

The logo for the International Special Dietary Foods Industries (ISDI) features the letters 'ISDI' in a bold, white, sans-serif font. The letter 'I' is positioned above the 'S' and 'D', and the letter 'I' is positioned to the right of the 'D'. The logo is set against a blue square background.

International Special
Dietary Foods Industries

GUIDANCE ON GLUTEN-FREE LABELLING

Based on STANDARD FOR FOODS
FOR SPECIAL DIETARY USE FOR
PERSONS INTOLERANT TO GLUTEN
CODEX STAN 118-1979



MEDICAL & ADULT
DIETETIC NUTRITION

ISDI GLUTEN-FREE BROCHURE USER GUIDE

TARGET GROUP

The brochure is for general information purpose. It can be used as a support for Food Business Operators (e.g. internal trainings programs) or as a background element for discussions with national authorities regarding Gluten-free Food.

PURPOSE OF THE BROCHURE

The brochure provides the international background regarding the labelling of gluten-free food based on Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN.

KEY MESSAGES OF THE BROCHURE

- 1) Within Codex Alimentarius, Gluten-free Foods are considered as Food for Special Dietary Use (FSDU) and are covered by a specific standard: Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN.
- 2) This Codex Standard applies to Gluten-free food in addition of or without prejudice with:
 - a) Any other relevant Codex texts, including among others:
 - i) CODEX STAN 1-1985 - GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS
 - ii) CODEX STAN 146-1985 - GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES
 - iii) All the specific Standards applicable to Food for Special Dietary Use
 - b) National provisions
- 3) The brochure provides explanations on the relationship between Gluten-free Foods provisions defined by Codex Standard 118-1979 and other Food For Special Dietary Use (FSDU) defined by a Codex text, in the context of Codex Alimentarius
- 4) The brochure provides a simplified decision tree to assess if a food can be specifically labelled as Gluten-free in the context of Codex Alimentarius
- 5) Food Business Manufacturers are responsible to ensure that all the relevant requirements are met when labelling a food as Gluten-free in specific markets
- 6) From a technical point of view:
 - a) Key threshold is **20 mg/kg in total, based on the food as sold or distributed to the consumer**
 - b) 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. Oat with a gluten **threshold 20 mg/kg is allowed in many countries.**
 - c) **Infant Formula should not carry Gluten-free statements unless authorised by national legislation**

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DISCLAIMER

This guidance document is intended to provide ISDI members and Food Business Operators with information on the requirements based on Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN - and is for general information purposes only. The information contained herein does not constitute legal or other professional advice. No member of ISDI accepts any responsibility or liability to users or any third parties in relation to the use of the information contained in this guidance.

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ABOUT ISDI

The International Special Dietary Foods Industries (ISDI) is the leading international expert association on special dietary foods which brings together national, regional and international associations that are active in this food sector from more than 20 countries over 6 continents. ISDI has a Non-Governmental Organization Observer status before Codex.

I) CONTEXT

Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN was revised in 2008. This standard applies to foods for special dietary uses that have been formulated, processed or prepared to meet the special dietary needs of people intolerant to gluten.

II) DEFINITIONS

ISDI recommendation

Without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing the products, and establishing requirements and in some cases specific status for foods for special dietary use for persons intolerant to gluten, ISDI has developed for information purpose only the following guidance document based on Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN. Sections directly taken from this Standard are highlighted in italic in this guidance.

A) Gluten-free food (section 2.1.1):

Gluten-free foods are 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, oats 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, oats 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.*

B) Foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg (section 2.1.2):

These foods consist 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, oats or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100 mg/kg in total, based on the food as sold or distributed to the consumer. Decisions on the marketing of products described in this section may be determined at the national level.

C) Gluten (section 2.2.1):

Gluten means a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M NaCl.

D) Prolamin (section 2.2.2):

Prolamins are defined as the fraction from gluten that can be extracted by 40 - 70% of ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats avenin. It is however an established custom to speak of gluten sensitivity. The prolamin content of gluten is generally taken as 50%.

