PURPOSE

This protocol describes the measures for controlling Aflatoxin risks in maize and maize by products and dairy feed.

PROCESS OWNER

Program Manager Products(PM-P)

REFERENCES

P-11 Reporting and assessing exceedances, nonconformities and threats
P-13 Calamity control
D-01 Action and rejection limits
D-25 Risk classification countries Aflatoxin B1 in maize and maize (by) products
D-28 Participants verification Aflatoxin B1 dairy feed
F-23 Verification Aflatoxin dairy feed
F-24 Results monitoring Aflatoxin and mycotoxins

WORK METHOD

SCOPE

Since 2012, feed companies are being confronted with maize and maize (by) products from Middle and Southeast Europe and North and South America, that – to a greater or lesser extent- are contaminated with Aflatoxin B1. The level of contamination varies between countries. Within countries, there sometimes is a strong variation between regions. In addition to the variation within countries, the contamination level also varies on a year by year basis. The contamination strongly depends on the weather conditions during critical phases of the development of the maize (bloom, cob formation, ripening, harvest).

Because in any random year, maize of various harvest years are on the market, it is important – in this procedure – to consider these various harvest years and their different contamination levels.
The prescribed measures apply both on maize and on Maize (by) products, dry and moist, both organic and conventional and form a supplement to GMP+ FSA protocol BA4, par 2.3. "*Protocol Monitoring Aflatoxin B1 a*nd BA10, appendix 5 "*Gatekeeper protocol for the purchase of grains, seeds and legumes*". Said GMP+ FSA requirements are the foundation and must be adhered to at all times

RISK GROUPS SECUREFEED

Maize and maize (by) products are classified in three risk groups, based on origin. This classification applies to maize grown in the relevant country. In maize (by) products it concerns the country where the maize from which the maize (by)product was produced, was grown. This country of cultivation is the country or origin.

- **Low Risk countries of origin**: For maize and maize (by) products from these counties, no additional requirements apply.
- **High Risk countries of origin**: It is not permitted to apply Maize from these countries in dairy feed, unless the Aflatoxin B1 levels in the hold analysis and the 4 analyses of the lighter / pushbin/inland waterway vessel/train/storage, are all < 0.001 mg/kg.
- **Medium Risk countries of origin**: maize and maize (by) products from these countries are allowed to be applied in dairy feed, provided they are sampled and analyzed as prescribed in this protocol ~~other countries~~.

In the tables in D-25 "*Risk classification maize and maize byproducts"* the current risk classification for maize and maize (by) products of the various countries are displayed for the current harvest year (and previous harvest years if applicable).

SAMPLING AND ANALYSIS OF MAIZE

1. General

With regard to the sampling and analysis of maize from High and Medium countries of origin the following applies:

a) *Analysis per hold of a seagoing vessel*: These are sampled and analyzed in accordance with:
   a. the current legal requirements referred to in Annex I of Reg. (EC) no. 152/2009 "*For the determination of the sampling and analysis methods for the official inspection of feed*".
   b. the current requirements of GAFTA sampling Rules No. 124.

b) *Analysis of batches that are transferred from the hold of a seagoing vessel to a storage or train (max. 2000 tons) or in a pushpin / inland waterway vessel / lighter*). These are sampled and analyzed in accordance with the legal requirements as referred to in Annex I sub 5.B of the original Reg. (EG) no. 152/2009 "*For the determination of the sampling and analysis method for the official inspection of feed*", provided that of each of the 4 aggregate samples, an end sample of at least 3 kg is send to the laboratory. The participant must have the results of these individual analysis prior to the receipt of a batch (hold/lighter/pushpin/inland waterway vessel/train/storage).

c) In case of direct delivery by truck without intermediate storage from countries falling in risk group "Medium" samples should be taken according to GMP BA13 guidelines. In case of direct delivery by truck without intermediate storage from countries falling in risk group "High". sampling should be carried out by an independent and accredited sample taker according to the current 152/2009. In both cases, the sample send to the lab shall not be less than 3 kg.

