BT-16

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Temporary monitoring

Feed Chain Alliance
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DOCUMENT HISTORY

Version and date of approval	Reasons for revision	Revision scope	Ultimate date of application
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	Reassessment of the risk classification for Brazil and Croatia	Protocol No. 1, point 2.3	23/02/2018
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1.28 17/09/2019	Adding history of countries' risk category	Protocol n° 1: point 2.3	~~17~~23/09/2019
	Moving of table of countries' risk category to external document		
	Correction of document history: ultimate date of application from 17/09/2019 to 23/09/2019	Document history	

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BT-16 : Temporary monitoring

1. Objectives

The application of this document aims at reinforcing, temporarily, the monitoring described in various documents and implemented by companies in function of their activities:

- AT-04-00 – Practical realization of the HACCP plan
- AT-05 – Monitoring
- BT-02 - Purchase: General Provisions
- BT-03 - Purchase: Special Provisions
- BT-04 – Purchase: Specific purchase protocols
- BT-05 – Sector based sampling
- BT-13 – Salmonella Control
- BT-15 – Monitoring of dioxins and dioxin-like PCBs in fats and oils

The additional monitoring described in this document may not be part of a sector based monitoring plan.

The control enhancement aims at responding in a swift and coordinated way, to any specific risk at the level of the companies.

2. Scope

The temporary monitoring as described in this document (protocols) must be applied by all FCA certified companies in function of their specific activities.

The controls are relating to feed mentioned here below.

N°	Protocol Title	Animal feed	Origin
1	Aflatoxine B1 in Maize	Maize	All origins

Unless stated otherwise, these protocols will be applicable, regardless of the qualifications submitted by the supplier (cf. 'BT-02 - Purchase: General provisions').

3. Definitions

Body Accredited for sampling:
Body accredited thereto by the national accreditation organization (such as BELAC in Belgium, COFRAC in France or RvA - Raad voor Accreditatie in the Netherlands) or by a foreign accreditation organization belonging to the multilateral agreements (MLA).

Batch (or lot):
'An identifiable quantity of a product of which has been established that it presents common characteristics, such as e.g. origin, variety, type of packaging, packer, sender or the labeling. In case of a production process, the batch is a quantity of product produced in one single factory, and using uniform production parameters.

Sampled portion:
A Batch or identified part of the batch or sub batch

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.

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 homogenized aggregate sample.

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

Sealed sample:
A sample sealed in such a manner as to prevent any access to the sample without breaking or removing the seal.

Protocol n° 1: Aflatoxin B1 in maize

1. Objective

The objective is to establish a protocol for monitoring the presence of Aflatoxin B1 in batches of cultivated maize originating from defined origins.

2. Application scope

2.1. Companies concerned

The protocol is applicable to all FCA certified companies, who are performing at least one of the following activities:

- Purchase/sale of maize from one of these origins, whatever the risk category may be;
- Processing of maize from one of these origins intended for use in feed (e.g. compound feed);
- Processing of maize from one of these origins intended for the placing on the market of secondary flows (all derived products originating from the industry are considered like, e.g. DDGS, gluten feed, gluten, cake or extraction of maize germs, etc.) and which shall be destined for animal feed;
- Storage and/or transshipment of maize from one of these origins (e.g. a port terminal).

2.2. Products

The protocol is applicable to all maize batches (grains of *Zea mays* L. ssp. *mays*) regardless the destination (food, feed or technical application).

Processed maize and maize derived products

Processed maize and maize derived products (such as, e.g., feed materials with numbers 1.2.2 to 1.2.17 in the European Catalogue of feed materials) are not affected by the protocol.

However, the focus of the company is drawn to the fact that:

- The origin of maize, used during the different processing stages, should be known with as much precision as possible. Indeed, the production of a maize derived product may take place in a country other than where it has been cultivated;
- Aflatoxin B1 may, because of the processing step, be concentrated at the level of derived products. A derived product may therefore contain higher levels of undesirable substances than the maize from which it originates;
- Maize, processed maize and maize derived products placed on the market, destined for animal feed must comply with the specific standards laid down in the Legislation in force and in document 'BT-01 – Additional standards for animal feed and for by-products for reprocessing'.

The company must adapt its control plan in function of this information.

2.3. Origin

All possible origins are classified within 3 different risk categories: high, medium or low risk. For each category, different specifications are of application.

It is difficult to establish a list of countries concerned by this hazard. The presence of Aflatoxin B1 in maize is linked to particular climatic conditions during culture (drought), harvest (humidity), or storage. Therefore, the classification is based on RASFF messages (Rapid Alert System for Food and Feed) issued in the 3 previous years and on available analysis results for recent deliveries. The precautionary principle however shall always prevail.

