Aflatoxin Protocol – Version September 2020

2 Sampling and testing of feed material

The next protocol has conform Article 11.1 of GMP+ A1 *General Regulations* to be considered as section 2.3 of GMP+ BA4 *Minimum Requirements for Sampling and Analysis* and as such obligatory and applicable as from the ~~29th of April 2020~~ 30th of September 2020

2.3 Protocol Monitoring Aflatoxin B1

2.3.1 Scope

This protocol gives specific requirements for sampling and analyzing Aflatoxin B1 in maize and by-products of maize which will be delivered in the GMP+ chain. It applies to all maize harvests.

2.3.2 Application

This protocol applies to the GMP+ FSA certified company which trades or processes

- maize, processed or unprocessed
- maize by-products.

The protocol has to be applied either to the maize or to the maize by-product.

The producer of the maize by-product shall apply the protocol to the end product. Food producing companies that purchase and process maize under the conditions of Regulation (EU) No. 1881/2006 (maximum levels for contaminants in foodstuff) are allowed to apply the protocol to the incoming flow of maize if they have a motivation in writing of the concentration factor in the production process and also do
a risk-based monitoring on the maize by-product.

If a batch of maize or a maize by-product has already been analyzed by a GMP+ certified supplier, this batch is not required to be analyzed again. This is also applicable when the supplier is participating in another, accepted feed safety assurance scheme, under the condition that the analysis results are available.

Guidance
In case of overlap with other GMP+ FSA requirements, compliance may be demonstrated via one overall monitoring plan.

The protocol applies to all kind of deliveries from existing and new contracts.

Note: In this protocol a country (or when possible a part or a region of a country) is categorized as High, Medium or Low Risk. For each category specific conditions are laid down regarding Aflatoxin B1 monitoring. The next table gives a summary of the main conditions.

Risk	***Batch size***	***Sample taker***	***Sampling method***	***Frequency of analysis***	***Responsible for application of protocol***	***Report***
High - excl. direct delivery by trucks (paragraph 2.3.6)	*See table 2 in 2.3.4*	*Independent superintendent organization accredited according to ISO 17020 or ISO 9001 with an appropriate scope in combination with a GAFTA approval.*	*Conditions based on Reg. (EC) No. 152/2009 including the amendments regulated by Reg. (EU) No. 691/2013* *In case of direct ship-to-ship transshipment the method described in chapter 2.3.6.2.1 applies.*	*Each final sample*	*First link in chain*	*Original certificate of analysis (positive release)*
High – direct delivery by trucks (paragraph 2.3.6)	*See table 2 in 2.3.4*	*GMP+ FSA certified company applying this protocol or the other options mentioned above*	*Conditions based on Reg. (EC) No. 152/2009 including the amendments regulated by Reg. (EU) No. 691/2013 or GAFTA sampling rules No. 124.*	*Each final sample*	*First link in chain*	*Original certificate of analysis (positive release)*
Medium – excl. direct delivery by trucks (paragraph 2.3.7)	*See table 2 in 2.3.4*	*Independent superintendent organization accredited according to ISO 17020 or ISO 9001 with an appropriate scope in combination with a GAFTA approval.*	*Conditions based on Reg. (EC) No. 152/2009 including the amendments regulated by Reg. (EU) No. 691/2013* *In case of direct ship-to-ship transshipment the method described in chapter 2.3.7.2.2 applies.*	*Each final sample*	*First link in chain*	*Original certificate of analysis (positive release)*
Medium – direct delivery by trucks (par. 2.3.7)	*See table 2 in 2.3.4*	*GMP+ FSA certified company applying this protocol*	*According to general GMP+ FSA requirements (GMP+ BA13).*	*Each final sample*	*Compound feed company that receives the trucks*	*Original certificate of analysis*
Low (paragraph 2.3.7)	*To be defined by GMP+ FSA certified company applying this protocol, based on HACCP principles*	*GMP+ FSA certified company applying this protocol .*	*According to general GMP+ FSA requirements (GMP+ BA13).*	*To be defined by GMP+ FSA certified company applying this protocol, based on HACCP principles*	*Responsibility of GMP+ FSA certified company applying this protocol, based on HACCP principles*	*Overview of monitoring results (on request)*

2.3.3 Countries of cultivation

The countries of cultivation[1] of maize are classified per harvest year into 3 categories: High, Medium and Low. Sampling and analysis of maize from a high risk country must be performed in accordance with the requirements in section 2.3.6. Maize from a Medium risk country must be sampled and analyzed in accordance with 2.3.7. For Low risk countries, sampling and analysis must be in accordance with 2.3.8.