Remarks:

- The obtained final samples are analyzed by a laboratory which is accredited fort he analyses of aflatoxin B1 in the matrix Maize/Cereals/ Feedstuffs (see the requirements in I-08-01).
- The Certificate of Analysis contains the county of cultivation, the identification of the lot (such as batch number, lighter name, vessel incl. hold), the size of the lot of which the sample is taken and the sampling date.
- Sampling and analysis is allowed to be done in the country of origin, so the customer has the results before the lot is processed.
- In case of situation c: If the mais is collected and stored in the country of origin, it is allowed to use the certificate of analysis of the storage location as representative for the trucks loaded from that storage, given the storage is sampled according to independent and accredited sample taker.

Maize from Low Risk countries of origin must be sampled and analyzed in accordance with the proprietary HACCP plan of the participant.

2. Start of new harvest

For countries classified in risk group Low at the start of a new harvest season, it is important to quickly get a good idea about the Aflatoxin B1 contamination level, to assure that the countries have been classified in the proper classification group.
To obtain sufficient reliable analysis results over a short period of time, participants have a good average sample of each of the first three deliveries of maize they receive from these countries of origin, analyzed for Aflatoxin B1. In this, the following items are important:

- On receipt of trucks, it must be prevented that the three deliveries to be sampled and analyzed, originate from one and the same batch of origin (lighter);
- This three deliveries rule applies for all countries of origin. If one receives French, German and Belgian maize, for instance, the first three loads of French maize, the first three loads of German maize and the first three loads of Belgian maize will be analyzed;
- To obtain a reliable analysis result, representative and sufficiently big samples are required. This means the following:
  - Deliveries per train/lighter/pushpin/inland waterway vessel are sampled and analyzed in accordance with the legal requirements as referred to in annex I sub 5.B of the original Reg. (EC) no. 152/2009 "*For the determination of the sampling and analysis methods for the official inspection of feed*", in which of the 4 aggregate samples one end sample of at least 3 kg is sent to the lab for analysis on aflatoxin B1.
  - Deliveries by truck, sampled in accordance with the requirements of GMP+ FSA BA13
  - "*Minimum requirements sampling*" 1 aggregate sample is made of which an end sample of at least 3 kg is sent to the lab for analysis on aflatoxin B1.
- The end samples obtained are analyzed by a laboratory accredited for the determination of Aflatoxin B1 in the matrix Maize/Grains/Feed materials according to I-08-01.

SAMPLING AND ANALYSIS MAIZE (BY) PRODUCTS
The requirements for sampling and analysis of maize are – due to the process progress and the processing of maize in the food and biofuel industry – not suitable for Maize (by)products that are released in these industries and are applied as feed. In addition, the following situation applies in said industries:

- Insight in the Aflatoxin B1 levels of maize purchased and inserted into the process;
- Insight in the concentration factors (= Aflatoxin B1 level in maize (by)product) / Aflatoxin B1 level in Maize)
- Strong homogeneity of the maize (by) products at the end of the process, also with regard to the Aflatoxin B1 level

For Maize (by)products – with the exception of the country classification according to D-25 "*Risk classification countries maize and maize byproducts"* the requirements for sampling and analysis from GMP+ FSA protocol BA4, par 2.3 "*Protocol Monitoring Aflatoxin B1"* apply.

SecureFeed participants who wish to use maize (by) products produced from maize grown in HIGH and MEDIUM risk countries for direct delivery to dairy farmers, must – prior to the delivery – by means of analyses, demonstrate that the maize (by) products to be delivered contain < 0,0025 mg/kg Aflatoxin B1.