It is therefore essential that the origin of «cultivation» is always known by the customers, including the final customer.
In case of doubt (e.g. origin of culture unknown, or not known with certainty), the origin shall be considered as "high risk".

High-risk countries	Medium-risk countries	Low-risk countries
See OVOCOM web site	See OVOCOM web site	See OVOCOM web site
Italy	Argentina	All EU-28 countries not mentioned under 'medium risk countries' for 'high risk countries'
	Brazil	
	Bulgaria	
	Canada	
	Croatia	
	Czech Republic	
	Egypt	Hungary Romania Slovakia
	Greece	
	India	
	Madagascar	
	Portugal	
	Russia	
	Serbia	
	Slovenia	
	Spain	
	Ukraine	
	All other origins which are not mentioned under 'high risk countries' or 'low risk countries'	

Table on risk categories for countries

OVOCOM will periodically evaluate this classification per country and adapt if necessary.
A country's current and previous risk categories can be found on the OVOCOM web site under part B of the FCA documents: Risk category for countries (time span). OVOCOM will periodically evaluate this classification per country and adapt if necessary.

2.4. Period

The elaborated protocol is applicable for all maize batches regardless the harvest year and will be regularly evaluated and updated if necessary. .

3. Application of the protocol

Maize can be shipped via four transportation channels, for which a specific application of the protocol has been defined:

1. Seagoing vessel (whose charge is directly loaded onto an inland waterway vessel or in a storage facility);
2. Inland waterway vessel;
3. Train;
4. Road transport.

The origin of the "cultivation" should always be known by the customer, including the final customer. In case of doubt, the origin will be considered "medium risk", and the batch must be sampled and analyzed in compliance with the protocol.

In case an origin is classified as 'low risk', no specific requirements for sampling or analysis methods are described within this protocol. For maize batches coming from these origins, the company must apply the monitoring as is described in its HACCP plan, and in accordance with the document 'AT-05: Monitoring'.

It goes without saying that any non-compliant analysis result, obtained in the context of this protocol, shall be subject to a mandatory notification to the competent authorities and to OVOCOM (cf. point 6).

3.1. 1st case: Seagoing vessel

The terminal, or storage and transshipment company shall draw the attention of the owner of the goods to his obligations. The latter is responsible for a correct application of the protocol (sampling and analysis).
The protocol is applicable to any seagoing vessel, whatever the country of destination, or its use (feed, food or technical application. The protocol may be applied when loading the seagoing vessel (so in the port of loading) and/or during unloading.

The samples must be taken by an independent superintendent organization accredited according to ISO 17020 and/or certified according to ISO 9001 in combination with a GAFTA[1] approval as superintendent for sampling in a relevant application domain (e.g. Animal feed). Samples taken in the context of this protocol, are considered to be representative for the entire batch. The FCA certified company will provide any information relating to the sampling protocol (point 4) to the independent superintendent organization.
The analysis must be performed in a qualified laboratory (cf. point 5).
The costs for the sampling and analysis shall be borne by the seller.
Analysis results shall be communicated to the seller, the customer and to the storage company.

If the result is not compliant with the applicable legal maximum content, the owner of the batch, or lack of evidence thereof, the terminal or the storage, must notify any exceeding of the maximum content to the competent authorities (for Belgium to the Provincial Control Unit (PCU) of the FASFC (Federal Agency for the safety of the Food Chain)).

The batch should not be used for as long as the analysis results are unknown or if results are non-compliant. The stored batch will remain in quarantine pending the results.
In case of exceeding the applicable legal maximum content, the batch will remain blocked until measures, in consultation with the competent authorities, have been taken. In case a non-compliant

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

result concerns a batch size of max. 2000 tonnes, the traceability and the risk analysis shall be extended to the remaining batches issued from the same hold.

Remarks:

- Any chartering, of an inland waterway vessel; with maize, coming from a sea vessel, already analyzed, is not required to be re-analyzed provided the following requirements are met in a demonstrable manner:
  - The analysis certificate shall explicitly indicate the same identification of the batch;
  - The sampling method used is the one described in point 4;
  - The batch size is equal to the one described in point 4;
  - The laboratory satisfies the qualifications required for the analysis of Aflatoxin B1 as indicated in point 5;
  - The analysis has been performed within the time limit mentioned in point 5.
- The analysis certificates must always accompany the batch which has been loaded into the waterway vessel;
- Without prejudice to the application of other legal and/or commercial requirements, an FCA certified company receiving a supply of maize from another FCA certified company is not required to apply such protocol again. However, a copy of the analysis certificate must be communicated by the supplier to the customer, at the latest upon delivery.

