

Changes are **highlighted in grey**

EFISC-GTP temporary monitoring for aflatoxin in maize crops and maize co-products derived thereof in feed materials

1. Introduction

High levels of Aflatoxin B1 in feed material are a real safety issue for the European Feed sector and the last years RASFF alerts and crisis showed that a more stringent monitoring of such risk is needed in order to assure safe feed material to our customers. This situation has resulted in the need for the GTP Certified Operators **(or certified against the EFISC-GTP code 4.0, scope G and F)**, to follow some specific ad-hoc testing protocols, such as this new Version of our **EFISC-GTP Code addendum**, to better monitor such risks, in coordination with other stakeholders of our maize and maize co-products feed material supply chain.

This protocol covers **supply of maize and maize co-products for feed uses**.

In order to cover the potential risk for Aflatoxin occurrence in maize from any origin, the protocol has been revised.

This protocol will be applicable until further notice.

2. Existing legal requirements

The applicable EU maximum limits for aflatoxin are:

For maize and maize co-products to be used as feed materials (as per amended version of Directive 2002/32/EC)

- 20 ppb for aflatoxin B1 (based on feed materials with a moisture content of 12 %).

3. Scope of application

3.1 Companies concerned

Companies certified against the GTP Code (version 1.3A) and EFISC-GTP code 4.0 (scope G and F), carrying out the following activities must apply the provisions laid down in this addendum to the currently applicable version of the GTP (or EFISC-GTP code 4.0, scope G and F):

- Trading and Collection of maize originating from countries listed in Annex 2 and the maize co-products derived thereof;

3.2 Products concerned

The protocol described further below is applicable to:

- Maize (grains of *Zea mays* L. ssp. *mays*.) or maize co-products destined to be used as feed materials directly or after processing.

3.3. Origin

The selection of countries listed in Annex 2 was based on the origin of the maize supply as mentioned in the RASFF notifications and on the Aflatoxin data collected from certified companies from the maize crop.

3.4 Boundaries

This protocol is applicable to intra-EU shipments of maize and maize co-products as well as shipments of maize and maize co-products from third countries to the EU territory.

3.5 Derogation

This protocol does not apply to maize and/or maize co-products which have

- already been sampled and analysed for aflatoxin B1 in compliance with the present EFISC-GTP protocol
- or from other mutually recognized or equivalent schemes (listed in Reference 2 in the [GTP Code or Annex 3 in the EFISC-GTP Code 4.0](#)) which have an aflatoxin protocol.

In this case, the company purchasing the maize and/or maize co-products must be informed about the analysis results of the delivered batch by means of a certificate of analysis from a laboratory which conforms to the requirements of this protocol under section 7.

The following conditions must however be fulfilled:

- The report analysis must explicitly indicate the same identification of the batch;
- The sampling method used as requirements referred to in section 5;
- The laboratory complies with requirements referred to in section 7.

4. Risk classification

Countries of cultivation of maize included in Annex 2 are classified into 3 categories: “High”, “Medium” and “Low”. Sampling must be performed in accordance with the requirements in point 5. and 6. of the current protocol.

Operator loading for first time a cargo from a new country not listed yet as high, medium or low risk, has to implement 100% monitoring¹ for aflatoxin B1 and once results are available, to classify the origin as “Low”, “Medium” or “High” with transmission of the information to EFISC-GTP with testing results which support the classification. The procedure to define or change the country risk categories is indicated in the Annex 1.

In accordance with the precautionary principle, GTP certified companies (or certified against the EFISC-GTP Code 4.0, scope G and F), must be vigilant and assess the possible aflatoxin risk when purchasing/selling maize, especially from countries not listed in Annex 2. In case of doubt about the country of cultivation (country of cultivation is unknown or not known with certainty), 100% monitoring applies until otherwise classified.

The latest version of the Annex 2 List of countries, published on the EFISC-GTP website, is the valid version.

5. Monitoring, sampling and analysis

If a GTP certified operator (or certified against the EFISC-GTP Code 4.0, scope G and F), has information that a certain country has a lower or a higher risk than the one indicated in the table in Annex 2, he must inform EFISC-GTP management supporting its statement by relevant data and any

¹ Batch by batch sampling. Batch max size according to the tables in paragraph 6.1 and 6.2 of this protocol

additional information available. It is the responsibility of the operator to apply the relevant addition controls that he might deem necessary.