BAN ON PROCESSING MAIZE IN DAIRY FEED
Maize from High Risk countries of origin cannot be applied in dairy feed (compound feed and direct single delivery) unless the Aflatoxin B1 levels in the hold analysis and the 4 analyses of the lighter / pushpit / inland waterway vessel / train / storage are all < 0,001 mg/kg.

VERIFICATION OF DAIRY FEED
There is an extra verification of Aflatoxin B1 in dairy feed in which maize and/or maize (by) products have been processed.

Production dairy feed
At every site where dairy feed is produced with maize and/or maize (by)products (regardless of origin), one sample is analyzed weekly of the dairy feed with the highest mixing percentage of maize and maize (by)products
If no new batches of maize or maize (by) products have been processed in the dairy feed, analysis of dairy feed is not necessary. Here, a batch is defined as being as a consignment originating from one barge or 1 truck load (when importing by truck or taken directly from a farmer/field).

If a production site for dairy feed demonstrably for 6 consecutive months has only weekly Aflatoxin B1 verification results ≤ 0,001 mg/kg (6-month-rule), this site is allowed to reduce the verification frequency from weekly to monthly. If during this monthly Aflatoxin B1 verification, results > 0,001 mg/kg are detected, the following applies:

- *0,001 mg/kg < Aflatoxin B1 analysis result ≤ 0,002 mg/kg*: Notification without delay at SecureFeed and root cause analysis (origin maize, assessment other sources, etc.). The verification frequency remains monthly;
- *Aflatoxin B1 analysis result > 0,002 mg/kg*: see point 1.1 "Action limits – dairy feed". The verification frequency changes to weekly. After another 6 consecutive months of only weekly Aflatoxin B1 verification results ≤ 0,001 mg/kg, the verification frequency can return to monthly.

The starting date of the 6-month rule is June, 1 2018, which means a production site can lower the frequency of monitoring of aflatoxin B1 in dairy feed from weekly to monthly on December, 1 2018, given it can demonstrate only weekly Aflatoxin ***B1*** verification results ≤ 0,001 mg/kg for 6 consecutive months from June 1 onwards.

New participants / participating production sites always start with a minimum of 6 months of weekly verification of Aflatoxin B1 in dairy feed, where the same rules as above apply in case results > 0,001 mg/kg are detected.

Participants share their verification results with SecureFeed (at least once every quarter, preferably once a month) using:
a) the GMP+ Monitoring Database, provided
- Aflatoxin B1 results are registered under product Compound Feed for cattle: dairy feed, Compound Feed for Goats, Compound Feed for Sheep. In case of manufacturing of dairy feed outside these GMP+ product categories, SecureFeed is informed on the chosen product category.
- Registered results of analysis are finalized and shared with group SecureFeed in the GMP+ Monitoring Database
- Weeks / months in which no verification has been done are registered in F-23, including explanation. If applicable, this form F-23 is shared with SecureFeed at least once every quarter via monitoring@securefeed.eu.

OR

b) the Excel form F-23 Verification Aflatoxin dairy feed form the SecureFeed Manual. Mail results to monitoring@securefeed.eu.

In case of a detection of Aflatoxin B1 in dairy feed (> SecureFeed action limit), the participant notifies SecureFeed and other participant immediately using the notification module in the SecureFeed Database.

Participant in the dairy feed verification are listed in D-28

Purchase of dairy feed
The participant is responsible, when purchasing dairy feed with maize and/or maize (by) products from third parties, for this purchased dairy feed, to demonstrably comply with the requirements of this protocol. In practice this means:

- *Purchased dairy feed supplied by dairy feed producing SecureFeed participants*: I-08-03c is applicable to all dairy feed with maize and/or maize (by) products, whether these are supplied directly or indirectly to dairy farmers;
- *Purchased dairy feed supplied by non-SecureFeed participants*:
  - The supplier complies with I-08-03c for all dairy feed with maize and/or maize (by) products it produces and/or supplies;
    OR
  - The supplier supplies batches (= production run) dairy feed with maize and/or maize (by) products, with positive release on Aflatoxin B1 to the SecureFeed participant.

