



FEMAS Sector Note No. 15 – Maize Aflatoxin Monitoring Protocol

These Sector Notes apply to any AIC Scheme Participant producing, processing or placing on the market within the UK or EU maize and / or maize by-products for use as animal feed. 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 feed safety risks associated with maize and / or maize by-products.

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 in this document. Its aim is to minimise the risk of Aflatoxin B1 at levels above those permitted by UK and EU legislation in feed materials and compound feeds.

Participants processing whole maize should also be aware of Sector Notes No. 4 – Whole Cereal Processing, No. 7 – Distillery & Malt products, No. 9 – Brewing, No. 14 - Biofuels.

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 additional sector-specific information to assist Participants in complying with **Requirements, Interpretation, Guidance and Further Information** of the FEMAS Scheme. The FEMAS Scheme Rules provide the following definitions:

Requirement – Sets mandatory standards with which Applicants and Participants must comply to achieve and maintain certification.

Interpretation — Provides specific means for Applicants and Participants to achieve the desired outcome of the preceding Requirement. Applicants and Participants are expected to consider Interpretation and apply as relevant to their business. Failure to follow interpretation, resulting in the desired outcome of the Requirement not being achieved will lead to a non-conformance being raised against the requirement.

Guidance – Non-mandatory suggestions of useful tools and techniques for achieving and maintaining compliance or continuous improvement.

Further information – External sources of useful information, typically including references/ web links to documents or other sources of information.

NOTE: Revisions introduced in this edition of the Sector Notes are highlighted in Blue.

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1 Definitions

Maize and	Grains of Zea mays L. ssp. mays in their natural state and any cereal
Maize By-	products produced from the whole kernel and any part thereof.
Products	

2 Sector-Specific Notes

Raw Materials	and Raw Material	Suppliers
C 1.3	Requirement	The Maize Aflatoxin Monitoring Protocol applies to any FEMAS Participant trading or processing maize and / or maize by-products and placing them on the market in the UK or EU.
		Risk ratings are assigned to countries of origin by a joint committee of the participating schemes based on anonymised analysis results from scheme Participants. The Current country risk ratings are summarised in Annex 1 of this document
C 1.3	Guidance	The presence of Aflatoxin B1 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.
		The initial risk classifications shown in <u>Annex I below</u> 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.
		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.

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C 1.6	Requirement	The Maize Aflatoxin Monitoring Protocol is to be applied to all maize/ maize by-product placed on the market by the Participant in the UK or EU, unless the maize is sourced from a supplier certified (with a relevant scope) to one of the following schemes:
		 FEMAS GMP+ International FSA OVOCOM FCA (formerly OVOCOM GMP) EFISC-GTP QS

Sales Contracts	/ Agreements/ Feed	Specifications
F 1.1	Requirement	Participants supplying maize and/ or maize by- products on 'any origin' contracts to the UK or EU markets must provide their customers with the source country of each consignment of maize and, as appropriate, the Aflatoxin B1 results required by this Protocol.
F 1.3	Requirement	For High and Medium Risk origins (see Annex I), 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 and/ or maize by-products. The sampling and analysis must have been carried out no more than three months prior to the delivery date.
F 1.4	Interpretation	Participants supplying products to the UK and EU should note that it is illegal under UK and EU Undesirable Substances legislation to blend feeds with the intention of diluting an undesirable substance to a level below the legal maximum.

Equipment Intended to Control Physical Contamination		
Н 13.4	Interpretation Consideration should also be given to the destination of	
		materials removed by any initial screening at intake.

Sampling Schedule			
I 1.1	Requirement	Batches of maize and / or maize by-products must	
		either be sampled at loading (country of origin) or at	
		discharge (country of delivery) in accordance with	
		Table A in Annex II.	

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I 1.1	Requirement	Where a batch of maize from a Medium or High Risk origin (See Annex I) 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.	
I 1.1	Requirement	 If sampling is to be carried out on stored maize and/ or maize by-products from Medium or High Risk origins (See Annex I) and the full batch is not accessible, the following requirements must be met: 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 1.2	Requirement	Samples of maize and/ or maize by-products must be taken in accordance with the methods described in Table B in Annex II.	

Analysis		
Analysis I 5.2	Requirement	 Where the Participant relies upon the monitoring done by their supplier, the following conditions must be met: 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 B1 results for the maize or maize byproducts 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 B1 is concentrated or reduced
		during the process

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Testing Facilit	Testing Facilities			
17.3	Requirement	Samples of maize and/ or maize by-products must be analysed in accordance with the requirements described in Table B in Annex II.		
17.3	Requirement	Analysis must be carried out in accordance with the requirements of 5B of Annex I to Regulation (EC) No 152/2009 (as amended).		

Evaluation of	Evaluation of Test Results		
I 8.1	Requirement	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, with the UK competent authorities.	
I 8.1	Guidance	AIC will share anonymous results with other scheme owners, and use the guidelines shown in Annex I to assess the risk of origins as the harvest progresses.	
I 8.3	Requirement	For Participants placing product on the market in the UK or EU, if the Aflatoxin B1 level exceeds the legal maxima laid down in Directive 2002/32 (as amended) these must be reported immediately to the Certification Body, and to the Competent Authorities.	

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Annex I – Country Risk Rating

High Risk	Medium Risk	Low Risk
Serbia	Argentina	Austria
Romania	Bosnia	Belgium
	Brazil	Croatia
	Bulgaria	Czech Republic
	Canada	Denmark
	Italy	Estonia
	Hungary	Finland
	Moldova	France
	Russia	Germany
	Slovakia	Iceland
	Spain	Ireland
	Ukraine	Latvia
	USA	Lithuania
	Any country not mentioned	Luxembourg
	elsewhere	Netherlands
		Norway
		Poland
		Sweden
		United Kingdom
		USA

Criteria used for Country Classification (for information only)

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

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Annex II – Sampling and Analysis Requirements

Table A

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

Table B

Risk	High	Medium	Low
Rating			
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	10kg	10kg	10kg
sample size Minimum	4kg	4kg	Alea
sample size	4kg	4kg	4kg
laboratory			
Minimum final sample size	500g	500g	500g
Analysis frequency	Each final sample	Each final sample	Each final sample

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