E) Wheat:

Wheat means all *Triticum* species, such as durum wheat, spelt, and khorasan wheat, which is also marketed under different trademarks such as KAMUT.

F) Specific status of Oat:

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.

ISDI comment

WHEAT ALLERGY VS. COELIAC DISEASE

Codex Standard 118-1979 does not define or describe adverse reactions to gluten. Non-toxic adverse reactions are typically classified as a food allergy or food intolerance. When a person is allergic to wheat, the immune system exhibits an abnormal reaction to wheat proteins and exhibits symptoms similar to those caused by other food allergies. The only way to manage wheat allergy is to completely avoid the allergen involved.

Coeliac disease is neither an allergy nor an intolerance. It is an autoimmune disease where the consumption of gluten triggers the immune system to react and damage the lining of the small intestine, causing intestinal malabsorption. People with coeliac disease suffer from a permanent intolerance to gluten. The conventional treatment is a gluten-free diet, however, very low gluten food or gluten-free food help manage the diet of most coeliac patients.

The malabsorption syndrome is precipitated by the ingestion of foods containing gluten, such as wheat, rye, and barley. It is characterized by inflammation of the small intestine, loss of microvilli structure, failed intestinal absorption, and malnutrition.

“Coeliac disease” [MeSH Terms], <https://www.ncbi.nlm.nih.gov/mesh/?term=coeliac+disease>

III) OTHER RELEVANT CODEX STANDARD & FOOD LAW CONCEPTS

ISDI recommendation

The elements below are for information purpose and can be referenced without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing the products, and establishing specific requirements related to the labelling of gluten related information.

It is the responsibility of the Food Business Operators to ensure that products that are put on the market meet the relevant regulations applying to the products in the market considered.

A) Codex Standards of relevance

- a) CODEX STAN 163-1987- STANDARD FOR WHEAT PROTEIN PRODUCTS INCLUDING WHEAT GLUTEN
- b) CODEX STAN 1-1985 - GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS
- c) CODEX STAN 146-1985 - GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES

B) Labelling general principles

CODEX STAN 1-1985 - GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS highlights in section 3 on General Principles:

3. GENERAL PRINCIPLES

- 3.1 *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.*
- 3.2 *Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.*

ISDI comment

It is to be noted that CODEX STAN 1-1985 - GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS applies to all prepackaged foods including foods for special dietary use for persons intolerant to gluten, without prejudice of national regulations or interpretations to be confirmed by Food Business Operators before marketing the product.

The above mentioned general principle has therefore consequences for foods for special dietary use where composition requirements in relevant Codex Standards or National Regulation prohibit the use of gluten in the food for special dietary use considered. In such cases, labelling information on the absence or a lower level of gluten is generally to be considered misleading and therefore prohibited. Such cases are further explained in this guidance.

C) Allergen Labelling

CODEX STAN 1-1985 - GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS SECTION ON MANDATORY ALLERGEN LABELLING in section 4.2.1.4 lists the foods and ingredients that are known to cause hypersensitivity and that shall always be declared on the label.

Among the listed foods and ingredients that are known to cause hypersensitivity and that shall always be declared on the label: "Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these".

ISDI comment

Products meeting the requirements established by Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN including a gluten level lower than 20 mg/kg still have to inform consumers on allergens presence including the cereals containing gluten listed in section 4.2.1.4 of the CODEX STAN 1-1985 - GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS SECTION ON MANDATORY ALLERGEN LABELLING.

IV) GLUTEN STATEMENTS AS DEFINED BY THE STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (CODEX STAN 118-1979)

A) GLUTEN-FREE

The statement 'gluten-free' may only be made by Gluten-free foods as defined by the Codex Standard, where the food as sold or distributed to the final consumer contains no more than 20 mg/kg of gluten. When such a statement is made, it shall be printed in the immediate proximity of the name of the product.

