AOECS - Association of European Coeliac Societies
Non-Profit Association, subject to Belgian Law with legal seat in Brussels
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AOECS STANDARD

FOR GLUTEN-FREE FOODS

Technical requirements for licensing the Crossed Grain Symbol

Liability

While the developers of this document have made every effort to ensure that the information contained herein is accurate and complete at the time of issuance, AOECS, its different National Coeliac Societies (NCSs) and other stakeholders who were involved in the development of this Standard cannot be held liable for any error or omission in this document.

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Document Validity

The present version 3.0 of the AOECS Standard supersedes all previous versions and becomes binding for all audits to be conducted as of 1st January 2023.

Where amendments or clarifications in the interpretation of the AOECS Standard and relevant implementation guidelines may be necessary, these will be published on the AOECS website **www.aoecs.org** as a Position Statement. Such statements are mandatory in their use from the date specified for implementation and until the new revision of the AOECS Standard.

Version Control Table

Version number	Publication date	Description
Version 1.0	2009	Final version AOECS Standard
Version 2.0	2016	Final version AOECS Standard
Version 3.0	2022	Final version AOECS Standard

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1. Introduction

The AOECS Standard for Gluten-Free Foods (AOECS Standard) is a private standard owned by the Association of European Coeliac Societies (AOECS), which is registered in Belgium as a Non-Profit Association.

The AOECS Standard for Gluten-Free Foods applies to food and drinks and provides the best possible guarantee for people with coeliac disease, dermatitis herpetiformis Duhring and other gluten related conditions.

The definition of gluten-free foods, subsidiary definitions, essential composition and the requested analytical method for gluten determination used in this document comply with the Codex Standard for Special Dietary Use for Persons Intolerant to Gluten 118-1979 (Revision: 2008, Amendment: 2015).

Therefore, the AOECS Standard for Gluten-Free Foods provides food business operators (FBOs) with technical requirements and practical guidance, to meet the regulations set out in the Codex Standard 118-1979, which is the global reference defined by the Codex Alimentarius (FAO/WHO) and adopted by several national legislations worldwide.

FBOs may be eligible to use the Crossed Grain Trademark (CGT) on the pre-packaged foods produced in line with the AOECS Standard, if they meet the AOECS European Licensing System's requirements and apply for a licence from the National Coeliac Society (NCS) of their region.

2. Gluten-free foods definitions

2.1. Gluten-free foods can be either gluten-free by nature or foods from which gluten has been removed. Gluten-free foods are 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.

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.

2.3. Foods which are not permitted to bear the CGT are listed in Annex I.

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.

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

4. Essential Composition

4.1 Foods as defined in 2.1 b) substitute important basic foods and should therefore have approximately the same nutritional level 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 CGT and consist of the ISO country code – licence number – product number.

5.2 Foods as defined in 2.1 containing oats, shall be labelled “gluten-free”. However, the word “OATS” (and in the local language, if agreed by NCS) shall be clearly displayed underneath the CGT 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’*, if permitted

by national legislation. Additionally, for products listed in 2.1.b they may be labelled *'specifically formulated for people intolerant to gluten'* or *'specifically formulated for coeliacs'*, if permitted by national legislation.

5.4. Further information regarding advertising and presentation of the CGT is given in the AOECS Licence Contract between NCS and licence holder.

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 and those of unknown composition** 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 or partially hydrolysed 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, a lateral flow test can be used.

If heat-treated materials are to be tested, the 'Cocktail' extraction or an equivalent extraction with a suitable reducing solvent must be used. In case of a positive result the gluten concentration must be determined by an ELISA* based on the R5 antibody.

* *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 are used, further information can be provided by the National Coeliac Society.*

7. Technical requirements for food production

7.1 **Legal compliance:** The FBO has to fulfill any national food legislation requirements of its country and of the market to which it wants to get access, regardless of whether the FBO manufactures the food itself or has subcontracted the manufacture to another FBO.

7.2 **Risk management:** 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. Further information can be found under section 9.

7.3 The FBO shall undertake a risk assessment regarding gluten contamination in ingredients (including raw materials, flavourings, food additives and food enzymes) and processing aids. For reasons of convenience both ingredients and processing aids are further referred to as 'ingredients' throughout this document.

7.3.1 High-risk: For high-risk ingredients (e.g. flours) gluten contamination shall be excluded and certified either by an independent and accredited gluten testing laboratory or through appropriate in-house controls. The analytical method is defined in Section 6.

7.3.2 Low-risk: For low-risk ingredients it shall be guaranteed by the FBO that they are gluten-free, supported by the necessary associated documentation.

7.3.3 Special considerations: as per 2. b) The ingredients wheat, rye, barley and oats may be used, but must be specially processed to remove gluten so that the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer. When using these ingredients to produce gluten-free foods, additional testing must be undertaken according to the risk assessment.

7.4 The **risk level** of ingredients shall be assigned according to:

7.4.1 **the food safety management system of the supplier**. For example, whether the supplier manufactures only gluten-free ingredients, or both gluten-free and gluten-containing ingredients.

7.4.2 **the type of ingredients**. For example, high-risk ingredients include flours, starches and starch products, cereals and pseudo-cereals, extruded and/or malted cereals, oats.

7.5 **Transportation and logistics conditions:** Transportation conditions of ingredients shall be organized in such a way that any accidental cross-contact with gluten is avoided. The FBO will have accurate documentation clearly identifying the product, lot number, quantity, source and destination. In the case of inappropriate or inadequate documentation or identification of

a critical point, further investigation and inspection of premises may be necessary.

7.6 **The packaging** shall be clean, original, undamaged, labelled, within the best-before-date of the product and in full compliance with the supply contract for the part related to gluten.

