AOECS

Association Of European Coeliac Societies

International not for profit association, subject to Belgian Law with legal seat in Brussels

AOECS Standard for Gluten-Free Foods

Technical requirements for licensing the Crossed Grain Symbol

AOECS Standard for Gluten-Free Foods **September 2016**
Issued by the Association Of European Coeliac Societies
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1. Preamble

1.1 The AOECS Standard for Gluten-Free Foods applies to food and drinks which comply with the Definition set out in Section 2 below to meet the special dietary needs of people intolerant to gluten.

1.2 The products covered by this Standard shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with gluten.

1.3 A Hazard Analysis and Critical Control Point System (HACCP) should be implemented to exclude contamination with gluten. The technical requirements for a safe food production are specified in Section 7.

1.4 The definition of foods described in this Standard are based on the worldwide Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten.

2. Definition

2.1 Gluten-free foods and drinks

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.

Foods which are not permitted to bear the Crossed Grain Symbol are listed in Annex I.

2.2 Oats

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

3. Subsidiary Definitions

3.1 **Gluten** is defined as 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.

3.2 **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.

3.3 The prolamin content of gluten is generally taken as 50 %.

4. Essential Composition

4.1 Foods as defined in 2.1 b) are substituting important basic foods and should therefore supply approximately the same amount of vitamins and minerals as the original foods they replace.

5. Labelling, advertising and presentation

5.1 Foods as defined in 2.1 without any oats shall be labelled “gluten-free”. The registration number shall be clearly displayed underneath the Symbol and consist of the country code – company code – product number.

5.2 Foods as defined in 2.1 containing oats either as an ingredient, or pure oats, shall be labelled “gluten-free”. However the word “OATS” shall be clearly displayed underneath the Symbol before the registration number to make consumers aware that most, but not all, people who are intolerant to gluten may consume these products.

5.3 Foods as defined in 2.1 may be accompanied by the additional statements ‘suitable for people intolerant to gluten’ or ‘suitable for coeliacs’. They may be labelled ‘specifically formulated for people intolerant to gluten’ or ‘specifically formulated for coeliacs’.

6. Analytical Methods

6.1 The analytical method to be used is the R5-sandwich-ELISA (Mendez-method)*, which has been endorsed by the Codex Committee on Methods of Analysis and Sampling as a Type 1 method. This method detects the prolamins from wheat, rye and barley in unprocessed and heat-processed products. For unprocessed products like flours, the Ethanol extraction can be used, however, for heat-processed products the ‘Cocktail’ extraction must always be used. For calibration the gliadin reference material from the Working Group on Prolamin Analysis and Toxicity (PWG-gliadin) must always be used. The R5-sandwich-ELISA is not applicable for products consisting of, or containing, fermented or partially hydrolysed gluten.

6.2 For the detection of fermented of partially hydrolyzed gluten like beer, syrups or sourdough the R5-competitive-ELISA has to be applied.

6.3 For a rapid in-house control of raw materials and surfaces, as well as to check the effectiveness of cleaning procedures in production equipment, the lateral flow test based also on the R5-antibody can be used. If heat-treated materials are to be tested, the 'Cocktail' extraction must be used. In case of a positive result the gluten concentration must be determined by ELISA.

* In the collaborative study for approval of the Codex Method the R5-antibody was used with the R5 ELISA RIDASCREEN® Gliadin R7001 test kit from R-Biopharm. If test kits from other companies based on the R5 antibody, but with extraction solutions other than the 'Cocktail' are used, it is recommended to compare the results with the RIDASCREEN® Gliadin R7001.

7. Technical requirements for food production

7.1 The company shall be a registered food producer in its country. This means that the company has to fulfill any national food legislation requirements and the production site will be inspected by the National Food Safety Authority.

7.2 A Hazard Analysis and Critical Control Point (HACCP) System shall be implemented which includes a risk assessment ensuring the avoidance of gluten contamination during all stages of production, storage, transportation and handling. The HACCP Guidance is attached in Annex II.

7.3 All kinds of foods for persons intolerant to gluten are specified in Section 2.

7.4 The company should undertake a risk assessment regarding gluten contamination in ingredients.

- For high-risk raw materials (e.g. flours) gluten contamination shall be excluded and certified either by an independent and accredited gluten testing laboratory or appropriate in-house controls. The analytical method is defined in Section 6.
- For low-risk ingredients it shall be guaranteed by the producer or supplier that these ingredients are gluten-free and supported by the necessary associated documentation.

The risk level of raw materials should be assigned according to:

- the food safety management system of the supplier (for example if the supplier manufactures only gluten-free raw materials or both gluten-free and gluten-containing raw materials)
- the type/kind of raw materials.