B) GLUTEN-FREE LABELLING AND FOODS FOR SPECIAL DIETARY USE CATEGORIES

i. STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (CODEX STAN 074-1981, REV. 1-2006)

Based on the Codex Standard for PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN in section 8.6.3 of this Standard, *when the product is composed of glutenfree ingredients and food additives, the label may show the statement "gluten-free", in accordance with the requirements of Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN.*

ISDI comment

It is to be noted that CODEX STAN 074-1981, REV. 1-2006 - STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN is intended for products for infants above 6 months of age.

ii. STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72-1981)

According to Section 3.1.1 of the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72-1981), *in Infant Formula and Formula for Special Medical Purposes intended for Infants, all ingredients and food additives shall be gluten-free.*

ISDI comment

It is to be noted that many countries specifically prohibit in their national regulations the provision of information on the absence or reduced presence of gluten in infant formula.

ISDI recommendation

Without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing the products, and considering the misleading aspects of such a communication, covered by the General Principles of CODEX STAN 1-1985 - GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS, and although it is not specified per se in the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS - (CODEX STAN 72-1981), ISDI considers gluten-free statements should not be made in relation to Infant Formula and Formula for Special Medical Purposes.

iii. STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987)

CODEX STAN 156-1987 - STANDARD FOR FOLLOW-UP FORMULA does not provide any elements regarding the provision of gluten information.

ISDI comment

Without prejudice of national regulations or interpretations to be confirmed by Food Business Operators before marketing the product, one can consider from the Codex Standards that Follow-up formula may use "gluten-free" or low in gluten statements, in accordance with the requirements of Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN and the General Principles of CODEX STAN 1-1985 - GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS. It is to be noted that several countries prohibit the use of "gluten-free" or low in gluten statements for follow-up formula, at least intended for 6 to 12 months. Without prejudice of national regulations or interpretations to be confirmed by Food Business Operators before marketing the product, Food Business Operators should also assess the provision of "gluten-free" or low in gluten statements on follow-up formula labels in light with the General Principles from CODEX STAN 1-1985 - GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS and ensure that such information could not be considered as false, misleading or deceptive or as likely to create an erroneous impression regarding the character of the products considered. For example, in countries:

- where all Follow-up Formulas present on the market are Gluten-free or with lower levels of gluten,
- or where the understanding of consumers is that such products are per se Gluten-free or with lower levels of gluten,

Statements on "Gluten-free" or lower gluten levels could be prohibited as the information could be considered as false, misleading or deceptive or as likely to create an erroneous impression regarding the character of the products considered.

In all cases, when considering the providing of information on "gluten-free" or low gluten levels for Follow-Up Formula, Food Business Operators should confirm with competent national or regional authorities that such statements are allowed for Follow-up Formula, before marketing the product.

iv. STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES (CODEX STAN 180-1991)

This section addresses adult FSMPs (see previous section for Infant Formula for Special Medical Purpose)

In section 4.5 of the STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES, the following and non-exhaustive list of requirements for information to be included in the labelling are provided:

- *The statement “For the dietary management of” with the blank to be filled in with the specific disease(s), disorder(s) or medical condition(s) for which the product is intended, and for which it has been shown to be effective.*
- *A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.*
- *If the product has been formulated for a specific age group, it should carry a prominent statement to this effect.*
- *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 comment

Without prejudice of national regulations or interpretations to be confirmed by Food Business Operators before marketing the product, ISDI considers that where a Food for special medical purpose – other than Infant Formula for Special Medical Purpose (see previous section) - is addressing gluten intolerance or coeliac disease, both STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES (CODEX STAN 180-1991) and STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (CODEX STAN 118-1979) are applicable.

v. Other Food for Special Dietary Use Products

ISDI recommendation

Without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing the products, meal replacements (FORMULA FOODS FOR USE IN WEIGHT CONTROL DIETS and FORMULA FOODS FOR USE IN VERY LOW ENERGY DIETS FOR WEIGHT REDUCTION), sports food and any other food for special dietary use product may show the statement “gluten-free” on their label, in accordance with the requirements of Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN and the General Principles of the GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CODEX STAN 1-1985).

C) FOODS SPECIALLY PROCESSED TO REDUCE GLUTEN CONTENT TO A LEVEL ABOVE 20 UP TO 100 MG/KG

The Codex Standard highlights that the labelling of products specially processed to reduce gluten content to a level above 20 up to 100 mg/kg as sold or distributed to the consumer, should be determined at the national level.

