



FEMAS Sector Note No. 15 – Maize Aflatoxin Monitoring Protocol

These Sector Notes apply to any FEMAS participant trading or processing maize and / or maize by-products. The sampling and monitoring required by this protocol is in addition to that required by the FEMAS Calculator but does not replace the need for the business to fully assess the risks associated with sourcing and processing maize.

The Protocol described in these Sector notes for the sampling and analysis of maize and maize by-products, is based on a common risk assessment agreed jointly by the schemes listed below. Its aim is to minimise the risk of Aflatoxin B1 at levels above those permitted by EU legislation in traded feed materials and compound feeds.

Participants must also note that it is illegal under EU Undesirable Substances legislation to blend feeds with the intention of diluting an undesirable substance to a level below the legal maximum.

In the interests of transparency, Participants supplying maize on ‘any origin’ contracts must provide their customers with the source country of each consignment of maize and, as appropriate, the Aflatoxin results required by this Protocol.

This Protocol applies from 1 September 2016, regardless of harvest year, and is to be applied to all maize / maize by-product traded and/ or processed by the Participant, unless the maize is sourced from a supplier certified with a relevant scope to one of the following schemes:

- GMP+ International FSA
- OVOCOM FCA (formerly OVOCOM GMP)
- EFISC-GTP
- QS

Participants processing whole maize should also be aware of Sector Note No. 6 – Whole Cereal Processing.

These Notes are not exhaustive, and are intended to assist in the application of the corresponding requirements of the FEMAS Standard and are not to be considered in isolation.

Section 1 of these Sector Notes includes definitions of specific relevance to this sector.

Section 2 of these Sector Notes includes those additional requirements of the FEMAS Scheme specific to this sector and with which Participants **must** comply in order to achieve certification under the FEMAS Scheme.

Section 3 of these Sector Notes includes additional guidance (shown in italics) specific to this sector, which will assist Participants in interpreting the FEMAS Standard for their sector.

1 Definitions

Maize and Maize By- Products	Grains of <i>Zea mays L. ssp. mays</i> in their natural state and any whole cereal products produced from the whole kernel and any part thereof.
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2 Additional Sector-Specific Requirements

<p>A 4.1</p>	<p>Communication with the Certification Body</p>	<p>Results from the samples analysed must be forwarded at least once a month to the Certification Body who will anonymise results and share with the Scheme Owner AIC, and upon request the UK competent authorities. If the Aflatoxin B1 level exceeds the legal maxima laid down in Directive 2002/32 these must be reported immediately to the Certification Body, and to the Competent Authorities.</p>
<p>F 1.3</p>	<p>Sales Contracts / Agreements / Feed Specifications</p>	<p>For High and Medium Risk origins, the end user and any intermediate storage sites must be notified of the results of the analyses that have been carried out prior to delivering the maize. The sampling and analysis must have been carried out no more than three months prior to the delivery date.</p>
<p>I 1.1</p>	<p>Sampling and Analysis Schedules</p>	<p>Where the Participant relies upon the monitoring done by their supplier, the following conditions must be met:</p> <ul style="list-style-type: none"> • The supplier confirms in writing (letter, email or fax are acceptable) that the sampling and analysis were carried out in accordance with the maize monitoring protocols contained within this Protocol • The supplier provides aflatoxin results for the maize or maize by-products supplied where origins are medium or high risk • The results relate to samples that are no more than three months old • Where the suppliers' results relate to maize prior to processing, the supplier must confirm the factor by which aflatoxin is concentrated or reduced during the process
<p>I 1.1</p>	<p>Sampling and Analysis Schedules</p>	<p>Batches must be sampled in accordance with Appendix 3 at loading (country of cultivation) or at discharge (country of delivery). Where sampling is carried out at discharge, the maximum batch size will be based on the means of transport in which the maize or maize by-product is then loaded.</p> <p>Sampling Methods must be in accordance with those described in Appendix 4</p>