High risk raw materials include: flours, starches and starch products, cereals and pseudo-cereals, extruded and/or malted cereals, oats.

7.5 Transportation conditions of ingredients shall be agreed and appropriate documentation shall accompany all supplies clearly identifying the product, lot number, quantity, source and destination in order to avoid any accidental contamination of gluten. In the case of inappropriate or inadequate documentation or identification of a critical point further investigation and inspection of premises may be necessary. The packaging shall be clean, original, undamaged, labelled, within the best-before-date and in full compliance with the supply contract.

7.6 All the procedures, GHP (general hygienic practice) and GMP (good manufacturing practice) shall be recorded and used as part of the risk assessment in the food manufacturing process taking into consideration:

- any and all points that are potentially subject to gluten contamination e.g. areas shared for warehousing, production, packaging, equipment facilities, transport lines etc.
- any and all activities aimed at minimizing the risk of gluten contamination.

7.7 The production of gluten-free foods shall be separated in place and/or in time. When the same production lines and equipment are used to manufacture gluten-free and gluten-containing products, the following actions shall be performed to avoid any risk of gluten contamination:

- cleaning operations that ensure there can be no mixing or any kind of cross-contamination
- appropriate sampling and analysis shall be performed according to the risk assessment.

7.8 The staff involved in the production shall be trained on hazard of gluten contamination; their clothes shall be clean and changed according to the risk assessment.

7.9 Gluten analysis shall be done according to the risk assessment regularly on the basis of a plan for sampling and analysis of the products as sold or distributed to the consumer (the plan may be revised, when significant historical data are available).

7.10 The company shall have a monitoring system which includes traceability and a non-conformance procedure and corrective actions (Annex III describes non-conformance).

7.11 Should non-conformance be detected when the finished product is already on the market, the company shall immediately inform the Licensor and agree appropriate actions.

8. Documentation of the analytical controls for the Licensor

8.1 The analytical certification of the product as sold or distributed to the consumer shall be sent to the Licensor (coeliac society authorised according to the AOECS Charta to act on of behalf of AOECS) at least once a year.

8.2 The analysis shall be made by an accredited and independent lab which is very familiar with the methods defined in Section 6. No other method is permitted. A list of laboratories may be provided by the Licensor.

8.3 In addition to the above the Licensor is encouraged to take random samples from time to time.

List of food products which are not permitted to bear the Crossed Grain Symbol

UNPROCESSED GRAINS

- Rice
- Maize

MEAT, FISH AND EGGS

- All sorts of fresh or frozen meat, fish and seafood not processed
- Tinned or canned fish and seafood with water/vegetable oil and salt, without additives or other substances
- Eggs

MILK AND MILK-DERIVATES

- Fresh milk, UHT milk and sterilized milk without additives, vitamins or other substances
- Infant formula and follow on formula
- Yogurt and other fermented dairy products without additives, vitamins or other substances
- Fresh milk cream and UHT milk cream
- Cheese*

VEGETABLES AND LEGUMES

- All sorts of plain, fresh, frozen, canned or dried vegetables and legumes

NUTS AND SEEDS

- All sorts of nuts and seeds, with or without shells, not processed

FRUITS

- All sorts of plain, fresh, frozen, canned or dried fruits

DRINKS

- Fruit juices
- Soft drinks
- Mineral waters
- Tea, pure coffee
- Wine
- Distillates for spirits

SWEETS

- Honey, sugar
- Marmalade and jam
- Sweeteners

DRESSINGS AND OTHERS

- Butter, bacon fat, lard
- Vegetable oil
- Vinegar
- Spices and aromatic herbs not processed

* according to Codex General Standard for Cheese CODEX STAN 283-1978). Processed cheeses are permitted to bear the Symbol.

HACCP Guidance for managing gluten-free production

PROCESS PHASE	HAZARD	PREVENTION	CORRECTION	INSTRUCTIONS Control Point (CP) Critical Control Point (CCP)	PERSON IN CHARGE
Suppliers' Qualification	Gluten contamination in raw material	Assesssment of suppliers (audit, questionnaire, etc.)	– choose another supplier – make the supplier aware of gluten contamination risks	– list of qualified suppliers – supplier documentation – audit of supplier, report, questionnaire, etc.	QM
Quality of raw material	Gluten contamination in raw material	Hazard analysis of the raw materials and association with a critical level (that is a risk that the raw material may be contaminated)	– change raw material or supplier	CCP – list of suitable raw materials – supplier documentation	QM
Receiving raw material	Gluten in raw material or surroundings/wrong (not GF) raw material	Inspection on delivery, control of documents: – certificate of gluten analysis from the producer and/or other documentation by the supplier – documents identifying the cargo (product, GF nature, lot number, quantity, source, destination) – random sampling (analytical plan)	– refuse the acceptance of the materials or – separate storage of the raw material (identified as not-to-be-used) while awaiting documents from supplier and/or analysis result	CCP – certificate of gluten analysis from the producer and/or – declaration/documentation by the supplier	Leader of production, QM
Pouring from sacks (e.g. flour/flour mixtures, pasta, etc.)	Gluten contamination from environment	Regular checking of the sacks	Elimination of the sacks involved	Instructions/procedures for – transport – storage	Leader of the warehouse, QM