The following classification is defined for countries of cultivation of the maize harvest.

Table 1: Classification of countries of cultivation

High	Medium	Low
	All other countries which are not mentioned under 'high risk countries or 'low risk countries'	Austria Belgium ~~Czech Republic~~ Denmark Estonia Finland France Germany ~~Hungary~~ Iceland Ireland Latvia Lithuania Luxembourg Netherlands Norway Poland ~~Spain~~ Sweden UK ~~Ukraine~~

The country of cultivation of the maize must always be known to every link in the supply chain, and the customer must be informed, including the end user.

Guidance
With 'end user' is meant the GMP+ FSA certified company that delivers compound feed to the farmer (= the final link in the GMP+ chain).

In case of doubt about the country of cultivation (country of cultivation is unknown or not known with certainty), the highest category applies.

The precautionary principle must always prevail. In case of concerns about the Aflatoxin B1 level(s) in maize or maize by-product, the company must assess whether his monitoring plan must be adapted.

[1] If applicable, a country can be divided in different regions.

Note: GMP+ International will periodically evaluate this classification per country and adapt if necessary according to criteria. As much as possible, the evaluation will be done in cooperation with other scheme owners.

2.3.4 Size of the batches

All batches must be sampled and analyzed, whereby the batch of maize or maize by-product is related to the means of transport and must have common characteristics, such as origin, variety, type of packing, packer, consignor or labelling (conform Regulation (EC) No. 767/2009).

Table 2 Maximum batch sizes

Means of transport	High risk countries	Medium risk countries	Low risk countries
Seagoing vessel	Max. 2,000 tons	Hold	HACCP based (at least in compliance with GMP+ FSA requirements)
Inland waterway vessel	Inland waterway vessel	Inland waterway vessel	
Train	Max. 1,500 tons	Train	
Truck, from Storage/ warehouse, production location or collection point	Max. 1,000 tons	Max. 2,000 tons	

2.3.5 Place of sampling

Batches must be sampled at loading (country of cultivation) or at discharge (country of delivery). In case the protocol is applied at discharge, the batch is determined by the means of transport in which the maize or maize by-product is then loaded.

Guidance
This means when a seagoing vessel is discharged in the country of delivery and the maize is directly loaded in an inland waterway vessel, the inland waterway vessel must be considered as a batch and has to be sampled.

2.3.6 Additional requirements for maize from High risk countries

2.3.6.1 Application

For maize from high risk countries, the first link in the chain is responsible for a correct application of this protocol.

2.3.6.2 Sampling

2.3.6.2.1 Sampling method

The sampler must take representative samples in accordance with the method described in Regulation (EC) No. 152/2009, including the amendments regulated by Regulation (EU) No. 691/2013, under the following conditions:

- sampling shall be undertaken of the whole batch. Sampling of part of the whole batch is not acceptable within the framework of this protocol.
  If the whole batch in the warehouse is not accessible for sampling, a sampling plan should 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.
- each aggregate sample shall not be less than 10kg.
- the sample to be send to the laboratory for preparation and analysis shall not be less than 4kg. See 2.3.10 for requirements regarding sample preparation and analysis by the laboratory.

In case of direct ship-to-ship transshipment (from a seagoing vessel, coaster, inland waterway vessel to an inland waterway vessel) the method described in “GAFTA sampling rules No. 124” is allowed under the following conditions:

- a representative sample must be taken during loading or unloading of the means of transport.
- at least 20 incremental samples per 500 tons and at least 40 incremental samples for batches smaller than 1,000 tons.
- maximum volume of the incremental sample: 1kg
- minimum 20 kg per (sub)batch of 500 tons
- at least 1 final sample, which shall not be less than 4 kg. Each final sample must be fully grinded and made homogeneous by the laboratory. See 2.3.10 for requirements regarding sample preparation and analysis by the laboratory.

2.3.6.2.2 Sample taker

Each batch is sampled by an independent superintendent organization accredited according to ISO 17020 for an appropriate scope or alternatively according to ISO 9001 for an appropriate scope in combination with a GAFTA[2] approval as superintendent for sampling in a relevant application domain (e.g. Animal feed).

In case of the direct transport by truck as described above, sampling can be performed and controlled by the GMP+ FSA certified company in compliance with the general GMP+ FSA requirements (GMP+ BA13 *Minimum Requirements for Sampling*), instead of the sampling rules as mentioned above.

2.3.6.2.3 Other requirements

The period between sampling and delivery is no longer than three months.