However, these products must not be called gluten-free. In addition, the labelling terms for such products should indicate the true nature of the food, and shall be printed in the immediate proximity of the name of the product.

ISDI comment

ISDI notes that to date, the mention «very low gluten» or similar expression is used very little by Food Business Operators to the extent that the tolerance to gluten in individuals is difficult to quantify.

D) ADDITIONAL STATEMENT FOR SPECIFICALLY FORMULATED PRODUCTS

“Special dietary”, “special dietetic” or any other equivalent term

The Codex STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (Codex Standard 118-1979) *applies to foods for special dietary uses that have been formulated, processed or prepared to meet the special dietary needs of people intolerant to gluten.*

ISDI comment

Without prejudice of national regulation and interpretations to be confirmed by Food Business Operators before marketing the products, GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES (CODEX STAN 146-1985) provides that the designation “special dietary”, “special dietetic” or an appropriate equivalent term, may be used in conjunction with the name only where the product is a Foods for Special Dietary Uses defines as follows (section 2.1):

Foods for Special Dietary Uses are 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. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.

ISDI recommendation

Therefore, without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing the products: Foods for special dietary uses that have been formulated, processed or prepared to meet the special dietary needs of people intolerant to gluten may bare the following statements on the label: “special dietary”, “special dietetic” or an appropriate equivalent term.

Food Business Operators have to be careful that statements such as ‘Suitable for people intolerant to gluten’, ‘Suitable for coeliacs’, ‘Specifically formulated for people intolerant to gluten’ or ‘Specifically formulated for coeliacs’ are only present on a label if the statements “Gluten-free” is also present (Gluten-free <20mg).

V) GLUTEN STATEMENTS AS DEFINED BY THE STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (CODEX STAN 118-1979)

Without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing the products, section 4.3 of Codex STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (Codex Standard 118-1979) provides that *a food which, by its nature, is suitable for use as part of a gluten-free diet, shall not be designated "special dietary", "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 gluten-free", provided that:*

- it complies with the essential composition provisions for gluten-free
- such a statement does not mislead the consumer (CODEX STAN 1-1985 - GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS highlights in section 3 on General Principles)

ISDI comment

Section 4.3 of Codex STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (Codex Standard 118-1979) also highlights that *more detailed rules in order to ensure that the consumer is not misled may be determined at the national level.* ISDI notes that for this specific case indeed, national regulation and/or interpretation often exist, establishing more detailed rules at the national level. Food Business Operators shall clarify this before marketing the products.

VI) FOOD AUTHORISED (OR NOT) TO LABEL GLUTEN-FREE

ISDI comment

On the basis of the STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (CODEX STAN 118-1979), ISDI considers that 3 categories of food can be defined and are embedded in the simplified decision tree developed by ISDI based on the STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (CODEX STAN 118-1979) and other relevant Codex texts.

CATEGORY 1: Food that naturally does not contain gluten and that based on the manufacturing process meets the requirements for Gluten-free labelling

Food which, by its nature, is suitable for use as part of a gluten-free diet, shall not be designated "special dietary", "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 gluten-free" provided that it complies with the essential composition provisions for gluten-free as set out in section 3.1 and provided that such a statement does not mislead the consumer. More detailed rules in order to ensure that the consumer is not misled may be determined at the national level.

CATEGORY 2: Food that based on the manufacturing process does not contain gluten and meets the requirements for Gluten-free labelling

Without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing, these products can claim "Gluten-free".

Under ISDI's scope of products, Complementary food, Follow-up formula in certain cases (see guidance), Food for special medical purposes (FSMP), Meal Replacements (Low calorie diet and very low calorie diet), Sports food and any other food for special dietary use covered by the GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES (CODEX STAN 146-1985) and not covered by specific Codex Standards can pertain to category 2 provided that the product meets the requirements established in STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (CODEX STAN 118-1979).