PROCESS PHASE	HAZARD	PREVENTION	CORRECTION	INSTRUCTIONS Control Point (CP) Critical Control Point (CCP)	PERSON IN CHARGE
Storing raw material	Gluten in the environment, gluten contamination	– adhering to cleaning/hygiene plan – storing GF products separately from gluten containing materials – covering – closed packages (air-tight)	– separation of GF raw materials – own storage/cupboard – cleaning	– instructions – clear identification of storage place (GF/gluten containing) – documentation – cleaning documentation	Leader of warehouse, QM
Product preparation e.g.: - milling, - storing, - mixing, - kneading, - dough, cakes, - raising, - baking, - preparation of creams, - glaze, icing, decoration - drying - cooling	Wrong raw material	– raw material labels checking recipe checking	– elimination of the contaminated/wrong lot/amount – cleaning – start a new production	– instructions of recipe/raw material labels checking - non-conforming raw material identification instruction	
	Gluten contamination from: – environment – equipment – from working staff – from previous production – other gluten-containing products (cross-contamination	– separate working/production area for GF – temporal separation (GF first) – separate equipment – separate silo/tank for GF raw materials – ensuring cleaning of equipment – regular and thorough cleaning of the equipment (cleaning plan) – cleaning procedures based on hazard analysis – regular checking of cleanliness of the working area – transportation in a closed tube/pipe		CCP – cleaning instructions – production recordings – surface cleanliness samples (analytical plan) – critical limits should be set (gluten contamination levels should not exceed 20 mg/kg (ppm) for “gluten-free” products)	Leader of production, QM
		– instructions – staff training		CP – instructions – procedures – staff training documentation	

PROCESS PHASE	HAZARD	PREVENTION	CORRECTION	INSTRUCTIONS Control Point (CP) Critical Control Point (CCP)	PERSON IN CHARGE
Production in mixed production unit	Gluten contamination from previous production (e.g. pasta production: pressing)	– cleaning after gluten containing production – evaluate the need for elimination of the first amount (the quantity necessary to be sure there is no more risk of contamination must be evaluated and validated) – precise registration of the eliminated quantities – regular checking of the cleanliness in the manufacturing area		CCP – cleaning instruction – first amount elimination instruction – production procedures – recordings – surface cleanliness samples (analytical plan)	
Packaging/casing	– wrong packaging/label – gluten contamination or – soiling of package	– correct and clean packaging materials, protective films and labelling – precise labelling – temporal separation (GF first)	elimination of the amount produced	CP Instructions/procedures – traceability – regular checks for labelling – analysing product for gluten contamination – critical limits should be set (gluten contamination levels should not exceed 20 mg/kg (ppm) for “gluten-free” products)	Leader of production, QM
Casing/freezing	Contamination with gluten	– separate casing/freezing and transport – staff training – checking	elimination of the lot of products	Instructions and procedures – storage – freezing – transport	Leader of logistics, QM

PROCESS PHASE	HAZARD	PREVENTION	CORRECTION	INSTRUCTIONS Control Point (CP) Critical Control Point (CCP)	PERSON IN CHARGE
Cleaning of machines, pipelines, working area etc.	Gluten contamination from previous gluten-containing production through equipment and environment	– emptying and cleaning machines and units – cleaning plan and temporal separation (GF first) – cleaning procedures based on hazard analysis	– elimination of the amount produced – cleaning – start a new production lot packaging	CCP – cleaning instructions/procedures – recordings – surface cleanliness samples (analytical plan)	Leader of production, QM
Complaints and product recalls	The company is not able to withdraw from the market a non-conformed FP	– The company should have a NC/complaints management system – Customer or third party complaints should be recorded and dealt with accordingly – The Licensor should be always informed about contaminated FP in the market	– alert on all lots – recall on all lots	- instructions and procedures - recordings	QM
Traceability	No traceability (the company is not able to alert consumers or withdraw from the market a specific lot of FP contaminated with gluten or where a RM contaminated with gluten has been used)	- All ingredients and raw materials used in the production should be traceable with clear information regarding handling or storage. - Final products should be traceable right up to the customer they are sold to, with clear information regarding production, handling or storage.	– alert on all lots – recall on all lots	- instructions and procedures - recordings	Leader of production, QM