Prior notification for sea vessels arriving in a Belgian port

The FASFC (Federal Agency for the safety of the Food Chain) must be notified within 72 hours before arrival of the vessel. If the operator is not Belgian, it will be the Belgian terminal or the storage and transshipment company who must notify the Provincial Control Unit (PCU) of the FASFC (Federal Agency for the safety of the Food Chain).
The information sent to the PCU (Provincial Control Unit) must at least contain the following information:

- Sender;
- Entrance Port;
- Addressee;
- Notifying person;
- Description of the goods (feed in question);
- Origin;
- Means of transport (type, name of vessel, loading space number or container number, seal number,…);
- Quantity.

3.2. 2nd case: Inland waterway transport (FOB or CIF)

The customer is responsible for the correct application of the protocol (sampling and analysis), and should be notified 48 hours prior to the loading of the vessel (regardless the loading place).
The operator having a purchase contract must notify his supplier that he wishes to be notified 48 hours prior to the loading of the inland waterway vessel. The supplier (intermediate) must be committed to submit this same question to his own supplier, and thus trace the demand of the final customer back to the very first (original) supplier.

The samples must be taken by an independent superintendent organization accredited according to ISO 17020 and/or certified according to ISO 9001 in combination with a GAFTA[2] approval as superintendent .for sampling in a relevant application domain (e.g. Animal feed). Samples taken in the

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

context of this protocol are considered representative for the entire batch. The FCA certified company will provide any information relating to the sampling protocol (point 4) to the independent superintendent organization.
The analysis must be performed in a qualified laboratory (cf. point 5).
The costs for sampling and analysis shall be borne by the seller.

The analysis result should, at the latest, be available upon the unloading of an inland waterway vessel in the installation of the final customer.
In the case where feed is not delivered directly to the final customer, the analysis results however, should be put at the disposal of the storage and transshipment company.
If the result is not compliant with the legal applicable maximum content, the owner of the batch, or lack of evidence thereof, the terminal or the storage , must notify any exceeding of the maximum content to the competent authorities (for Belgium: to the Provincial Control Unit (PCU) of the FASFC (Federal Agency for the safety of the Food Chain)).
The batch should not be used for as long as the analysis results are unknown or if results are non-compliant.
In case of exceeding the applicable legal maximum content, the batch will remain blocked until measures, in consultation with the competent authorities, have been taken.

Remarks:

- If a batch of maize has already been analyzed, this batch is not required to be analyzed again, on the condition that the following requirements are met in a demonstrable manner:
  - The analysis certificate shall explicitly indicate the same identification of the batch;
  - The sampling method used is the one described in point 4;
  - The batch size is equal to the one described in point 4
  - The laboratory satisfies qualifications required for the analysis of Aflatoxin B1, as indicated in point 5;
  - The analysis has been performed within the time limit mentioned in point 5.
- The analysis certificates must always accompany the batch;
- Without prejudice to the application of other legal and/or commercial requirements, an FCA certified company receiving a supply of maize from another FCA certified company is not required to apply such protocol again. However, a copy of the analysis certificate must be communicated by the suppliers to the customer, at the latest upon delivery.

3.3. 3rd case: railways

The terminal or storage and transshipment company shall draw the attention of the owner of the goods to his obligations. The latter is responsible for the correct application of the protocol (sampling and analysis).
The protocol should be applicable to any train, whatever the country of destination or its use (feed, food or technical application). The protocol may be applied when loading the train (so in the station of loading) and/or during unloading.
The samples must be taken by an independent superintendent organization accredited according to ISO 17020 and/or certified according to ISO 9001 in combination with a GAFTA [3] approval as superintendent for sampling in a relevant application domain (e.g. Animal feed). Samples taken in the context of this protocol, are considered to be representative for the entire batch. The FCA certified company will provide any information relating to the sampling protocol (point 4) to the independent superintendent organization.

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

The analysis must be performed by a qualified laboratory (cf. point 5).
The costs for sampling and analysis shall be borne by the seller.
The laboratory will send the analysis results to the owner of the goods AND to the FCA certified company (e.g. terminal). In the case where feed is not delivered directly to the final customer, the analysis results however, should be kept at the disposal of the storage and transshipment company.

If the result is not compliant with the legal applicable maximum content, the owner of the batch, or lack of evidence thereof,, the terminal or the storage company, must notify any exceeding of the maximum content to the competent authorities (for Belgium: to the Provincial Control Unit (PCU) of the FASFC (Federal Agency for the safety of the Food Chain)).

