



AOECS

GLUTEN FREE

ADDENDUM

AOECS
Association of European Coeliac Societies



**Gluten Free
Alliance™**

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INTRODUCTION

This AOECS Addendum document serves to cover all requirements and expectations within the current AOECS Standard for Gluten-Free Foods ver. 3 - 2023 when delivered in combination with a GFSI Benchmarked Food Safety Standard (referred to as Main Audit and as listed in Appendix 1).

As the AOECS Addendum is not linked directly to any GFSI Benchmarked Food Safety Standard and is operated independently it is not subject to any certification or licence fees, except those related to the use of the Crossed Grain Trademark, which are payable directly to the relevant AOECS member society.

The AOECS Addendum is unaccredited but has been benchmarked against the AOECS Standard for Gluten-Free Foods ver.3 - 2023 and the specific GFSI standard in use.

ACKNOWLEDGEMENT

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BACKGROUND

AOECS (Association of European Coeliac Societies) founded in 1988, is an independent non-profit organisation. It is the umbrella organisation of European national coeliac societies with currently 39 enrolled member societies.

AOECS represents people who are affected by Coeliac Disease. The AOECS Standard for Gluten-Free Foods is set out to meet the special dietary needs of people intolerant to gluten. It adopts an approach that is preventative in nature and aims to address all potential hazards, including the risk of cross contact with gluten, as part of a manufacturer's overall safety and quality management system to meet the requirements of the Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten CXS 118-1979.

An audit to confirm compliance to the AOECS Standard is one of the mandatory steps that must be completed before a company can be licensed to use the Crossed Grain Trademark on its products.

It should be noted that the successful completion of the AOECS audit does not allow a Food Business Operator to use the AOECS Crossed Grain Trademark. The use of the Trademark is allowed following the granting of a licence by an AOECS member society.

Certification bodies intending to carry out an AOECS Addendum Audit must contact the relevant AOECS member society prior to scheduling the audit to initiate the licence contract process.



1. SCOPE

The AOECS Addendum document aims to provide a clear account of the compliance requirements, audit and certification delivery and operational specifications of the AOECS Standard for Gluten-Free Foods when this is delivered in combination with a recognised Food Safety scheme (GFSI-benchmarked or another GMP/HACCP-based).

2. AUDIT PLANNING AND DELIVERY

The audit frequency is no longer than annual re-certification, but frequency must be consistent with that of the Main Audit, if this is more frequent.

Audits are to be announced, except for those delivered alongside an unannounced GFSI audit, in which case the whole visit is unannounced.

For announced visits the site must be in gluten-free production on the day of the audit.

For unannounced audits it is acceptable for the site not to be in gluten-free production at the time of audit (provided this occurs due to the site's routine production planning).

For the subsequent audit of the site, gluten-free production is mandatory for if certification is to be granted. This can be achieved by methods including:

- use of blackout dates to limit unannounced audits to periods when the site is producing a gluten-free product
- moving to an announced audit GFSI schedule
- scheduling an announced AOECS audit separate to the unannounced GFSI audit

In the event of gluten-free production not being observed on the second audit visit to any site, then an additional visit will need to be booked at the client cost when a gluten-free product is being manufactured.

In any event all audited sites must have produced a gluten-free product in the previous 12 months, or if new to gluten-free production, they must have completed full product trials (for gluten-free product) within the last 6 months.

The AOECS Addendum audits cannot be delivered as standalone audits but always in combination with a Main Audit.

Main and AOECS Addendum audits can be completed by one auditor (or audit team) during a single visit to the client site.

Additional time to the Main audits is added to ensure completion of the AOECS Addendum audit on-site. Usually, the additional time is 0.5 days, however, this may vary depending on the size and complexity of the site, or the number of products to be certified.

Non-conformity reporting follows the AOECS Standard requirements – see section 6 below.

3. AUDIT REQUIREMENTS

3.1 HACCP AND RISK MANAGEMENT

3.1.1

The site must have a formal and documented risk study (based around Codex Alimentarius Principles) completed by a team with appropriate knowledge and experience in relation to the risks of gluten cross contact in gluten-free products and of Coeliac Disease.

Guidance

Knowledge in relation to gluten management may be via previous experience in the area, or specific training.

3.1.2

Gluten cross contact must be assessed as a separate and specific risk in the site's HACCP plan, with specific controls and monitoring processes attributed to it.