GLOSSARY

GF	Gluten-free
INSTRUCTIONS	Working procedures are controlled by the instructions
CP	Control point, continuous monitoring and documentation
CCP	Critical control point
QM	Quality Manager
RM	Raw materials
FP	Final products
NC	Non conformance

Auditors guide to non-conformance

Non-conformance is when the requirements laid down by the AOECS Standard are not fulfilled.

Non-conformances and corrective action

The level of non-conformity assigned by an auditor against a requirement is an objective judgement with respect to severity and risk and is based on evidence collected and observations made during the audit.

Non-conformities

Non-conformances against requirements shall be graded as:

- **Critical**: Where there is a critical failure to comply with a product safety or legal issue within the scope of the Standard. Examples include:
  - Placing a product that contains gluten on the market bearing the Crossed Grain symbol/labelled gluten-free
  - A severe risk of cross contamination e.g. gluten-containing ingredients contaminating gluten-free ingredients in storage
- **Major**: Where there is a substantial failure to meet the requirements of a 'statement of intent' or any clause of the Standard or a situation is identified which would, on the basis of available objective evidence, raise significant doubt as to the conformity of the product or service to the Standard. Examples include:
  - A minority of staff members have not completed recent round of training but training is in place
- **Minor**: Where a clause of the Standard has not been fully met but, on the basis of objective evidence, the conformity of the product or service to the Standard is not in doubt. Examples include:
  - Crossed Grain licence number is not displayed correctly

Procedures for handling non-conformances and corrective action

Following identification of any non-conformances against the requirements of the Standard during the audit, the company must undertake corrective action to remedy the immediate issue (correction). The process for 'closing out' non-conformances depends upon the level of non-conformance and the number of non-conformities identified.

Critical non-conformances

If a critical non-conformity is identified against a requirement of the Standard, then the site cannot be certificated against the Standard without a further full audit of the Standard.

Major non-conformances

If a major non-conformance occurs during the audit, corrective procedure should be initiated and an additional audit implemented after three months. If the producer provides evidence that the non-conformance has been corrected, the additional audit may not be necessary.

Minor non-conformances

If minor non-conformance occurs during the audit, corrective procedure should be initiated and monitored during the next annual audit and if it is not corrected it may be considered a major non-conformance.

Technical definitions

Appropriate in-house controls: High risk materials as defined in 7.4 are delivered to food producers usually with an analytical certification from an independent accredited laboratory using the R5-ELISA for gluten quantification as described in 6.1. Food producers are obliged to check the papers with the received raw material to be sure that no false lots have been delivered.

If food producers have own labs the staff should be very familiar with the R5-ELISA and work in accordance with the principles and requirements of ISO 17025:2005. It is recommended that they should compare their results with these of an independent accredited laboratory to be sure about their own results.

If food producers do not have own labs, the lateral flow test as described in 6.3 shall be used. It is a yes/no-test, the threshold is far below the 20 mg/kg gluten. In case of positive result, the gluten concentration must be determined by ELISA.

For checking the effectivity of cleaning procedure in the production equipment the lateral flow test can be used. Details are explained in 6.3.

Audit: A systematic independent examination (survey, evaluation, assessment, decision) to determine whether quality and food safety measures and outcomes comply with previously established gluten-free manufacturing requirements and whether all of the procedures and processes are implemented effectively and are adequate to achieve objectives. In the European Licensing System an audit refers to the verification of the fulfillment of the requirements of the AOECS Standard by the Licensee by inspections of the production plant/s and product/s. Non-conformities and deviations with, and from, the AOECS Standard are to be documented in an audit report. Audits are recurrent and on the site of the production facility to maintain and improve food safety and quality.

Critical Control Point (CCP): A point, step, or procedure at which controls can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

HACCP: Abbreviation of “Hazard Analysis and Critical Control Points”, which is a system that identifies, evaluates and controls hazards which are significant for food safety.

Hazards: A biological, physical or chemical agent that is reasonably likely to cause illness or injury in the absence of their control in food.

Independent, accredited laboratory: a laboratory accredited by the National Accreditation Body in accordance with standard ISO 17025:2005 for the analytical method as defined at point 6.

Lot: The amount of product that is homogenous and that is identifiable and separable from any other amount, thereby allowing it to be traced.