CATEGORY 3: Food categories that should not carry Gluten-free statements

Without prejudice of national regulations including those covering special denominations and national interpretations to be confirmed by Food Business Operators before marketing the products, ISDI considers that according to CODEX STAN 72-1981 Infant Formula products should not carry Gluten-free statements.

ISDI recommendation

For category 1 and 2, without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing, ISDI recommends Food Business Operators to keep information regarding the manufacturing processes and the Good Manufacturing Practices (GMP), HACCP and tests (see guidance below). In many countries, keeping those records for a defined amount of time is a legal requirement.

A SPECIFIC CASE - OAT

CODEx STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (CODEX STAN 118-1979) highlights that 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.

However, a major concern is the contamination of oats with wheat, rye or barley that can occur during grain harvesting, transport, storage and processing. Therefore, the risk of gluten contamination in products containing oats should be taken into consideration with regard to the relevant information provided on those food products by food business operators.

ISDI recommendation

Without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing the products, ISDI recommends if oats are used, that they need to have been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley, or their crossbred varieties and the gluten content of such oats cannot exceed 20 mg/kg.

FOOD BUSINESS OPERATORS RESPONSIBILITY – RISK MANAGEMENT & COMMUNICATION

Codex GENERAL PRINCIPLES OF FOOD HYGIENE (CAC/RCP 1-1969) highlights that people have the right to expect the food they eat to be safe and suitable for consumption.

Section 2.1.2 also establishes the provisions that Industry should apply the hygienic practices set out by Codex to provide food which is safe and suitable for consumption.

In the specific case of FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN, section 3.4 provides that the products covered by the STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (Codex Standard 118-1979) shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with gluten.

It is important that the information on gluten provided by any product placed on a specific market does not contravene any of the Codex Standards and relevant national legislations of the country where the food is marketed, and also that it is compliant with any other relevant laws.

HOW TO ENSURE COMPLIANCE?

Beyond the general requirements to be safe, applicable to all food, there are actually no specific requirements in the Codex standard on how to ensure compliance to the Codex Standard and what are the GMP for manufacturing of products covered by the STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN (Codex Standard 118-1979). This falls under the responsibility of the Food Business Operator. The elements highlighted below are therefore linked to general hygiene and good manufacturing practice.

ISDI recommendation

It is recommended that manufacturers producing foods for people intolerant to gluten ensure that their facilities are either adequately cleaned down or dedicated to the production of such foods to eliminate any risk of cross-contamination that could occur from multi-purpose food manufacturing.

If challenged, the food producer will need to demonstrate that they had put in place appropriate procedures and controls, in order to ensure that the final product does not contain more than the specified level of gluten.

Showing due diligence through Critical Control Points, a system of record keeping and regular testing to demonstrate consistent results is advisable.

HAZARD ANALYSIS CRITICAL CONTROL POINT – HACCP

Risk Analysis

As a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing, the Hazard Analysis and Critical Control Point (HACCP) should take into consideration the specific hazards linked to a Gluten-free production line.

This should therefore be integrated in the hazard analysis that is used as a premise to the establishment of the HACCP system, under the responsibility of the Food Business Operators.

Specific control points

Food Business Operators shall include gluten control in the HACCP plan for processing as a critical control point. Relying on the statements of the suppliers in ingredient specifications is not sufficient.

Food Business Operators will need to ensure verification of legal compliance by analytical control.

The extent of these controls will depend on the production environment (e.g. the risk of cross contact) and the level of assurance given by the suppliers of the raw materials.

If the products are produced in an environment in which also wheat containing products are produced, stored or used, it is more difficult to avoid cross-contamination. Quality assurance measures should be in place (in the context of the HACCP plan) to avoid such cross contact.

In addition, verification should be carried out on an appropriate number of samples of every batch of the final product. If manufacturing is taking place in an environment where no wheat containing ingredients are used, the risks are easier to manage and appropriate sampling of the raw materials and/ or final products will be required, as relevant.