The batch should not be used for as long as the analysis results are unknown or if results are non-compliant. The stored batch will remain in quarantine pending the results.
In case of exceeding the applicable legal maximum content, the batch will remain blocked until measures, in consultation with the competent authorities, have been taken.,.

Remarks

- If a batch of maize, has already been analyzed, this batch is not required to be analyzed again, provided the following requirements are met in a demonstrable manner:
  - The analysis certificate shall explicitly indicate the same identification of the batch;
  - The sampling methods used are the ones described in point 4;
  - The batch size is equal to the one described in point 4;
  - The laboratory satisfies the qualifications required for analysis of Aflatoxin B1 as indicated in point 5;
  - The analysis has been performed within the time limit mentioned in point 5.
- The analysis certificates must always accompany the batch;
- Without prejudice to the application of other legal and/or commercial requirements, an FCA certified company receiving a supply of maize from another FCA certified company is not required to apply such protocol again. However, a copy of the analysis certificate must be communicated by the suppliers to the customer, at the latest upon delivery.

Prior notification for trains arriving in a Belgian terminal

The FASFC (Federal Agency for the safety of the Food Chain) must be notified within 72 hours before arrival of the train. If the operator is not Belgian, it will be the Belgian terminal or the storage and transshipment company who shall notify the Provincial Control Unit (PCU) of the FASFC (Federal Agency for the safety of the Food Chain).
The information sent to the PCU (Provincial Control Unit) must at least contain the following information:

- Sender;
- Entrance Port;
- Addressee;
- Notifying person;
- Description of the goods (feed in question);
- Origin;
- Means of transport (type, wagon or container number, seal number);
- Quantity.

3.4. 4th case: Road transport

This point is only applicable to road transport of maize directly originating from companies located in regions or countries classified as 'high risk' or 'medium risk' as defined in point 2.3. Maize originating

from other regions/countries, transported by road are not concerned by the application of this protocol, except in the case of an internal decision by the FCA certified company (e.g. following the HACCP analysis).

In case of road transport concerned by the protocol, the FCA certified company must inform the owner of the goods, of his responsibilities. It is the owner of the goods who is responsible for the correction application of the protocol (sampling and analysis).
The protocol shall be applied to any batch transported by road, whatever the country of destination, or its use (feed, food or technical application).

The samples must be taken by an independent superintendent organization accredited according to ISO 17020 and/or certified according to ISO 9001 in combination with a GAFTA[4] approval as superintendent, for sampling in a relevant application domain (e.g. Animal feed). Samples taken in the context of this protocol are considered representative for the entire batch. The FCA certified company will provide any information relating to the sampling protocol (point 4) to the independent superintendent organization.
The analysis must be performed in a qualified laboratory (cf. point 5).
Costs for sampling and analysis shall be borne by the seller.
The analysis results shall be communicated to the seller and to the buyer of the goods . In case the feed is not delivered directly to the final customer, the analysis results however, must be kept at the disposal of the terminal/storage facility.

If the result is not compliant with the legal applicable maximum content, the owner of the batch, or lack of evidence thereof, the FCA-certified company, must notify any exceeding of the maximum content to the competent authority (for Belgium the Provincial Control Unit (PCU) of the FASFC (Federal Agency for the safety of the Food Chain)).

The batch should not be used for as long as the analysis results are unknown or if results are non-compliant. The batch must remain in quarantine pending the results.
In case of exceeding the applicable legal maximum content, the batch will remain blocked until measures, in consultation with the competent authorities, have been taken.

<u>Remarks</u>

- If a batch of maize has already been analyzed, this batch is not required to be analyzed again, provided the following requirements are met in a demonstrable manner:
    - The analysis certificate shall explicitly include the same identification of the batch;
    - The sampling method used is the one described in point 4;
    - The batch size is equal to the one described in point 4;
    - The laboratory satisfies the qualifications required for analysis of Aflatoxin B1 as indicated in point 5;
    - The analysis has been performed within the time limit mentioned in point 5.
- The analysis certificates must always accompany the batch;
- Without prejudice to the application of other legal and/or commercial requirements, an FCA certified company receiving a supply of maize from another FCA certified company is not required to apply such protocol again. However, a copy of the analysis certificate must be communicated by the supplier to the customer, at the latest upon delivery;
- If specified in the national legislation, the importation must be notified in advance to the competent authority.