5.1 Monitoring frequency

Based on the defined risk level, the operator shall respect the following monitoring frequency:

Table 2. Monitoring frequency

Risk estimate to be established	100% monitoring Send data to EFISC-GTP until a country is categorized
High	100% monitoring
Medium	100% monitoring
Low	Based on the operators risk assessment as described in the GTP Code, Annex 1 <u>(or in the Sector reference document on the collection, storage, trade and transport of safe feed/food ingredients)</u>

5.2 When collecting maize in warehouses located in the countries “at risk”

If collection is done on the basis of receipt of truck, batches and wagons, all incoming trucks or trains should be sampled according to point 6 in the current protocol based on applicable GAFTA 124 contract rules or in accordance with [Commission Regulation \(EU\) 691/2013](#) amending [Regulation \(EC\) 152/2009](#).

- If the test results are above the EU maximum limits applicable for the foreseen feed use of the products, the cargo **cannot be used in feed**. The suppliers and the authorities shall be duly and quickly informed as per applicable local regulations or rules. If the results are confirmed, the relevant authorities and the **EFISC-GTP** management should be informed.

5.3. When purchasing maize and/or maize co-products on an in or ex-warehouse basis

Each batch/cell of the cargo in the warehouse will be sampled. The batch tested **cannot** be physically delivered to EU locations of customers as long as the analysis results² are unknown or if results are not compliant with EU maximum limits for aflatoxins in feed materials³. The stored batches will remain in quarantine pending the results. If the whole batch in the warehouse is not accessible for sampling, a sampling plan **shall** be made and documented, that covers the accessible part of the batch. The part of the batch that has not yet been sampled and tested, should be monitored once it’s possible and safe to get access.

- If the results are compliant with EU maximum limits, the tested batches can be loaded into sea going vessels, inland waterway transports or trucks or railways without further testing, as long as all measures are taken to preserve the identity of the concerned batches. These analyses done before loading will be accepted as long as sampling/analyses have been done no more than three months prior to the delivery⁴.

² Analyses done before loading will be accepted as long as sampling/analyses has been done no more than three months prior to the loading operation

³ In cases where maize is stored longer than 3 months in a silo and is not accessible for sampling before delivery to the customer, sampling may be carried out during loading. The results must be available before unloading at the customer or at least before the next processing step or feeding (if there is a written agreement between the seller and the customer).

⁴ For low risk countries, this requirement is based on the operator’s risk assessment.

- If the results are above EU maximum limits for the intended use, the suppliers and the authorities shall be duly and quickly informed as per applicable local regulations or rules. If the results are confirmed, the relevant authorities and the EFISC-GTP management should be informed.
- In case of stored batches and reanalysis after three months, the highest measured Aflatoxin B1 value (from all sampling moments) is leading since it is not obvious that Aflatoxin B1 content could decrease over time. All analysis results applicable for the batch (also the expired ones) must accompany the batch.

Testing results are to be supplied to the concerned customers.

The remainder of each aggregated samples should be also sealed, duly labelled and kept in adequate storage conditions as indicated in the GTP Code (or EFISC-GTP code 4.0, scope G and F). Finally, this requirement is not applicable to samples taken during collection if made on a truck per truck or wagon per wagon basis. Samples must be stored at a temperature that will not alter their composition and in such conditions that the samples are not adversely affected by light.

5.4 When buying F.O.B. or C.I.F.: Loading (or unloading) of a seagoing vessel or of an Inland waterway transport

The batches tested should not be physically delivered to EU locations of customers as long as the analysis results are unknown or if results are not compliant with EU maximum limits for aflatoxins in feed materials.

For cargoes coming from High and Medium risk countries outside EU/in EU, the discharging or transshipment is allowed, in segregated spaces, as long as products are not delivered to Customer in EU till the results are known.

The analysis results for the other categories will be available upon request.

- If the results are compliant with EU maximum limits, the tested batches can be unloaded/released/marketed/used. Additional local testing requirements must be taken into account, where appropriate.