7.7 **Potential cross-contact with gluten:** 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:

7.7.1 any and all points that are potentially subject to cross-contact with gluten e.g. areas shared for warehousing, production, packaging, equipment facilities, transport lines etc.

7.7.2 any and all activities aimed at minimizing the risk of cross-contact with gluten.

7.8 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 cross-contact with gluten:

7.8.1 cleaning operations that ensure there can be no mixing or any kind of cross-contact.

7.8.2 appropriate sampling and analysis according to the risk assessment.

7.9 **Staff training:** The staff involved in the production shall be trained in the hazard of gluten cross-contact; their clothes shall be clean and changed in accordance with the risk management procedures.

7.10 **Gluten analysis:** Gluten analysis shall be done regularly according to the risk assessment 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). The gluten analysis of the final product shall take place even when ingredients have been tested.

7.11 **Non-conformance management:** The company shall have a monitoring system which includes traceability and a non-conformance procedure and corrective actions.

7.12 Should non-conformaties be detected when the registered finished product is already on the market, the licence holder shall immediately inform the relevant NCS and agree appropriate actions. The relevant certification body shall also be informed.

8. Documentation of the analytical controls for the National Coeliac Society

8.1 The analytical certification of the product as sold or distributed to the consumer shall be sent to the relevant NCS at least once a year.

8.2 The analysis shall be made by an accredited and independent laboratory, which has obtained ISO 17025 accreditation from a competent authority. The methods are as defined in Section 6. No other method is permitted. A list of laboratories may be provided by the relevant NCS.

8.3 If FBOs have their own labs, the staff shall be well trained in using the R5-ELISA method and work in accordance with the principles and requirements of ISO 17025:2018. The FBO will, as part of its own risk management procedure, compare its results with those of an independent accredited laboratory to cross-check and verify the results on a regular basis.

8.4 In addition to the above, the relevant NCS is encouraged to take random samples from time to time, based on potential risks.

9. Non-conformities and corrective actions

9.1. Non-conformities - definitions and grading

9.1.1. Non-conformity is when the requirements laid down by the AOECS Standard are not met.

9.1.2. 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.

9.1.3. Non-conformity 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 AOECS Standard. Examples include:
  - Placing a product that contains gluten above 20mg/kg on the market bearing the CGT and labelled as gluten-free.
  - A severe risk of cross-contact, 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 AOECS 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 AOECS Standard. Examples include:
  - A minority of staff members have not completed a recent round of training, but training is in place.
- **Minor:** Where a clause of the AOECS Standard has not been fully met but, on the basis of objective evidence, the conformity of the product or service to the AOECS Standard is not in doubt. Examples include:
  - Registration number is not displayed correctly.

9.2. Procedures for handling non-conformities and corrective action

9.2.1. **Immediate issues:** Following identification of any non-conformities against the requirements of the AOECS Standard during the audit, the FBO must undertake corrective actions to remedy the immediate issue.

9.2.2. **Closing Out non-conformities:** The process for closing out non-conformities. This depends upon the level of non-conformity and the number of non-conformities identified.

9.2.3. **Non-conformities can be graded as:**

- **Critical:** If a critical non-conformity is identified against a requirement of the AOECS Standard, then the production site of the FBO cannot be certified against the AOECS Standard without a further audit to confirm that the critical non-conformities are resolved, and preventive procedures are in place.
- **Major:** If a major non-conformity occurs during the audit, corrective actions shall be initiated, and an additional audit will be conducted after three months. If the FBO provides satisfactory evidence that the non-conformity has been corrected, the additional audit may not be necessary.
- **Minor:** If minor non-conformity occurs during the audit, corrective actions shall be initiated and monitored during the next annual audit. If it is not corrected by the next annual audit, it may be considered a major non-conformity.

10. Minimum Criteria on HACCP for managing gluten-free production

List of acronyms used.

GF	Gluten-free
CP	Control point, continuous monitoring and documentation
CCP	Critical control point
QM	Quality Manager
RM	Raw materials
FP	Finished products
NC	Non-conformity

PROCESS PHASE	HAZARD	PREVENTION	CORRECTION	INSTRUCTIONS Control Point (CP) Critical Control Point (CCP)	PERSON IN CHARGE
Suppliers' Qualification	Cross contact with gluten in raw material	Assessment of suppliers (audit, questionnaire, etc.)	– choose another supplier – make the supplier aware of the risks of cross-contact with gluten	– list of qualified suppliers – supplier documentation – audit of supplier, report, questionnaire, etc.	QM
Quality of raw material	Cross contact with gluten in raw material	Hazard analysis of the raw materials and association with a critical level (i.e. 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 gluten-free (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 packaging (e.g. flour/flour mixtures, pasta, etc.)	Cross contact with gluten from the environment	Regular checking of the packaging	Elimination of the packaging 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, cross contact with gluten	– 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 contact)	– 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	Cross contact with gluten 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	– elimination of the contaminated/wrong lot/amount – cleaning – start a new production	CCP – cleaning instruction – first amount elimination instruction – production procedures – recordings – surface cleanliness samples (analytical plan)	Leader of production, QM
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	Cross contact with gluten	– separate casing/freezing and transport – staff training – checking	elimination of the lot/amount 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-conforming finished products (FP)	– The company shall have a complaints management system – Customer or third-party complaints shall be recorded and dealt with accordingly – The NCS shall be immediately 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 raw material (RM) contaminated with gluten has been used)	– All ingredients and raw materials used in the production shall be traceable with clear information regarding handling or storage. – Final products shall 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

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

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

Contact

If you want to obtain the Crossed Grain Symbol or have any questions regarding this document, please contact the national coeliac society in your country.