METHODS OF ANALYSIS AND SAMPLING

Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN, provides for the following elements regarding methods of analysis and sampling that can be applied by Food Business Operators without prejudice of any national regulations and interpretations to be confirmed by Food Business Operators before marketing the products. Food Business Operators are responsible in establishing methods of analysis and sampling that are compliant with the requirements linked to the country where the food is marketed

General outline of the methods (Section 5.1)

The quantitative determination of gluten in foods and ingredients shall be based on an immunologic method or other method providing at least equal sensitivity and specificity.

- *The antibody used should react with the cereal protein fractions that are toxic for persons intolerant to gluten and should not cross-react with other cereal proteins or other constituents of the foods or ingredients.*
- *Methods used for determination should be validated and calibrated against a certified reference material, if available.*
- *The detection limit has to be appropriate according to the state of the art and the technical standard. It should be 10 mg gluten/kg or below.*
- *The qualitative analysis that indicates the presence of gluten shall be based on relevant methods (e.g. ELISA-based methods, DNA methods).*

Method for determination of gluten (Section 5.2)

Enzyme-linked Immunoassay (ELISA) R5 Mendez Method.

ISDI recommendation

Food Business Operators shall apply an appropriate testing system to ensure that the critical control point is adequately controlled.

USE OF GLUTEN-FREE LOGOS AND SYMBOLS

ISDI recommendation

Without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing the products, including those covering special denominations and national interpretations to be confirmed by Food Business Operators before marketing the products, ISDI considers that Food Business Operators are not prohibited from using a logo/symbol in conjunction with the claims “gluten-free”, to reinforce the suitability of products for this particular group of consumers.

If using a logo/symbol, it must however be clear that this has the same meaning as the statement “gluten-free”.

Such logo/symbol cannot be used on its own.

Certain third party certification/auditing bodies have established specific logos that Food Business Operators can use on the package of their products after being audited.

NOTIFICATION OF GLUTEN-FREE FOOD PRODUCTS

ISDI recommendation

Food Business Operators are invited to contact national authorities or national associations in order to assess the situation within a specific market.

ADDITIVES AUTHORISED IN FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN

Without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing the products, the General Codex Standard on Food Additives (GSFA) is establishing category 13 to cover food for special dietary use.

Category 13 - Foodstuffs intended for particular nutritional uses

Description:

Foods for special dietary use are specially processed or formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological condition and/or specific disease and disorder. The composition of these foods must differ significantly from the composition of ordinary foods of comparable nature, if such foods exist (1). Dietetic foods other than those in 13.0 are included in the categories for their standard counterparts (2).

(1) General Standard for Labelling of and Claims for Prepackaged Foods for Special Dietary Use (CODEX STAN 146-1985).

(2) For example, diet soda is found in 14.1.4.1, and low-joule jam is found in 04.1.2.5.

Within category 13, Foods for Special Dietary Use for persons intolerant to gluten can fall under category 13.5, when they meet the requirements of this sub category.

Category 13.5 - Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6 (13.5)

Description:

Products of high nutritional content, in liquid or solid form (e.g. protein bars), to be used by individuals as part of a balanced diet to provide supplemental nutrition. Products are not intended to be used for purposes of weight loss or as part of a medical regimen. Dietetic foods for persons intolerant to gluten other than those in 13.5 are included in the categories for their standard counterparts.

ISDI recommendation

Without prejudice of national regulations and interpretations to be confirmed by Food Business Operators before marketing the products, ISDI recommends for Food Business Operators to keep on file information regarding the decision-making process that led to the decision to classify a product in a specific additives category. Rationale should be kept to explain why a Food Business Operator has decided to classify a product under category 13 and its subcategories including 13.5, or in a counterpart category of the General Codex Standard on Food Additives.