If the results are above EU maximum limits for the intended use, and if the results of the testing at loading are available prior to the arrival of the transport at destination, then a full re-testing of the cargo should be done, using the same methodology /procedure previously described, in order to ascertain newly the exact safety status of the cargo. If the results are confirmed, the relevant authorities and the EFISC-GTP management should be informed if cargo has been shipped in EU. Available testing results are to be supplied to the concerned customers, on request.

The remainder of each aggregated samples should be also sealed, duly labelled and kept in adequate storage conditions as indicated in the GTP Code (or EFISC-GTP Code 4.0, scope G and F). Samples must be stored at a temperature that will not alter their composition and in such conditions that the samples are not adversely affected by light.

6. Table overview of sampling requirements

6.1 As per GAFTA 124 contractual rules

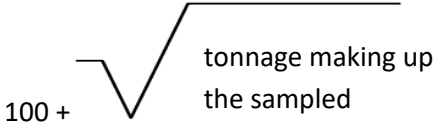
	Trucks	Trains	Barges/coasters	Vessels
Sampling point	Representative sample should be taken at loading or unloading of the transport means ⁵			
Batchmax size	1000 mt	1500 mt	1 final sample per barge	1 final sample per hold
Minimum number of incremental samples	<p>Minimum 5 incremental samples per truck when weight of truck <15 mt.</p> <p>Minimum 8 incremental samples per truck when truck weight >15 mt.</p> <p>A minimum of 40 incremental samples should be taken per parcel of various trucks.</p>	Minimum 20 incremental samples every 500 metric tons sub lot, ensuring a minimum of 40 incremental samples in case the parcel is below 1000 mt		
Weight of each incremental sample	Max 1 kg			
Minimum bulk aggregate sample per lot	Min 20 kg sample per sub-lot of 500 mt (batch size 0 to 5000 mt) or min 30 kg per sub-lot of 1000 mt (batch size 5001 to 10 000 mt)			
Final sample	<p>Min 1 sample of min 4kg to be fully grinded by the laboratory and well homogenized before extraction of the final sample (at least 500 grams).</p> <p>(For contractual samples required for analysis tests and arbitration purpose as of GAFTA Sampling Rules No. 124: min. 10kg)</p>			
Sample for the analysis	The sample for the analysis is prepared from the final sample. The remains of the final sample have to be retained for re-analysis			
Analyses	To be done by laboratory accredited according ISO 17025			
Sampling⁶	To be done by an inspection company accredited according to ISO 17020 or according an ISO 9001 certified + GAFTA approved body			

⁵Analyses done before loading will be accepted as long as sampling/analyses has been done no more than three months prior to the loading operation

⁶ The use of an accredited sampler for road transport is not required if a batch of maize has already been analyzed (original batch). The batch is not required to be analyzed again if the following requirements are met in a demonstrable manner:

- The analysis certificate shall explicitly include the same identification of the batch;
- The sampling method, batch size and laboratory satisfy the requirements indicated in the protocol;
- The analysis has been performed within the time limit mentioned in this protocol.

Moreover, for maize transported by truck in low and medium risk countries, sampling can be performed by a qualified person, who is trained and experienced in the sampling of feed and can take the appropriate care when sampling. This qualification is to be documented by records of education, experience and training of the sampler.

	Trucks	Trains	Barges/coasters	Vessels
Sampling point	Representative sample should be taken at loading or unloading of the transport means ⁷			
Batchmax size	1000 mt	1500 mt	1 final samples per barge	1final samples per hold
Minimum number of incremental samples	<p>Minimum 5 incremental samples per truck when weight of truck <15 mt.</p> <p>Minimum 8 incremental samples per truck when truck weight >15 mt.</p> <p>A minimum of 40 incremental samples should be taken per parcel of various trucks.</p>			
Weight of each incremental sample	Max 1 kg			
Minimum bulk aggregate sample per lot	Min 4 kg			
Final sample to be analysed	<p>Aggregate sample can be representatively reduced to at least 4kg to be fully grinded by the laboratory and well homogenized before extraction of the sample for the analysis (at least 500 grams).</p> <p>(Recommended volume is 10kg which would lead to less false negatives and positives)</p>			
Sample for the analysis	The sample for the analysis is prepared from the final sample. The remains of the final sample have to be retained for re-analysis			
Analyses	To be done by laboratory accredited according ISO 17025			
Sampling⁸	To be done by an inspection company accredited according to ISO 17020 or according an ISO 9001 certified + GAFTA approved body			

⁷Analyses done before loading will be accepted as long as sampling/analyses has been done no more than **three months** prior to the loading operation

⁸ The use of an accredited sampler for road transport is not required if a batch of maize has already been analysed (original batch). The batch is not required to be analysed again if the following requirements are met in a demonstrable manner:

- The analysis certificate shall explicitly include the same identification of the batch;
- The sampling method, batch size and laboratory satisfy the requirements indicated in the protocol;
- The analysis has been performed within the time limit mentioned in this protocol.

