



AOECS

Association Of European Coeliac Societies

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

AOECS Standard for Foods for Persons Intolerant to Gluten

Technical requirements for licensing the Crossed Grain
Symbol

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1. Preamble

- 1.1 The AO ECS Standard for Foods for Persons Intolerant to Gluten applies to foods for general consumption and drinks as defined below and to foods and drinks for special dietary uses that have been formulated, processed or prepared 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 Point System (HACCP) should be implemented to exclude contamination with gluten. The technical requirements for a safe food production are specified in 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

2.1.1 Foods for general consumption and drinks

The purpose of this Standard for these food products is to exclude, as far as possible, the risk of contamination with gluten in products gluten-free by nature and ingredients of foods which are derived from wheat starch derivatives and to ensure 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.

2.1.2 Foods for special dietary uses

- 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 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 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 Foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg

These foods consist of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt and 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.

2.3 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 It is, however, an established custom to speak of gluten sensitivity. The prolamin content of gluten is generally taken as 50 %.

4. Essential Composition

4.1 Foods as defined in 2.1.2 b) and 2.2 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 2.1.1 and 2.1.2 without any oats shall be labeled "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 2.1.1 and 2.1.2 containing oats either as an ingredient, or pure oats, shall be labeled "gluten-free". However the word "OATS" shall be clearly displayed underneath the Symbol to make consumers aware that most, but not all, people who are intolerant to gluten may consume these products. The registration number shall be displayed underneath and begin with OATS before the country code.

5.3 Foods as defined in 2.2 without any oats shall be labeled "very low gluten". The term "100" shall be clearly displayed underneath the Symbol to make consumers aware that most, but not all, people who are intolerant to gluten may consume these products. The registration

number shall be displayed underneath and begin with 100 before the country code.

- 5.4 Foods as defined in 2.2 containing oats as an ingredient shall be labeled "very low gluten". The term "100/OATS" shall be clearly displayed underneath the Symbol to make consumers aware that most, but not all, people who are intolerant to gluten may consume these products. The registration number shall be displayed underneath and begin with 100/OATS before the country code.

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 natural and heat-processed foods.
- 6.2 For the detection of hydrolyzed gluten a modification of the R5 ELISA (competitive ELISA) has to be applied.

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 for special product groups is attached in the Annexes II - VI.
- 7.3 All kinds of foods for persons intolerant to gluten are specified in 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 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.

- 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, labeled, 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 VII 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 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 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 CEREAL GRAINS

- Rice
- Maize

MEAT, FISH AND EGGS

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

MILK AND MILK-DERIVATES

- Fresh milk, UHT milk, sterilized milk without additives, vitamins or other substances
- Infant formula
- Yogurt 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

DRESSINGS AND OTHERS

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

HACCP Guidance for flour, flour mixture and mill

PROCESS PHASE	HAZARD	PREVENTION	CORRECTION	INSTRUCTIONS CP/CCP	PERSON IN CHARGE
Suppliers' Qualification	Gluten contamination in raw material	Assessment of suppliers (audit, questionnaire, etc.)	To choose another supplier / to make the supplier aware of gluten contamination risk	<ul style="list-style-type: none"> - 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 the risk that the raw material might be contaminated)	To change raw material/supplier	CCP <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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 / analysis result or Use of the raw material in another with-gluten production	CCP <ul style="list-style-type: none"> - Certificate of gluten analysis from the producer and / or - Declaration / documentation by the supplier 	Leader of production, QM

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Storing raw material	Gluten in the environment, gluten contamination	Adhering to cleaning / hygiene plan, storing GF products separate from with-gluten materials, covering, closed packages (air tight)	Separation of GF raw materials, own storage/cupboard, cleaning	Instructions, clear identification of storage place (GF/ with-gluten), documentation, cleaning documentation	Leader of warehouse, QM
Pouring from the sacks	Gluten contamination from environment	Regular checking of the sacks	Elimination of the sacks involved or use for conventional food production	Transport/storage instructions/procedures	Leader of warehouse, QM
Milling	Gluten contamination from environment or equipment / from working staff / from other	Ensuring cleaning of equipment Regular and thorough cleaning of the equipment, cleaning procedures based on hazard analysis Transportation in a closed tube /pipe	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instructions / procedures, recordings, surface cleanliness samples (analytical plan)	Leader of production, QM
Storing in silo	with-gluten products (cross-contamination) or from wrong raw material	Instructions Staff training		CP Instructions/procedures, staff training documentation	
Mixing		Separate silo/tank for GF flours Separate room/place and equipment Raw material labels checking Recipe checking		CCP Instructions/procedures, production recordings recipe/raw material labels/ NC raw material identification instruction	
Cleaning of packing machine	Gluten contamination: equipment and environment	Emptying and cleaning packing machine Cleaning plan and temporal separation (GF first)	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production lot packaging	CCP Cleaning instructions / procedures, recordings, surface cleanliness samples (analytical plan)	Leader of production, QM

