

PURPOSE

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

PROCESS OWNER

Programme Manager Conformity Assessment (PM-C)

REFERENCES

[P-11 Reporting and assessment of exceedances, nonconformities and threats](#)

[P-13 Calamity control](#)

[D-01 Action and rejection limits](#)

[D-25 Risk classification of countries Aflatoxin B1 in maize and maize \(by-\)product](#)

[D-28 Participants verification of Aflatoxin B1 in dairy feed](#)

[F-23 Verification of Aflatoxin in dairy feed](#)

F24 Results of [aflatoxin](#) and [mycotoxin](#) monitoring

WORKING 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 yearly basis. The contamination strongly depends on the weather conditions during critical phases of the development of the maize (bloom, cob formation, ripening, harvest).

Because each year, maize of various harvest years can be on the market, it is important – in this procedure – to consider these various harvest years and their different contamination levels

The prescribed measures apply to maize and maize (by-)products, dry and wet, both organic and conventional, and are an addition to: GMP+(2010) protocol BA4, par 2.3 '*Protocol Monitoring Aflatoxin B1*' or GMP+(2020) TS 1.7 '*Monitoring chapter 2 and 3*, and GMP+(2010) BA10, appendix 5 '*Gatekeeper protocol for the purchase of grains, seeds and legumes*' or GMP+(2020) TS 1.2 '*Purchasing*' chapter 4. The aforementioned GMP+ FSA requirements are used as the basis and should be observed at all times.

SECUREFEED RISK GROUPS

Maize and maize (by-)products are classified into three risk groups according to their origin. This classification applies to maize grown in the country concerned. For 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 of origin.

- **Low-risk origin countries:** No additional requirements apply to maize and maize (by-)products from these countries.
- **High-risk origin countries:** It is not permitted to use maize from these countries in dairy cattle feed, unless the aflatoxin B1 level in the hold analysis and the 4 analyses of the inland waterways vessel/barge/train/storage, are all < 0,001 mg/kg.
- **Medium risk countries of origin:** Maize and maize (by-)products from these countries may be used in dairy cattle feed, provided that they have been sampled and analysed as prescribed in this protocol.

The table in [D-25 "*Risk classification countries maize and maize by-products*"](#) shows the current risk classification for maize and maize (by-)products of the different countries for the current harvest year (and previous harvest years if applicable).

SAMPLING AND ANALYSIS OF MAIZE

1. General

The following applies to the sampling and analysis of maize from HIGH and MEDIUM Risk countries of origin:

- a. *Analysis by seagoing ship hold*: These are sampled and analysed in accordance with:
 - I. the current legal requirements set out in Annex I to Regulation (EC) no. 152/2009 “*For the determination of the sampling and analysis methods for the official inspection of feed*”.
 - or
 - II. The current regulations of GAFTA sampling Rules No. 124.
- b. *To be analysed on consignments which are transferred from the hold of a seagoing vessel into storage or onto a train (max. 2000 tonnes) or in a barge / inland waterways vessel / lighter*.
 - I. the legal requirements as referred to in Annex I under 5.B of the original Regulation (EC) no. 152/2009 “*For the determination of the sampling and analysis methods for the official inspection of feed*”.
 - or
 - II. **The current regulations of GAFTA sampling Rules No. 124**
- c. In the case of delivery by lorry of consignments which have not yet been sampled and analysed in accordance with subsection b), the following shall apply:
 - I. From countries with risk class MIDDLE, sampling should take place in accordance with GMP+(2010) BA13 **or GMP+(2020) TS 1.6 Sampling guidelines**.
 - II. From countries with risk class HIGH, an independent and accredited sampler according to Annex I of Regulation (EC) no. 152/2009 “*For the determination of the sampling and analysis methods for the official inspection of feed*”.

