dietary recommendations of recognised authoritative scientific bodies (e.g. energy contribution from macronutrients, contribution of micronutrients to recommended daily intake etc.). In addition, optional ingredients are permitted once their safety and suitability has been evaluated and demonstrated. This ensures that formula manufacturers continually engage in pioneering research and development to ensure innovative ingredients with greater functionality are available for young children.

On this basis, ISDI considers that Follow up formula (6-12) and (12-36) should generally be excluded from FOPNL established for General Food; all of which do not take into account the specificity of the Follow up Formula category. This is in alignment with Annex 2 (Guidelines on Front-Of-Pack Nutrition Labelling) of the Guidelines on Nutrition Labelling [CXG 2-1985](#).

Baby Food

Codex

Baby food is covered within Codex Alimentarius via 4 standards:

- Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children ([CAC/GL 10-1979](#))
- Formulated Complementary Foods for Older Infants and Young Children ([CODEX CAC/GL 8-1991](#)) *means foods that are suitable for use during the complementary feeding period. **These foods are specifically formulated with appropriate nutritional quality to provide additional energy and nutrients** to complement the family foods derived from the local diet **by providing those nutrients which are either lacking or are present in insufficient quantities.***
- Processed Cereal-Based Foods for Infants and Young Children ([CODEX STAN 74-1981](#)) covers *processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet.*

Four categories are distinguished:

1. *Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids;*
2. *Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid;*
3. *Pasta which are to be used after cooking in boiling water or other appropriate liquids;*
4. *Rusks and biscuits which are to be used either directly or, after pulverization, with the addition of water, milk or other suitable liquids.*

- Standard for Canned Baby Foods ([CODEX STAN 73-1981](#)) defines canned baby food as foods that are *intended primarily for use during the normal infant's weaning period and also for the progressive adaptation of infants and children to ordinary food. They may be either in ready-to-eat form or in dry form requiring reconstitution with water only. They do not include products covered by the Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants ([CODEX STAN 72-1981](#)) or by the Standard for Processed Cereal-Based Foods for Infants and Young Children ([CODEX STAN 74-1981](#)).*

All these FSDU products are regulated with specific requirements on composition (macro and micro-nutrients), food additives, labelling, hygiene, packaging etc. The nutritional compositional requirements are tailored to meet the particular nutritional needs of older infant and young children and are based on science including the dietary recommendations of recognised authoritative scientific bodies (e.g. energy contribution from macronutrients, contribution of micronutrients to recommended daily intake, allowance of energy and nutrients from milk which is a significant part of the diet during complementary feeding, etc.). Baby foods are specifically formulated to deliver a texture that is developmentally appropriate and does not pose a risk of choking.

On this basis, ISDI considers that those products should generally be excluded from FOPNL established for General Food; all of which do not take into account the specificity of the Baby Food category.

The exclusion of the baby food category from FOPNL established for General Food, is all the more important that this category of products shall be distinguished from General Food products that can appear to consumers as of the same type, but that are actually not falling under this FSDU category and the specific requirements linked to that regulatory status - e.g. adapted composition for the target population (macro and micro-nutrients), food additives, labelling, hygiene, food contaminants, pesticides residues etc.

Food for Special Medical Purpose

General

Foods for special medical purposes (FSMPs) are designed to meet the specific nutritional or dietary needs arising from a wide range of medical conditions that affect patients of all ages. Consequently, their composition may differ substantially from general food.

They are used under the supervision of a healthcare professional to support nutritional intervention on patients with diverse nutritional challenges, e.g. renal disease, head and neck cancer, cystic fibrosis, intestinal failure, metabolic disorder, etc.

A general FOPNL or Nutrient Profiles scheme applicable to FSMPs would be confusing and misleading to healthcare professionals and patients, resulting in a potential deterioration of care through suboptimal nutritional support.

Food for Special Medical Purpose

Codex

The Standard for Labelling of and Claims for Foods for Special Medical Purposes (FSMP) ([CODEX STAN 180-1991](#)) defines FSMP 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.*

Foods for special medical purposes (FSMPs) are designed to meet the specific nutritional or dietary needs arising from a wide range of medical conditions that affect patients of all ages. Consequently, their composition may differ substantially from general food.

They are used under the supervision of a healthcare professional to support nutritional intervention on patients with diverse nutritional challenges, e.g. renal disease, head and neck cancer, cystic fibrosis, intestinal failure, metabolic disorder, etc.

A general FOPNL or Nutrient Profiles scheme applicable to FSMPs would be confusing and misleading to healthcare professionals and patients, resulting in a potential deterioration of care through suboptimal nutritional support.