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

4. The protocol for sampling

4.1. General

The applicable procedure as part of this protocol, for the collection of samples, is described below:

One must take into account that the undesirable substance (Aflatoxin B1) is not homogeneously distributed in feed (bulk). Any maize batch, in bulk, must be sampled, irrespective of the loading space.

4.2. Size of a batches

For the definition of a « batch » is referred to document 'AC-00: Introduction' (point 5). However, depending on the origin of the maize batch, maximum batch sizes are defined within this protocol:

Means of transport	High risk countries	Medium risk countries
Seagoing vessel	Max. 2000 tonnes	Tonnage as transported per hold
Inland waterway transport	Tonnage as transported by one barge or lighter	Tonnage as transported by one barge or lighter
Train	Max. 1500 tonnes	Total volume of entire train
Road transport	Max. 1000 tonnes	Max. 2000 tonnes

For road transport, the batch size is determined in function of the time of sampling, and the obligation as regards the representativeness of this batch. For example, sampling when unloading a truck shall only be representative for the volume present in the loading space. In this case, the batch size shall be equal to the transported quantity.

4.3. Sampling

The samples must be taken by an independent superintendent organization accredited according to ISO 17020 and/or certified according to ISO 9001 in combination with a GAFTA[5] approval as superintendent for sampling in a relevant application domain (e.g. animal feel.)

Incremental samples must be taken randomly throughout the whole sampled portion and must be of approximately equal sizes.

If only part of a batch can be sampled in the silo, a monitoring plan must be prepared and documented relating to the accessible part. That part of the batch for which no any samples were taken, must be sampled as soon as it is safe and accessible.

The samples must be taken and prepared as quickly as possible, bearing in mind the precautions necessary to ensure that the product is neither changed nor contaminated. Instruments and also surfaces and containers intended to receive samples must be clean and dry.

The hazard «aflatoxin» may be distributed non-uniformly throughout the feed, in which case the procedure as described in the consolidated version of Regulation (EC) No 152/2009, as amended by Regulation (EU) 691/2013, as regards methods of sampling and analysis, annex I shall apply.

[5] *Website GAFTA: http://www.gafta.com/members/superintendent*

A batch is considered compliant if the analyzed final sample is compliant with the applicable legal maximum content (analysis result after taking into account measurement uncertainty).

All final samples, not analyzed, will be stored and kept at the disposal of the customer for a period of 3 months.

The FCA certified company applying this protocol sends at least a 4 kg sample to the laboratory for preparation and analysis. The following working method should be applied by the laboratory:

- The sample is fully ground and homogenized before the final sample and the sample for analysis (which is issued from the final sample) 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 by the laboratory.
- The sample for analysis is analyzed on Aflatoxin B1.

The information regarding this method should be transferred to the laboratory by the FCA company for every analysis request.

5. Analysis

The companies will have the final samples analyzed in Laboratories accredited according to ISO 17025 standards, for the determination of the Aflatoxin B1 level.

Validity of an analysis

If the analysis has been performed by another operator, he should be able to demonstrate that the analysis had been performed within maximum 3 months preceding the date of unloading/delivery to an FCA certified company (e.g. by means of the date indicated on the analysis certificate from the laboratory). Should this not be the case, a new analysis must be performed.

In the event of a new analysis, after 3 months, the highest value between all measured Aflatoxin B1 results are applicable. All analysis results of that batch (including expired batches) must accompany the batch.

If storage and/or transport conditions are favorable, a production as regards Aflatoxin B1, subsequent to the completion of a compliant analysis, cannot always be excluded. The period of 3 months prior to the date of unloading/delivery to an FCA certified company, shall be considered as an indicative maximum time limit.

For example, the following factors may justify the conducting of a new analysis within a shorter time frame:

- Conditions for storage and preservation, and/or unfavorable transport circumstances leading to the development and the production of aflatoxin B1 ;
- The analysis certificate indicating a result which is close to the maximum level in force for this hazard;
- Intended for use in feed destined for animals susceptible to the monitored hazard (e.g. dairy cows).

The hazard analysis remains an important part as regards 'Aflatoxin' monitoring inherent to the FCA certified company.

6. Communication of analysis results to OVOCOM

FCA certified companies shall communicate the analysis results, which result from the application of this protocol, to OVOCOM (info@ovocom.be). This is valid only in case the FCA certified company orders the analysis itself .

At least the following information shall be communicated:

- Product;
- Means of transport;
- Sample number;
- Sample date;
- Origin;
- Analysis result.

OVOCOM will use these data only to evaluate the classification of the different origins within the specified risk categories. External communication, e.g. to other scheme owners, will only be done in an anonymous way.