Moreover, for maize transported by truck in low and medium risk countries, sampling can be performed by a qualified person, who is trained and experienced in the sampling of feed and can take the appropriate care when sampling. This qualification is to be documented by records of education, experience and training of the sampler.

7. Analysis requirements

Samples must be analysed on aflatoxin B1 level. This analysis must be carried out by a laboratory which is accredited according to ISO17025 for the aflatoxin analysis in the products covered by this protocol.

8. Reporting analysis results

GTP certified companies (or certified against the EFISC-GTP Code 4.0, scope G and F) must report every month to EFISC-GTP (fulvio.pernice@efisc-gtp.eu) the analysis results in line with the GTP monitoring template. Collected data will be handled with confidentiality. They will be compiled into an internal monitoring database for the products covered by this protocol as per rules stated in paragraph 4 of this addendum. Collected data will only be shared anonymously and in the framework of the mutual recognition between scheme owners. If the results show level of aflatoxin above the EU maximum limits, requirements laid down in the currently applicable GTP Code (or EFISC-GTP Code 4.0, scope G and F) must be complied with.

9. Definitions

Lot (or Batch): an identified quantity of a product, determined to have common characteristics, such as origin, variety, type of packing, packer, consignor or labelling, and in 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 (Commission Regulation (EC) No 767/2009 as amended). Based on the above statement, the batch is to be defined by the operator based on the physical hold (ship compartment) or a combination of holds (train, truck).

Sampled portion: a lot or an identified part of the lot and/or of the sub-lot.

Sealed sample: a sample sealed in such a manner as to prevent any access to the sample without breaking or removing the seal. The seal's mark should be clearly identifiable and clearly visible. Alternatively, the sample can be put in a recipient which can be closed in such a manner that it cannot be opened without irreversibly damaging the recipient, avoiding the re-use of the recipient.

Identification of the sample: the sample has to be indelibly marked and must be identified in such a way that there is an unambiguous link to the sampling report.

Incremental sample: a quantity taken from one point in the sampled portion.

Aggregate sample: an aggregate of incremental samples taken from the same sampled portion. From each aggregate sample at least two (or three) final samples are taken: 1 for control (enforcement), one for trade (defence) and eventually one for reference

Reduced sample: a part of the aggregate sample, obtained from the latter by a process of representative reduction.

Final sample: a part of the reduced sample or of the homogenised aggregate sample.

Laboratory sample: a sample intended for the laboratory (as received by the laboratory) and can be the final, reduced or aggregate sample.

Test aliquot: a measured portion of the final sample taken for analysis.

Annex 1 - Internal procedures to define or change risk categories

EFISC-GTP, will share anonymously results with the other mutually recognized schemes in order to evaluate the country risk classification (on a monthly basis) based on the criteria as given in the table below:

Risk level by region	% of analyses per country	Analysis results (x)
High	> 1%	> 20ppb; OR
	> 10%	10ppb < x ≤ 20ppb
Medium	Any scenario not listed as High or Low	
Low	< 1%	5ppb < x ≤ 10ppb; AND
	> 90%	< 2ppb; AND
	Remaining (max 9%)	≤ 5ppb

- a. For upgrading a country of cultivation to a higher risk level, the number of samples to be tested is at least 1.
- b. For downgrading a country of cultivation to a lower risk level, the number of samples to be tested is at least 50 (new results).
- c. In addition to a. and b., other relevant criteria and resources can be used for reclassifying a country of origin

Annex 2 – Table of countries of origin

HIGH RISK	MEDIUM RISK	LOW RISK
	All other countries not listed as low or high level	Austria Belgium Denmark Estonia Finland France Germany Hungary Iceland Ireland Latvia Lithuania Luxembourg Netherlands Norway Poland Serbia Sweden UK Ukraine