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Packaging	Wrong package/label, gluten contamination or soiling of package	Correct and clean packaging materials, protective films, labelling Precise labelling Temporal separation (GF first)	Elimination of the amount produced or selling as conventional food	CP Instructions/procedures, traceability procedure, regular check-ups for labelling, analysing product for gluten contamination	Leader of production, QM
Casing	Contamination with gluten	Separate casing and transport, staff training, checking	Elimination of the lot of products involved or selling as conventional food	Storage / transport instructions / procedures	Leader of logistic, QM

Glossary

INSTRUCTIONS

- working procedures are controlled by the instructions

CP

- control point, continuous monitoring and documentation

CCP

- critical control point: health hazards may occur if not controlled

health hazards are eliminated or their risk lowered to an acceptable level

QM

- quality manager

GF

- gluten-free

HACCP Guidance for bakery products

PROCESS PHASE	HAZARD	PREVENTION	CORRECTION	INSTRUCTIONS CP/CCP	PERSON IN CHARGE
Suppliers' qualification	Gluten contamination in raw material	Assessment of suppliers (audit, questionnaire, etc.)	To choose another supplier /to make aware the supplier of gluten contamination risk	- 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 (meaning a risk that the raw material might be contaminated)	To change raw material / 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 at the 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 Separated storage of the raw material (identified as not-to-be used) waiting: to receive documents from supplier / to receive analytical testing result or Use of the raw material in another with-gluten production	CCP - Certificate of gluten analysis from the producer and / or - Declaration / documentation by the supplier	Leader of production, QM

AOECS Standard
Annex 1II

Storing raw Material	Gluten in the environment, gluten contamination	Adhering to cleaning / hygiene plan, storing GF products separate from with-gluten materials, covering, closed packages (air tight)	Separation of GF raw materials, own storage / cupboard, cleaning	Instructions, clear identification of storage place (GF / with-gluten), documentation, cleaning documentation	Leader of warehouse, QM
Making and kneading dough	Gluten contamination from equipment or environment	Separate working area / thorough cleaning of working area and equipment (cleaning plan), temporal separation (GF first) Regular checking of cleanness in the manufacturing area	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instruction, production procedures, recordings, surface cleanliness samples (analytical plan)	Leader of production, QM
Preparing into product	Gluten contamination from environment or equipment / from working staff / from other	Ensuring cleaning of equipment Regular and thorough cleaning of the equipment, cleaning procedures based on hazard analysis	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instructions/ procedures, recordings, surface cleanness samples (analytical plan)	Leader of production, QM
Raising	with-gluten products (cross-contamination) or from wrong raw material	Instructions Staff training		CP Instructions / procedures, staff training documentation	
Baking		Separation in place and / or in time Checking recipe/raw material labels		CCP Instructions / procedures, recipe / raw material labels / NC raw material identification instruction / production recordings	

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Annex 1II

Cooling	Gluten contamination: equipment and environment	Ensuring cleaning of equipment Regular and thorough cleaning of the equipment, cleaning procedures based on hazard analysis	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	Cleaning instructions/ procedures, recordings, surface cleanness samples (analytical plan)	Leader of production, QM
Packaging	Wrong package / label, gluten contamination of soiling of package	Correct and clean packaging materials, protective films, labeling Precise labeling	Elimination of the amount produced or selling as conventional food	CP Instructions /procedures, traceability procedure, regular check-ups for labelling, analysing product for gluten contamination	Leader of production, QM
Casing/freezing	Contamination with gluten	Separate casing/freezing and transport, staff training, Checking	Elimination of the lot of products involved or selling as conventional food	Storage instructions / freezing procedures	Leader of logistic, QM

- Instructions - working procedures are controlled by the instructions
CP - control point, continuous monitoring and documentation
CCP - critical control point: health hazards may occur if not controlled
health hazards are eliminated or their risk lowered to an acceptable level
QM - quality manager
GF - gluten-free