I 1.1	Sampling and Analysis Schedules	<p>If sampling is to be carried out on stored maize from Medium or High Risk origins, and the full batch is not accessible the following requirements must be met:</p> <ul style="list-style-type: none"> • A sampling plan must be designed and documented to cover the accessible portion of the stored batch • As the store is emptied, and new portions of the maize become accessible these must be sampled in accordance with this protocol • The sampling approach and results must be communicated to the customer
I 1.1	Sampling and Analysis Schedules	<p>Where a batch of maize from a Medium or High Risk origin is stored for more than three months after sampling and analysis, the batch must be sampled and analysed again prior to delivery to the customer.</p>
I 3.1	Feed Samples	<p>A batch must meet the definition of batch or lot in EC Regulation No. 767/2009:</p> <p>'batch' or 'lot' means an identifiable quantity of feed determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together</p> <p>In addition, the maximum permissible batch size is based on the means of transport being used, and the risk rating of the origin as shown in Appendix 3</p>
I 7.1	Testing Facilities	<p>Analysis must be carried out in accordance with the requirements of 5B of Annex I to Regulation (EC) No 152/2009.</p>

3 Sector-Specific Guidance

C 2.2	<i>Selection and Approval of Raw Materials</i>	<p><i>The presence of Aflatoxin in maize is related to the climatic conditions under which it is grown, so it is important that Participants fully assess the risk associated with all sources of maize, and where there is a significant risk of Aflatoxin B1 above legal maxima, the appropriate risk rating should be applied. AIC, in conjunction with other scheme owners, will be frequently reviewing industry analysis data with a view to updating the risk rating list when necessary.</i></p> <p><i>The initial risk classifications shown in Appendix 1 are based on Rapid Alert System for Food and Feed (RASFF) notifications issued in the three previous years and on available analysis results for recent deliveries.</i></p> <p><i>The participant should also consider the risk posed by contamination of maize with that from another origin which could lead to the presence of Aflatoxin B1 above the legal maxima.</i></p>
H 12.4	<i>Equipment Intended to Control Physical Contamination</i>	<p><i>Consideration should also be given to the destination of materials removed by any initial screening at intake.</i></p>
I 8.1	<i>Evaluation of Test Results</i>	<p><i>AIC will share anonymous results with other scheme owners, and use the guidelines shown in Appendix 2 to assess the risk of origins as the harvest progresses.</i></p>

Appendix 1

Country Risk Ratings

High / Unknown Risk	Medium Risk	Low Risk
None	Argentina	Austria
	Bosnia	Belgium
	Brazil	Denmark
	Bulgaria	Estonia
	Canada	Finland
	Croatia	France
	Italy	Germany
	Moldova	Iceland
	Romania	Ireland
	Russia	Latvia
	Serbia	Lithuania
	Slovakia	Luxembourg
	Spain	Netherlands
	USA	Norway
	Any country not mentioned elsewhere	Poland
		Sweden
		United Kingdom
		Ukraine

Appendix 2

Risk Evaluation of Results from Monitoring

Risk Rating	Percentage of Analysis	Results
High	>1% >10%	>20ppb OR >10ppb and \leq 20ppb
Medium	Any scenario not listed as high or low risk	
Low	<1% <2% >90%	>10 and \leq 20ppb AND >5 and \leq 10ppb AND <2ppb

Appendix 3

Maximum Permissible Batch Sizes

Means of Transport	High Risk Countries	Medium Risk Countries	Low Risk Countries
Seagoing vessel	Max. 2,000 tonnes	Hold	HACCP-based and to comply with the FEMAS Calculator requirements
Inland waterway vessel	Inland waterway vessel	Inland waterway vessel	
Train	Max. 1,500 tonnes	Train	
Truck from storage / warehouse, production location or collection point	Max. 1,000 tonnes	Max. 2,000 tonnes	

Appendix 4

Sampling Methods

Risk Rating	High	Medium	Low
Sampling Method	Regulation (EU) No. 691/2013 for whole batch	Regulation (EU) No. 691/2013 for whole batch	Representative sample in accordance with industry good practice
Sampled by	Independent superintendent organization with appropriate scope of accreditation to ISO 17020 or to ISO 9001 plus GTAS Supervision, Sampling and Weighing certification.	Independent superintendent organization with appropriate scope of accreditation to ISO 17020 or to ISO 9001 plus GTAS Supervision, Sampling and Weighing certification.	Scheme Participant or appointed representative
Minimum Aggregate sample size	10kg	10kg	10kg
Minimum sample size sent to laboratory	4kg	4kg	4kg
Minimum final sample size	500g	500g	500g
Analysis frequency	Each final sample	Each final sample	Each final sample