REJECTION AND ACTION LIMITS AFLATOXIN B1 (based on 88% DM)

1. Action limits

1.1. Dairy feed

The action limits for end feed for dairy feed (cows, sheep, goats etc), is 0.002 mg/kg. When drawing up recipes of end feed for dairy feed, the Aflatoxin level in maize and maize (by) products is to be considered. SecureFeed participants are also advised to consider other Aflatoxin critical raw materials in the recipe. These include:

- Palm kernel (by) products;
- Coconut (by) products;
- Rice (by) products;
- Peanut (by) products
- Sunflower seed (by) products.

In addition, the GMP+ requirements apply for these products as described in GMP+ BA4.

The spread on analysis results must be considered as well. It is about 30% of the reported value.

The action limit of 0.0002 mg/kg also applies for all feed materials delivered directly to the farmer with destination dairy feed.

If action limits are exceeded, action must be taken immediately to reduce the level of contamination.

1.2. Other

The action limit for the use of maize and maize (by)products for applications other than direct delivery for dairy feed is 0.0025 mg/kg.

2. Rejection limits

2.1. Dairy feed

The rejection limit for end feed for dairy feed and for feed materials delivered directly to the farmer with destination dairy feed, is 0.0025 mg/kg.

2.2. Other

The rejection limits for all other feed are in accordance with Dir. 2002/32/EG and GMP+FSA. All said action and rejection limits are included in D-01 *Action and Rejection limits*.

REPORTING ANALYSIS RESULTS

End feed and raw materials with an analysis result above the indicated action and rejection limits, must be reported to SecureFeed immediately in accordance with P-11 *Reporting and assessing exceedances, nonconformities and threats* and P-13 *Calamity control*.
All other analysis results Aflatoxin B1 of maize arising from own monitoring or received by participant from third parties in the context of the Aflatoxin protocols of GMP+ FSA (and equivalent certifications schemes) or this protocol are reported by e-mail to the secretariat at least once a month (monitoring@securefeed.eu). Preferably, the participant uses form F-24 *Results monitoring Aflatoxin and mycotoxins* in this.

REVISION OF RISK GROUPS

1. Determination of risk group new harvest

Every year, at the beginning of the new harvest season, SecureFeed determines whether maize / maize (by)products from a certain country of origin has been classified in the correct risk group.
To this end, information is to be gathered at the start of the new harvest.

Work method:

a. As long as there is no new classification of the risk groups, the country classification of the previous harvest year applies;
b. Principle for the classification in risk groups of countries or origin for a new harvest year, is the classification such as GMP+ FSA establishes it in its Aflatoxin protocol Maize for the relevant harvest year;
c. Shippers of maize are asked to share information about countries of origin with SecureFeed;
d. Participants are required to sample the first thee deliveries per country of origin and to have them analyzed for Aflatoxin B1. The participant must make sure that these three deliveries do not originate from the same lighter. For the details about sampling and analysis, see section “SAMPLING AND ANALYSIS MAIZE, 2. Start of new harvest” ;
e. The risk classification of SecureFeed is equal or higher than the classification of GMP+ FSA, never lower;
f. Countries are classified based on the following criteria:

Risk classification	% of analyses per country	Analysis result (x)
High	> 1% > 10%	> 0,020 mg/kg; **OR** 0,010 mg/kg < x ≤ 0,020 mg/kg
Medium	Percentages of analysis results not mentioned under risk classification “High” or “Low” fall under risk classification “Medium”.	
Low	> 95% Rest	< detection limit; **AND** ≤ 0.0049 mg/kg

g. For the re-evaluation of countries, the following amount of analysis are required at least:
Increasing risk classification:
- At least one analysis
Decreasing risk classification:
At least 50 analyses of samples, being,
- 50 lighters (regardless of size)
- 50 trains (regardless of size)
- 500 trucks
- A combination of the analyses above, in which every 10 analyses of trucks are considered equal to one lighter (4 analyses/lighter / train