HACCP Guidance for pasta production

PROCESS PHASE	HAZARD	PREVENTION	CORRECTION	INSTRUCTIONS/ CP/CCP	PERSON IN CHARGE
Suppliers' qualification	Gluten contamination in raw material	Assessment of suppliers (audit, questionnaire, etc.)	To choose another supplier / to make the supplier aware of the gluten contamination risk	- 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 (meaning a risk that the raw material might be contaminated)	To change raw material / 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 at the 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 Separated storage of the raw material (identified as not-to-be-used) waiting: to receive documents from supplier / to receive analytical testing result or Use of the raw material in another with-gluten production	CCP - Certificate of gluten analysis from the producer and / or - Declaration / documentation by the supplier	Leader of production, QM

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Annex 1V

Storing raw material	Gluten in the environment, gluten contamination	Adhering to cleaning / hygiene plan, storing GF products separate from ordinary materials, covering, closed packages (air tight)	Separation of GF raw materials, own storage / cupboard, cleaning	Instructions, clear identification of storage place (GF/with-gluten), documentation, cleaning documentation	Leader of warehouse, QM
Kneading	Gluten contamination from equipment or environment	Separate working area / thorough cleaning of working area and equipment (cleaning plan), temporal separation (GF first) Regular checking of cleanness in the manufacturing area	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instruction, production procedures, recordings, surface cleanness samples (analytical plan)	Leader of production, QM
Preparing product (pressing)	Gluten contamination from previous productions	Spatial and / or temporal separation, cleaning after with-gluten production, elimination or selling as conventional food of the first amount (the quantity necessary to be sure there is no more risk of contamination must be evaluated and validated) Regular checking of cleanness in the manufacturing area / registration of the amount eliminated	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instruction, first amount elimination instruction, production procedures, recordings, surface cleanness samples (analytical plan)	Leader of production, QM
	Gluten contamination from environment or equipment / from working staff / from other with-gluten products	Ensuring cleaning of equipment Regular and thorough cleaning of the equipment, cleaning procedures based on hazard analysis	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instructions / procedures, recordings, surface cleanness samples (analytical plan)	Leader of production, QM
Raw pasta		Instructions Staff training		CP Instructions / procedures, staff training documentation	

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Drying	(cross contamination) or from wrong/ contaminated raw material	Separation in place and / or in time Raw material labels checking Recipe checking		CP Instructions / procedures, production recordings recipe / raw material labels / NC raw material identification instruction	
Packaging	Wrong package/label, gluten contamination or soiling of package	Correct and clean packaging materials, protective films, labelling Precise labelling Temporal separation (GF first)	Elimination of the amount produced or selling as conventional food	CP Instructions / procedures, traceability procedure, regular check-ups for labelling, analysing product for gluten contamination	Leader of production, QM
Casing / Freezing	Contamination with-gluten	Separate casing / freezing and transport, staff training, Checking	Elimination of the lot of products involved or selling as conventional food	Storage instructions / freezing procedures	Leader of logistic, QM

Glossary

Instructions

- working procedures are controlled by the instructions

CP

- control point, continuous monitoring and documentation

CCP

- critical control point: health hazards may occur if not controlled

health hazard are eliminated or their risk lowered to an acceptable level

QM

- quality manager

GF

- gluten-free

HACCP Guidance for foods for general consumption

PROCESS PHASE	HAZARD	PREVENTION	CORRECTION	INSTRUCTIONS/ CP/CCP	PERSON IN CHARGE
Suppliers qualification	Gluten contamination in raw material	Assessment of suppliers (audit, questionnaire, etc.)	To choose another supplier / to make aware the supplier of gluten contamination risk	- 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 (meaning a risk that the raw material might be contaminated)	To change raw material / 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 at the 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 Separated storage of the raw material (identified as not-to-be-used) waiting: to receive documents from supplier / to receive analytical testing result or Use of the raw material in another with-gluten production	CCP - Certificate of gluten analysis from the producer and / or - Declaration / documentation by the supplier	Leader of production, QM