In both cases, at least 3 kg of the bulk sample should be sent to the laboratory for analysis for aflatoxin B1. **The participant should have the results of this analysis available before receiving a batch, if the batch is delivered directly to dairy cattle or is intended for processing into dairy cattle feed.**

Remarks:

- **If a batch of maize comes from several origins, the highest country classification shall apply.**
- The final samples obtained are analysed by a laboratory accredited according to I-08-01 for the determination of aflatoxin B1 in the matrix Maize/Grains/Feed Materials.
- The certificate of analysis shall mention at least the country of cultivation of the maize, the lot identification (such as batch number, lighter, sea-going vessel name and hold), the size of the lot from which the sample was taken and the date of sampling.
- It is allowed to sample and analyse in the country of origin, so that the results are known to the customer before the batch is processed.
- In case of situation c: If the maize is collected and stored in the country of cultivation, 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 point b) by an independent and accredited sample taker.

Maize from LOW Risk countries of origin should be sampled and analysed according to the participant's company specific HACCP plan.

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 an impression of the Aflatoxin B1 contamination level, to assure that the countries have been classified in the proper risk group.

To obtain sufficient reliable analysis results over a short period of time, participants should have a good average sample from each of the first three deliveries of maize they receive from these countries of origin analysed 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 analysed, originate from one and the same batch of origin (lighter);
- This three deliveries rule applies for all countries of origin. If one were to receive, German and Belgian maize, for instance, the first three loads of German maize and the first three loads of Belgian maize would have to be analysed;
- To obtain a reliable analysis result, representative and sufficiently big samples are required. This means the following:
 - Deliveries per train/lighter/barge/inland waterways vessel are sampled and analysed 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 final sample of at least 3 kg is sent to the lab for analysis on aflatoxin B1.

- For deliveries by truck, sampled in accordance with the conditions in GMP (2010) BA13 "Minimum conditions for sampling" or GMP+(2020) TS 1.6 Sampling, one overall sample is made, from which a final sample of at least 3 kg is sent to the lab for analysis for Aflatoxin B1.

The final samples obtained are analysed by a laboratory accredited for the determination of Aflatoxin B1 in the matrix Maize/Granes/Feed Materials according to [I-08-01 Selection laboratories](#).

SAMPLING AND ANALYSIS OF MAIZE PRODUCTS AND (BY-)PRODUCTS

The requirements for sampling and analysis of maize are, due to the process and processing of maize in the food and biofuel industry, not appropriate for maize (by-)products released in these industries and used as animal feed.

The level of Aflatoxin B1 in the maize (by-)products released in the industries mentioned above depends on the maize purchased and injected in the process as well as on the concentration factor during the production process. The maize (by-)products have a high homogeneity regarding the Aflatoxin B1 content.

The maize (by-)products should be sampled and analysed in accordance with the requirements in GMP+ (2010) BA4 or GMP+ (2020) TS 1.7. **The country classification according to D-25 of the SecureFeed manual applies here.**

SecureFeed participants who wish to use maize (by-)products produced from maize grown in MIDDLE risk countries for direct supply to dairy farmers must comply with one of the following conditions:

- The maize (by-)products to be delivered must demonstrably comply with the norm $< 0,0025$ mg/kg Aflatoxin B1 by means of analyses prior to delivery.
- **The supplier or producer of the maize (by-)products works on the basis of a protocol demonstrably approved by SecureFeed. This protocol must describe at least the concentration factor in the production process and a risk-based monitoring.**

SecureFeed participants who want to use maize (by-)products produced from maize grown in HIGH-risk countries for direct supply to dairy farmers must demonstrably comply with the standard $< 0,0025$ mg/kg Aflatoxin B1 through analyses prior to delivery.

BAN ON PROCESSING MAIZE IN DAIRY FEED

Maize from High Risk countries of origin may not be used 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/barge/train/storage, are all $< 0,001$ mg/kg.

VERIFICATION ON DAIRY FEED

Additional verification of aflatoxin B1 in dairy feed containing maize and/or maize (by-)products shall take place.

Dairy feed production

At each location where dairy feed containing maize and/or maize (by-)products is produced (irrespective of origin), one sample is analysed every week from the dairy feed with the highest percentage of maize and maize (by-)products in it.