Guidance

The GFSI requirement is that “A Hazard and Risk Management System including prerequisite programmes to identify and control food safety hazards, including allergens, must be implemented”.

It is acceptable to include gluten within the wider HACCP study (i.e. as an allergen) provided it is considered as a risk in its own right, i.e. not managed under generic allergen controls.

3.1.3

The GMP/GHP processes on site must be designed specifically via the risk assessment process, to mitigate cross contact risks from gluten.

3.1.4

The HACCP study must identify the presence of oats in the site’s products and highlight this as a potential risk.

Note:

- Oats must always be considered a high-risk raw material
- Where oats are present in a gluten-free product the Crossed Grain Trademark specific registration code must be applied to reflect this.

3.2 TECHNICAL REQUIREMENTS FOR FOOD PRODUCTION

3.2.1

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

3.2.2

The site must have an original copy of the AOECS Standard for Gluten-Free Foods, Technical requirements for licensing the Crossed Grain Symbol.

3.2.3

A formal supplier management program must be in place.

3.2.4

All raw materials and packaging must be specifically risk assessed in terms of gluten presence and/or cross contact risks.

The risk level of raw materials should be assigned as high or low 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.

3.2.5

For high-risk raw materials (e.g. flours) gluten contact must be excluded and certified either by an independent and accredited gluten testing laboratory or appropriate in-house controls.

Analytical methods must comply with the requirements in section 3.4 below.

Guidance

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

3.2.6

For low-risk ingredients it must be guaranteed by the producer or supplier that these ingredients are gluten-free and supported by the necessary associated documentation.

3.2.7

The storage and despatch of materials from site must be covered in the HACCP and appropriate checks and controls must be in place to prevent cross contact with gluten.

3.2.8

Where third-party transport companies are used, the contract with these must state the requirements regarding control of gluten cross contact risks.

3.2.9

Full traceability of gluten-free products must be maintained until delivery to the customer or client (one level only- i.e. customer directly sold to).

3.2.10

The site’s GMP/GHP processes must be fully implemented to prevent hygiene risks and cross contact risks.

Where there are specific controls in relation to gluten, these must be fully implemented and covered by documented records.

3.2.11

The production of gluten-free foods must 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 must be performed to avoid any risk of gluten contact:

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

3.2.12

During the audit a traceability test against a randomly selected gluten-free product (manufactured on-site within the last 12 months and linked to a current Crossed Grain Trademark Licence) must be demonstrated. Where a gluten-free product has not been manufactured for sale by the site over the last 12 months (e.g., a site new to gluten-free production), then the expectation is for traceability to be confirmed by the review of trial batch data for a product planned to be linked to a current Crossed Grain Trademark Licence.

3.2.13

All staff must be trained in the specific risks related to gluten contact and the potential effects to people with Coeliac Disease.

3.2.14

Should gluten levels above 20 mg/kg be detected when the finished product is already on the market, the company must immediately inform the Licensor and certification body and agree appropriate actions.

3.3 LABELLING, ADVERTISING, AND PRESENTATION

3.3.1

A documented label management and control process must be in place. This must ensure that where labels make a specific gluten-free claim these are available and applied only to the associated products.

3.3.2

The Crossed Grain Trademark must be printed and displayed correctly. The registration number must be clearly displayed underneath the Trademark and

consist of the country code + company code + product code as required.

Guidance

Please see the requirements in Section 5 of the AOECS Standard.

3.3.3

Foods containing pure oats either as ingredient or as single ingredient, must be labelled “gluten-free”. Where the Crossed Grain Trademark is in use, the word “OATS” must be clearly displayed underneath the Trademark before the registration number to make consumers aware that most, but not all, people who are intolerant to gluten may consume these products.

3.3.4

Additional statements on labels associated with a gluten-free claim and the Crossed Grain Trademark are limited to the following text:

- Suitable for people intolerant to gluten
- Suitable for Coeliacs
- Specially formulated for people intolerant to gluten
- Specifically formulated for Coeliacs

3.4 ANALYSIS AND TESTING

3.4.1

Formal analysis to determine gluten content for reporting to the Licensor (relevant AOECS member society) may only be completed by an external laboratory using the methods as stated below and accredited in relation to these tests against ISO17025 or equivalent.