Terminology

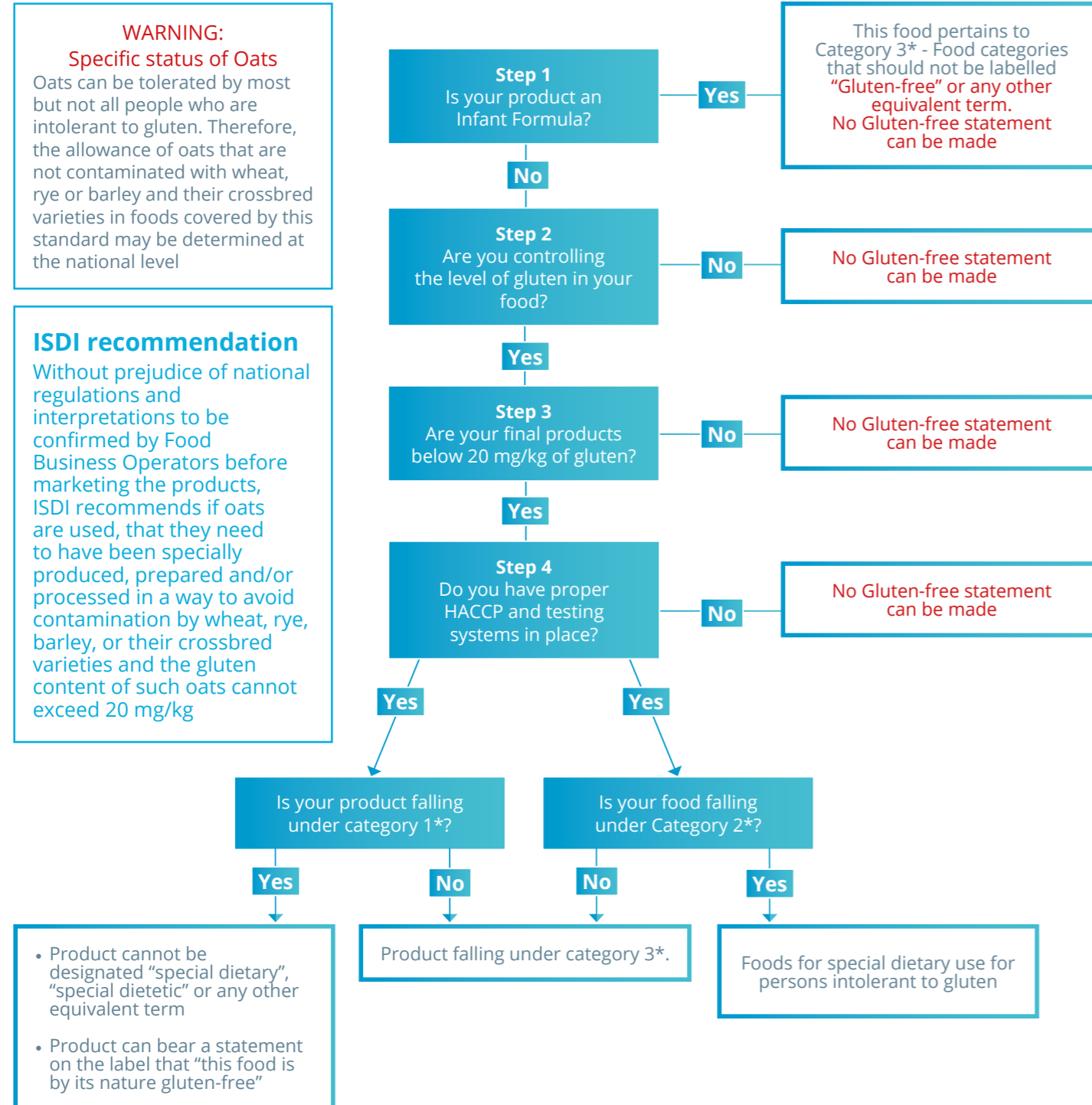
DNA	Deoxyribonucleic acid
ELISA	Enzyme-linked Immunoassay
FBO	Food Business Operator
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point
ISDI	International Special Dietary Industries

ISDI GLUTEN-FREE LABELLING DECISION TREE

BASED ON CODEX STAN 118-1979 FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN



International Special Dietary Foods Industries



***Category 1:**
Food that naturally does not contain gluten and that based on the manufacturing process meets the requirements for Gluten-free labelling

***Category 2:**
Food that based on the manufacturing process does not contain gluten and meets the requirements for Gluten-free labelling

***Category 3:**
Food categories that should not be labelled Gluten-free

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

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