On the basis of this very definition, ISDI considers that FSMP should generally be excluded from FOPNL established for General Food; all of which do not take into account the specificity of the FSMP categories. This is in alignment with Annex 2 (Guidelines on Front-Of-Pack Nutrition Labelling) of the Guidelines on Nutrition Labelling [CXG 2-1985](#).

<p>Meal Replacement & Total Diet Replacement</p> <p><i>General</i></p>	<p>Foods specifically intended for weight loss and weight control are ready-to-use or easy-to-prepare food products containing a limited amount of calories packed with essential nutrients that can be used to replace one or two meals per day, or the whole diet.</p> <p>They aim to help manage body weight in a safe and efficient manner. They are specially formulated and manufactured to respond to the particular dietary needs of certain groups of consumers, such as those who are overweight or obese, and are often used with the help of a healthcare professional.</p> <p>A general FOPNL scheme applicable to slimming foods would mislead consumers on the specific nutrition requirements that are linked to a restricted calorie intake diet.</p>
<p>Meal Replacement & Total Diet Replacement</p> <p><i>Codex</i></p>	<p>The Codex Standard on Formula Foods for Use in Weight Control Diets (CODEX STAN 181-1991) define these FSDU as <i>Formula foods for use in weight control diets are foods which, when presented as “ready-to-serve” or when prepared in conformity with the directions for use, are presented as a replacement for all or part of the total daily diet.</i></p> <p>For Formula foods for use in very low energy diets the Codex Standard on Formula Foods for Use in Very Low Energy Diets for Weight Reduction (CODEX STAN 203-1995) define these FSDU as foods for special medical purposes and must be used under medical supervision by individuals with moderate or severe obesity.</p> <p>A general FOPNL scheme applicable to such foods would mislead consumers on the specific nutrition requirements that are linked to a restricted calorie intake diet.</p> <p>These FSDU/FSMP are replacing one or more meals or the entirety of the diet. On the basis of these definitions, ISDI considers that these FSDU/FSMP should generally be excluded from FOPNL established for General Food; all of which do not take into account the specificity of these categories. This is in alignment with Annex 2 (Guidelines on Front-Of-Pack Nutrition Labelling) of the Guidelines on Nutrition Labelling CXG 2-1985.</p>
<p>Sports food</p> <p><i>General</i></p>	<p>Sports people have nutritional needs that differ from the general adult population. These nutritional needs, such as higher requirements for carbohydrates, sugar and salt. For example, carbohydrates contribute to muscle recovery and endurance. The application of FOPNL and nutrient profiles to sport foods has the potential to mislead consumers in terms of the role that sport food plays in meeting their specific nutritional needs before, during, and after physical activity.</p>
<p>Sports food</p> <p><i>Codex</i></p>	<p>Sports food are FSDU not covered by a specific Codex Sub-Commodity Standard in the FSDU framework of Codex. ISDI defines sports food as <i>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).</i></p> <p>On the basis of these definitions, ISDI considers that Sports food should generally be excluded from FOPNL established for General Food; all of which do not take into account the specificities of this category.</p>

ISDI NOTES THAT THE FOLLOWING FSDU CATEGORIES DO NOT NEED TO BE EXCLUDED FROM FOPNL.

Gluten Free Food

Codex

The Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten ([CODEX STAN 118-1979](#)) defines Gluten-free foods as *dietary foods*:

a) *consisting of or made only from one or more ingredients which do not contain wheat (i.e. all Triticum species, such as durum wheat, spelt, and khorasan wheat, which is also marketed under different trademarks such as KAMUT), rye, barley, oats¹ or their crossbred varieties, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer, and/or*

b) *consisting of one or more ingredients from wheat (i.e. all Triticum species, such as durum wheat, spelt, and khorasan wheat, which is also marketed under different trademarks such as KAMUT), rye, barley, oats¹ or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer.*

1 Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level.

Unless Gluten-free food also falls under another FSDU subcategory for which FOPNL established for General Food, cannot apply, ISDI considers that General Food that are specifically processed and manufactured to be gluten free can be covered by FOPNL established for General Food.

Low Sodium Food

Codex

The Codex Standard for Special Dietary Foods with Low-Sodium Content (Including Salt Substitutes) ([CODEX STAN 53-1981](#)), defines Special Dietary Foods with Low-Sodium Content as *foods which are represented directly or indirectly or by implication, as intended for special dietary uses by reason of their low sodium content. It also applies to salt substitutes with low sodium content. Special dietary foods with low sodium content are foods whose special dietary value results from the reduction, restriction, or removal of sodium.*

Unless Low Sodium food also falls under another FSDU subcategories for which FOPNL for General Food, cannot apply, ISDI considers that General Food that are specifically processed and manufactured to be Low Sodium can be covered by FOPNL established for General Food.

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