It is possible to separate a batch at a storage location in the country of cultivation within the framework of direct transport per inland waterway vessel, train or truck to the end user. The following requirements apply:

[2] Website GAFTA : http://www.gafta.com/members/superintendents

- The maximum batch size is in accordance with Table 2 in 2.3.4.
- The batch should be kept in quarantine (separate and identifiable) at the storage location in the country of cultivation.
- The location must be set up in such a way that representative (cross-section) samples can be taken.
- Each batch is sampled by an independent superintendent organization accredited according to ISO 17020 for an appropriate scope or alternatively certified according to ISO 9001 for an appropriate scope in combination with a GAFTA[3] approval as superintendent for sampling in a relevant application domain (e.g. Animal feed).

2.3.7 Additional requirements for maize from Medium risk countries

2.3.7.1 Application

For maize from medium risk countries, the first link in the chain is responsible for a correct application of this protocol.
Only in case of direct delivery with trucks, the receiving company (in most cases the compound feed company) is responsible for correct application of this protocol.
In case of an end user receives maize from a Medium country by truck it is possible to process this maize

- In dairy feed, only after results of analysis are available.
- In all other feed, the results do not necessarily have to be available before processing. These results can be received later.

Note: This requirement may be different by another scheme. In those case, the first link in the chain is responsible for applying the protocol.

2.3.7.2 Sampling

2.3.7.2.1 Batches

See for defined batches in section 2.3.4.

2.3.7.2.2 Sampling method

The sampler must take representative samples in accordance with the method described in Regulation (EC) No. 152/2009, including the amendments regulated by Regulation (EU) No. 691/2013, under the following conditions:

- sampling shall be undertaken of the whole batch. Sampling of part of the whole batch is not acceptable within the framework of this protocol.
  If the whole cargo in the warehouse is not accessible for sampling, a sampling plan should be made and documented, that covers the accessible part of the cargo. The part of the cargo that has not yet been sampled and tested, should be monitored once it´s possible and safe to get access.
- each aggregate sample shall not be less than 10kg.
- the sample to be send to the laboratory for preparation and analysis shall not be less than 4kg. See 2.3.10 for requirements regarding sample preparation and analysis by the laboratory.

[3] Website GAFTA : http://www.gafta.com/members/superintendents

In case of direct ship-to-ship transshipment (from a seagoing vessel, coaster, inland waterway vessel to an inland waterway vessel) the method described in "GAFTA sampling rules No. 124" is allowed under the following conditions:

- a representative sample must be taken during loading or unloading of the means of transport.
- at least 20 incremental samples per 500 tons and at least 40 incremental samples for batches smaller than 1,000 tons.
- maximum volume of the incremental sample: 1kg
- minimum 20 kg per (sub)batch of 500 tons
- at least 1 final sample, which shall not be less than 4 kg. Each final sample must be fully grinded and made homogeneous by the laboratory. See 2.3.10 for requirements regarding sample preparation and analysis by the laboratory.

Note: In cases where maize is stored longer than 3 month 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).

2.3.7.2.3 Sample taker

For medium risk countries, each batch is sampled by an independent superintendent organization accredited according to ISO 17020 for an appropriate scope or alternatively according to ISO 9001 for an appropriate scope in combination with GAFTA[4] approval as superintendent for sampling in a relevant application domain (e.g. Animal feed).

In case of the direct transport by truck as described above, sampling can be performed and controlled by the GMP+ FSA certified company in compliance with the general GMP+ FSA requirements (GMP+ BA13 *Minimum Requirements for Sampling*), instead of the sampling rules as mentioned above.

2.3.7.2.4 Other requirements

See section 2.3.6.2.3.

2.3.8 Additional requirements for maize from Low risk countries

2.3.8.1 Application

For maize from low risk countries, every GMP+ FSA certified company is responsible for a correct application of this protocol, based on HACCP principles.

2.3.8.2 Sampling

2.3.8.2.1 Batches

See for defined batches in section 2.3.4.

2.3.8.2.2 Sampling method

[4] Website GAFTA : http://www.gafta.com/members/superintendents

The sampler must take representative samples in accordance with general GMP+ FSA requirements as described in GMP+ BA13 *Minimum Requirements for Sampling*.

2.3.8.2.3 Sample taker

For low risk countries, sampling can be performed by the GMP+ FSA certified company, but must be in accordance with general GMP+ requirements (GMP+ BA13 *Minimum Requirements for Sampling*).

2.3.9 Frequency of analyzing

Analysis must be performed according to the frequency belonging to the category as mentioned in Table 3.

Table 3 Frequency of analysis per category of countries of cultivation

Batch	Frequency of analysis		
	High	Medium	Low
see table 2	Each final sample	Each final sample	Risk based

A batch is considered compliant if the result of each analyzed final sample is within the Aflatoxin B1 product standard (see GMP+ BA1 *Specific Feed Safety Limits*).