AOECS Standard
Annex V

Storing raw material	Gluten in the environment, gluten contamination	Adhering to cleaning / hygiene plan, storing GF products separate from ordinary materials, covering, closed packages (air tight)	Separation of GF raw materials, own storage / cupboard, cleaning	Instructions, clear identification of storage place (GF/with-gluten), documentation, cleaning documentation	Leader of warehouse, QM
Production	Gluten contamination from previous productions	Spatial and / or temporal separation, cleaning after with-gluten production, elimination or selling as conventional food of the first amount (the quantity necessary to be sure there is no more risk of contamination must be evaluated and validated) Regular checking of cleanness in the manufacturing area, / registration of the amount eliminated	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instruction, first amount elimination instruction, production procedures, recordings, surface cleanness samples (analytical plan)	Leader of production, QM
Production	Gluten contamination from environment	Ensuring cleaning of equipment Regular and thorough cleaning of the equipment, cleaning procedures based on hazard analysis	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CP Cleaning instructions / procedures, recordings, surface cleanness samples (analytical plan)	Leader of production, QM
Production	Gluten contamination from working staff	Instructions Staff training	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CP Instructions / procedures, staff training documentation	Leader of production, QM

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Production	Gluten contamination from other with-gluten products (cross-contamination) / from wrong / contaminated raw material	Separation in place and / or in time Raw material labels checking Recipe checking	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CP Instructions / procedures, Recipe / raw material labels / NC raw material identification instruction / production recordings	Leader of production, QM
Packaging	Wrong package / label, gluten contamination of soiling of package	Correct and clean packaging materials, protective films Precise labelling	Elimination of the amount produced or selling as conventional food	CP Instructions / procedures, traceability procedure, Regular check-ups for labelling, analysing product for gluten contamination	Leader of production, QM
Storage	Contamination with gluten	Separate casing and transport, staff training, Checking	Elimination of the lot of products involved or selling as conventional food	Storage instructions / procedures	Leader of logistic, QM

INSTRUCTIONS = working procedures are controlled by the instructions

CP = control point, continuous monitoring and documentation

CCP = critical control point: health hazards may occur if not controlled

health hazard are eliminated or their risk lowered to an acceptable level

QM = Quality Manager

GF = Gluten-free

HACCP Guidance for confectionery products

PROCESS PHASE	HAZARD	PREVENTION	CORRECTION	INSTRUCTIONS/ CP/CCP	PERSON IN CHARGE
Suppliers' qualification	Gluten contamination in raw material	Assessment of suppliers (audit, questionnaire, etc.)	To choose another supplier / to make aware the supplier of gluten contamination risk	- 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 (meaning a risk that the raw material might be contaminated)	To change raw material / 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 at the 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 Separated storage of the raw material (identified as not-to-be-used) waiting: to receive documents from supplier / to receive analytical testing result or Use of the raw material in another with-gluten production	CCP - Certificate of gluten analysis from the producer and / or - Declaration / documentation by the supplier	Leader of production, QM

AOECS Standard
Annex VI

Storing raw material	Gluten in the environment, gluten contamination	Adhering to cleaning / hygiene plan, storing GF products separate from ordinary materials, covering, closed packages (air tight)	Separation of GF raw materials, own storage / cupboard, cleaning	Instructions, clear identification of storage place (GF/with-gluten), documentation, cleaning documentation	Leader of warehouse, QM
Making and kneading dough, cakes	Gluten contamination from equipment or environment	Separate working area / thorough cleaning of working area and equipment (cleaning plan), temporal separation (GF first) Regular checking of cleanness in the manufacturing area	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instruction, production procedures, recordings, surface cleanness samples (analytical plan)	Leader of production, QM
Mixing, dosing	Gluten contamination from previous productions	Spatial and / or temporal separation, cleaning after with gluten production, elimination or selling as conventional food of the first amount (the quantity necessary to be sure there is no more risk of contamination must be evaluated and validated) Regular checking of cleanness in the manufacturing area / registration of the amount eliminated	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instruction, first amount elimination instruction, production procedures, recordings, surface cleanness samples (analytical plan)	Leader of production, QM
	Gluten contamination from environment or equipment /from	Ensuring cleaning of equipment Regular and thorough cleaning of the equipment, cleaning procedures based on hazard analysis	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instructions / procedures, recordings, surface cleanness samples (analytical plan)	Leader of production, QM

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Annex VI

Raising	working staff / from other with- gluten products (cross- contamination)	Instructions Staff training		CP Instructions / procedures, staff training documentation	
Baking	or from wrong / contaminated raw-material	Separation in place and / or in time Raw material labels checking Recipe checking		CP Instructions / procedures, production recordings Recipe / Raw material labels / NC raw material identification instruction	
Preparation of creams, glaze, icing, decoration	Gluten contamination from environment or equipment / from working staff / from other with-gluten	Ensuring cleaning of equipment Regular and thorough cleaning of the equipment, cleaning procedures based on hazard analysis Staff Instructions Staff training	Elimination of the amount produced (or selling as conventional food), cleaning and start a new production	CCP Cleaning instructions procedures, recordings, surface cleanness samples (analytical plan) Instructions procedures, staff training documentation	Leader of production, QM
Cooling	products (cross- contamination) or from wrong / contaminated raw material	Separation in place and / or in time Raw material labels checking Recipe checking		CP Instructions procedures, production recordings recipe / raw material labels / NC raw material identification instruction	