3.4.2

All laboratory (in-house and external) based gluten testing of products must be completed using the methods below:

- R5-sandwich-ELISA (Mendez-method) - see a) below
- R5-competitive-ELISA - see b) below



Guidance

a) 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 to products consisting of, or containing, fermented or partially hydrolysed gluten.

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

3.4.3

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.

Guidance

Clear limits must be in place in relation to these tests. As required these tests should be associated with the wider hygiene, allergen sampling and testing protocols across the site as determined by risk assessment.

3.4.4

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



4. AUDITOR QUALIFICATIONS

- Current lead auditor status against a GFSI recognised food safety scheme (as listed in Appendix 1).
- Formal HACCP qualification.
- Successful completion of the certification bodies’, AOECS-specific auditor training program, and attendance at annual calibration sessions (to maintain qualification).

5. NON-CONFORMITIES AND CORRECTIVE ACTION

5.1 NON-CONFORMITY DEFINITION AND GRADING

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

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 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 Trademark 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 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:
 - Crossed Grain licence registration number is not displayed correctly

5.2. PROCEDURES FOR HANDLING NON-CONFORMITIES AND CORRECTIVE ACTION

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

Critical non-conformities

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

Major non-conformities

If a major non-conformity occurs during the audit, corrective procedure shall be initiated, and an additional audit action will be conducted after three months. If the producer provides satisfactory evidence that the non-conformity has been corrected, the additional audit may not be necessary.

Where an additional visit is required, this may be combined with a GFSI revisit if applicable.

Minor non-conformities

If minor non-conformity occurs during the audit, corrective action shall be initiated and monitored during the next annual audit. If it is not corrected it may be considered a major non-conformity.

6. GRADING AND CERTIFICATION

Certification against the AOECS Addendum is only granted if a pass grade is achieved in the Main audit.

Audits are not graded but are assessed as either pass or fail. No certificate will be issued until all non-conformities have been closed (as confirmed by the auditor and technical reviewer).

Note: for minor non-conformities receipt of an appropriate corrective action plan is acceptable and can be considered to close the non-conformity (monitoring and review of the CAP are still required at the next visit).

AOECS Addendum certificates will be issued by the certification body.

Note: Licences to use the Crossed Grain Trademark may only be issued by AOECS member societies and not by the certification bodies.

Certificate expiry and revisit dates on the AOECS Addendum certificate are to be as for the associated Main Certification Audit.

If the Main Audit certification associated with the AOECS Addendum is lost or suspended, then the AOECS Addendum certification will also be suspended until:

- the Main Audit certification is reinstated
- another AOECS audit (standalone or AOECS Addendum) has been successfully completed



7. APPENDICES

APPENDIX 1. GFSI SCHEMES

This AOECS Addendum is intended for use alongside the current version of the following GFSI Benchmarked Food Safety Standards:

- BRC Global Standard for Food Safety
- FSSC 22000
- IFS Food Version
- SQF Safe Quality Food Code

APPENDIX 2. DEFINITIONS

AOECS AOECS Addendum

A document designed for use as a certification AOECS Addendum when the AOECS Standard for Gluten-Free Foods is delivered in combination with a GFSI benchmarked Food Safety Standard.

AOECS AOECS Addendum Report

A report template that lists the complete set of compliance clauses based on or derived from the AOECS Standard for Gluten-free Foods, used to report audit findings.

AOECS Standard for Gluten-Free Foods

The AOECS Standard for Gluten-Free Foods applies to food and drinks which comply with the requirements listed with it to meet the special dietary needs of people intolerant to gluten.

Foods

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

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.

** 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 AOECS Addendum may be determined at the national level.*

High risk raw materials

In the context of this AOECS Addendum, high-risk raw materials are those which could normally be expected to contain gluten (e.g., flours, milled ingredients, oats, ingredients processed to remove gluten including gluten-free wheat starch and barley malt extract), or at high risk of cross contact with gluten, (for example cereals, pseudo cereals and extruded/ malted cereals and oats).

Prolamins

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%.

Standard

The audit standard represents a set of quantifiable requirements against which an audit supplier can assess a location or product to confirm compliance against a specific set of criteria – in the case of the AOECS Standard for Gluten-Free Foods the criteria being the safe manufacture of gluten-free foods and drinks.



QUESTIONS?

If you have any questions regarding the content in this brochure, please contact us at helpdesk@aoecs.org, or visit our webpage www.aoecs.org



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