The general GMP+ FSA requirements regarding non-conforming products must be followed. These include separation of products, informing customers, sending a EWS notification to GMP+ International and the certification body, and inform the authorities.

2.3.10 Sample preparation and Analysis method

The GMP+ FSA certified company applying this protocol sends at least a 4 kg sample of maize (by-product) to the laboratory for preparation and analysis. The preparation and analysis by the laboratory are in accordance with the following conditions:

- The sample is fully grinded and homogenized before the final sample and out of it the sample for analysis are taken.
- The final sample is at least 500 grams.
- The sample for analysis is prepared from the final sample.
- The remains of the final sample are retained for re-analysis.
- The sample for analysis is analyzed on Aflatoxin B1.
- This analysis is carried out by a laboratory which is GMP+ B11 Registered ~~ISO 17025 accredited or GMP+ B10 certified~~ for the Aflatoxin B1 analysis in feed products.

2.3.11 Reporting analysis results

The GMP+ FSA certified company that applies this protocol must enter the following data at least every month into the GMP+ Monitoring database and (anonymously) share them with the GMP+ community:

- Product
- Sample number
- Sample date
- Origin (meant is: country of cultivation)
- Analysis result

Note: This applies for all results (High, Medium and Low) that are generated in the framework of application of this protocol. GMP+ International will use these data only to evaluate the classification of the countries and regions of origin. It is therefore very important to enter the results in the database as soon as possible. Incomplete reports (e.g. one or more required fields in the database are not filled) cannot be taken into account as value for the reclassification. Please be aware to enter the correct value (in mg/kg!). External communication, e.g. to other scheme owners, will only be done in an anonymous way.

Guidance
A laboratory might report the results in ppb's. Be sure to check on this. If so, please divide this result by 1000 before entering in the database. Example: 3 ppb = 0.003 mg/kg.

The GMP+ FSA certified company who makes use of analysis results from other companies (for example suppliers) should not enter the results into the GMP+ Monitoring database.

2.3.12 Information to client and end user

Positive release: In case of category High and Medium, the analysis results (by means of an original certificate of analysis or an original analytical report of an approved lab) must accompany the batch, so each link in the chain is informed. The end user must be informed about the results of the analysis that have been carried out before using or processing the maize or maize by-product in feed ~~(excluding deliveries by truck)~~.
There must be a clear link between the delivered batch and the certificate of analysis / analytical report from an approved lab (positive release). The information has to demonstrate that the sampling was conducted not longer than 3 months before the date of delivery.

In case of stored batches and re-analysis after 3 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.

Information in case products come from low risk countries
In case of the category Low Risk, all links in the chain, including the end user, must be informed (on request) periodically about the analysis results and receive a summary or overview of the results of the application of this protocol.

Information in case of maize by-products
In case of maize by-products, the food producing company must declare in writing that he has applied the protocol to the incoming flow of maize.

Guidance
With 'end user' is meant the GMP+ FSA certified company that delivers feed to the farmer.

Note: Delivery from storage locations may be from batches that are put together after positive release. In that case the end user will be informed about all results, and must assess the results according to HACCP principles.

Background information

Each GMP+ FSA certified company is primarily responsible for the control of all hazards according to the HACCP principles, including monitoring. The GMP+ FSA certified company should be able to motivate its own *HACCP system*

Following a large-scale Aflatoxin B1 contamination in maize originating from the Balkan region in 2012, GMP + International established a specific monitoring protocol. Other feed safety assurance schemes have developed similar protocols.

The protocol requires intensive monitoring of Aflatoxin B1 in maize. The results enables a GMP+ FSA certified company to carefully and responsibly process the maize, particularly in dairy cattle feed, so that aflatoxins in milk remain at a very low level. The establishment of this particular protocol means that each GMP+ FSA certified company, regardless of the outcome of the company's own risk analysis, at least must comply with the monitoring requirements of this protocol.

This protocol provides the minimum requirements for monitoring of Aflatoxin B1 in maize and maize by-products, based on actual risks. In fact, this protocol requires nothing more than what each company already should do to demonstrate that the aflatoxin risk is managed. By establishing this in a special protocol, the GMP+ FSA certified company is required to include the requirements of this protocol in its own monitoring and to demonstrate that the requirements of the protocol are met.

This protocol applies to all harvests.
Classification is made by GMP + International in collaboration with other scheme holders, who have a similar protocol in their scheme, and is regularly evaluated and updated.
The classification is based on:

- *Information about cultivation and harvest conditions.*
- *Results of analyses, which GMP+ FSA certified companies provide.*
- *Other information*

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