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Annex VI

Packaging	Wrong package / label, gluten contamination of soiling of package	Correct and clean packaging materials, protective films, labelling Precise labelling Temporal separation (GF first)	Elimination of the amount produced or selling as conventional food	CP Instructions / procedures, traceability procedure, regular check-ups for labelling, analysing product for gluten contamination	Leader of production, QM
Casing / Freezing	Contamination with gluten	Separate casing / freezing and transport, staff training, Checking	Elimination of the lot of products involved or selling as conventional food	Storage instructions / freezing procedures	Leader of logistic, QM

Instructions - working procedures are controlled by the instructions; CP - control point, continuous monitoring and documentation; CCP - critical control point: health hazards may occur if not controlled / health hazard are eliminated or their risk lowered to an acceptable level; QM - quality manager; GF - gluten-free

Auditor's guide to non-conformance

Non-conformance is when the requirements laid down by the AOECS Standard (Standard Annexes II - VI) are not fulfilled.

If the company fails to meet the following requirements this is a major non-conformance.

1. Final products must be uncontaminated (gluten < 20 mg/kg (ppm) for "gluten free" products or gluten < 100 mg/kg (ppm) for "very low gluten" products).
2. All ingredients and raw materials used in the production should be traceable with clear information regarding handling or storage. Suppliers of ingredients and raw materials should document that they are gluten-free or very low gluten* (by analytical certification or supplier's Certificate of Compliance or document appropriately) signed by the supplier guaranteeing that the lot consists of gluten-free/very low gluten ingredients/raw materials (gluten <20 mg/kg (ppm) or gluten < 100 mg/kg (ppm)).
3. Final products should be traceable right up to the customer they are sold to, with clear information regarding production, handling or storage.
4. If products are manufactured in sites or line/s where there are ingredients containing gluten, measures should be taken to ensure that there is no possibility of product contamination (cross-contamination or environmental contamination) during any phase of the process: production, storage and distribution.

The following actions should be performed:

- Cleaning operations that ensure the elimination of any cross-contamination.
- The first "batch" of gluten-free product produced from the production lines should not be considered suitable for coeliac and should be eliminated or sold as a conventional product.

*except those which have been specially processed to remove gluten, like wheat starch, barley malt extract, etc. according to the Codex Alimentarius Standard 118-1979 adopted in 1979; amended 1983; revised 2008.

5. Gluten-free products should be clearly identified in whatever phase they may be.
6. The raw materials used in the production and handling of gluten-free products should not contain gluten* (*except those which have been specially processed to remove gluten, like wheat starch, barley malt extract, etc. according to the Codex Alimentarius Standard 118-1979 adopted in 1979; amended 1983; revised 2008).
7. The production, transformation, handling and warehouse centre for special gluten-free products should have a Hazard Analysis and Critical Control Point (HACCP) System in place that includes:
 - A risk assessment taking into consideration gluten contamination during all production phases.
 - Critical limits should be set so that in the event of gluten contamination, gluten contamination levels do not exceed 20 mg/kg (ppm) for “gluten free” products or 100 mg/kg (ppm) for “very low gluten” products.
 - Setting up of a verification procedure for the HACCP system. An end product sampling plan should be defined to verify that the products manufactured do not exceed a gluten content of 20 mg/kg (ppm) for “gluten free” products or 100 mg/kg (ppm) for “very low gluten” products.
8. When a lot or a batch is detected to have been contaminated by gluten (gluten >20 mg/kg (ppm) for “gluten free” products or gluten >100 mg/kg (ppm) for “very low gluten” products) outside the production facility, a plan of action should be set up which should include: the immediate withdrawal (and if necessary the recall) of the product from the market and a communication sent to the Licensor and/or the AOECS and the Public Administration informing about the affected products and lot, a study on the situation, its results and the actions taken. Customer or third party complaints should be recorded and dealt with accordingly.
9. If any activities involved in the production process are subcontracted out, such activities should meet all the applicable technical requirements of the AOECS Standard.
10. All staff members should receive regular training on the tasks they perform and must receive information on gluten contamination risk and its significance in coeliac disease management.
11. 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.
12. 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.