h. SecureFeed assesses the supplied analysis results and determines the desired SecureFeed risk group of a country of origin;
i. If the assessment of the analysis results give rise to determine a lower risk group classification than the risk group classification of GMP+ FSA, GMP+ International will notified about this. However, as long as GMP+ FSA maintains its original risk group classification, SecureFeed will not deviate from it.
j. Countries that are given a downgrade from MEDIUM to LOW, will be monitored. SecureFeed analyzes 5 samples / month of these countries (= 5 lighters; = 50 trucks, or a combination thereof, in which 10 analyses of a batch supplied per truck is considered equal to an analyzed lighter (4 analyses / lighter)).

2. Revision risk group classification throughout the year

As soon as maize or maize (by)products from a certain country of origin is analyzed with a value of ≥ 0.0025 mg/kg Aflatoxin B1, this is reason to be alert.
SecureFeed evaluates reports of elevated levels and updates the Aflatoxin protocol based on this.

SCHEMATIC SUMMARY
In the table "*Overview application maize and maize by products"* the previously described control measures are summarized. Of course, the prerequisite always is that SecureFeed participants meet the requirements under Law and regulations and GMP+ FSA and that they determine control measures based on their proprietary HACCP plan.

Overview application maize and maize byproducts

Product	Application dairy feed	Application animal groups other than dairy feed
General	Weekly / Monthly verification dairy feed per production site (end feed for dairy cattle) for the presence of Aflatoxin B1 (see section "Verification of dairy feed, production dairy feed" for details. For purchased dairy feed see section "Verification of dairy feed, purchase of dairy feed".	N/a
Maize from *column SF Low Risk*	Application permitted.	Application permitted.
Maize from *column SF Medium Risk*	Application permitted, provided that sampling and analysis are as described in this protocol. Analysis results must be known to / available for the participants prior to processing / delivery to dairy farmer.	Application permitted, provided that sampling and analysis are as described in this protocol.
Maize from *column SF High Risk*	Application forbidden, unless the Aflatoxin B1 level in the hold analysis and the 4 analyses of the lighter / pushpit / inland waterway vessel / train / storage are all < 0.001 mg/kg. Sampling and analysis as described in this protocol.	Application permitted, provided that sampling and analysis are as described in this protocol.
Maize (by)products met Maize from *column SF Low Risk*	Application permitted.	Application permitted.
Maize (by)products met Maize from *column SF Medium Risk*	Application permitted, provided that sampling and analysis are as described in this protocol. For direct delivery to dairy farmers, the SecureFeed participant must – prior to delivery – provide an analysis result of the maize (by)product) confirming that the Aflatoxin B1 level of the batch < 0.0025 mg/kg.	Application permitted, provided that sampling and analysis are as described in this protocol.

Product	Application dairy feed	Application animal groups other than dairy feed
Maize (by)products met Maize from *column SF High Risk*	Application permitted, provided that sampling and analysis are as described in this protocol. For direct delivery to dairy farmers, the SecureFeed participant must – prior to delivery – provide an analysis result of the maize (by)product) confirming that the Aflatoxin B1 level of the batch < 0.0025 mg/kg.	Application permitted, provided that sampling and analysis are as described in this protocol.

Where reference is made to "GMP+ protocol", reference is made to the current version of the GMP+ FSA BA4, par. 2.3
-Please note: In permitted application, the product must also always meet the action and rejection limits of SecureFeed (D-01)

SECUREFEED PARTICIPANT
The participant assures that the purchased maize or maize byproducts meet set requirements.

DURATION, MANAGEMENT AND EVALUATION OF THE PROTOCOL
This protocol and changes to this protocol will take effect immediately. SecureFeed evaluates this protocol at least once a year, prior to the new European maize harvest season.