If no new batches of maize or maize (by-)products have been incorporated into dairy cattle feed in a week, then the examination of dairy feed is not necessary. A batch is defined as a batch from 1 truck (from a field or import via a truck). If a production site for dairy feed can demonstrate for 6 consecutive months that it only has weekly Aflatoxin B1 verification results $\leq 0,001$ mg/kg (6-month rule), this site may reduce the frequency of verification 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 $\leq 0,002$ mg/kg: report to SecureFeed immediately and analyse cause (origin of maize, assessment of other sources, etc.). The verification frequency will remain monthly;
- Aflatoxin B1 analysis result $> 0,002$ mg/kg: see point 1.1 "Action limits - dairy feed". The verification frequency goes to weekly. After a further 6 months of exclusively weekly Aflatoxin B1 verification results $\leq 0,001$ mg/kg, the verification frequency can return to monthly.

The starting date for the 6-month rule is June 1 2018, which means that a production location may reduce the frequency of monitoring for aflatoxin B1 in dairy cattle feed from weekly to monthly as of December 1 2018, if it has demonstrably had weekly Aflatoxin B1 verification results only $\leq 0,001$ mg/kg for 6 consecutive months.

New participants / participating production locations always start with a minimum of 6 months of weekly verification of Aflatoxin B1 in dairy cattle feed, with the same system for results > 0.001 mg/kg as described above.

The participant can/must share the results of the dairy feed verification with SecureFeed (at least quarterly, preferably monthly):

a) via the GMP+ monitoring database on the condition that:

- The Aflatoxin B1 result is registered under the product Mixing feed for cattle: dairy feed; Mixing feed for goats, Mixing feed for sheep. Should you produce dairy feed which falls outside of these GMP product categories, please inform SecureFeed of the product name under which you will upload these results
- The registered results are finalised and shared with the SecureFeed group in the GMP+ monitoring database
- The weeks/months when no sampling was performed, including the reason, are documented in F-23, and shared at least quarterly via monitoring@securefeed.eu if applicable to your company.

OR

b) via Excel form [F-23 Verification Aflatoxin B1 in Dairy Feeds](#) from the SecureFeed handbook. Email results to monitoring@securefeed.eu.

In case of detected increases in aflatoxin B1 in dairy feed (> SecureFeed action limit), the participant will inform SecureFeed and other participants immediately using the notification module in the SecureFeed database.

The participants in the dairy feed verification are listed in [D-28 Participants in dairy feed verification](#).

PURCHASE OF DAIRY FEEDS

The participant is responsible for ensuring, when purchasing dairy feeds containing maize and/or maize (by-)products from third parties, that these dairy purchased feeds demonstrably meet the requirements of this protocol. In practice this means:

Purchased dairy feeds delivered by SecureFeed participant: I-08-03c is fully applicable to all dairy feeds containing maize and/or maize (by-)products, whether these are supplied directly or indirectly to dairy farmers;

Purchased dairy feed delivered by non-SecureFeed participant:

- The supplier follows I-08-03c completely for all the dairy feed containing maize and/or maize (by-)products that he produces and/or supplies;
- OR
- The supplier supplies batches (= production run) of dairy feed containing maize and/or maize (by-)products, based on positive release on Aflatoxin B1, to the SecureFeed participant.

REJECTION AND ACTION LIMITS AFLATOXIN B1 (BASIS 88% DS)

1. Action limits

1.1 Dairy feed

The action limits for end feed or dairy feed (cows, sheep, goats etc.) is 0.002 mg/kg. When drawing up the recipes of final feed for dairy feed, the Aflatoxin B1 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 (co-)products;
- Rice (by-)products;
- Peanut (by-)products;
- Sunflower seed (co-)products.

The GMP+ requirements as described in GMP+ (2010) BA4 or GMP+(2020) TS 1.7 also apply to these products. The spread of analysis results should also be taken into account. This amounts to approximately 30% of the reported value. The action limit of 0.002 mg/kg also applies to all feed materials which are delivered directly to the farmer with the purpose of dairy feed.

If action limits are exceeded, immediate action must be taken 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 dairy feed and 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 feeds are in accordance with Ri. 2002/32/EG and GMP+FSA. All action and rejection limits mentioned are included in [D-01 Action and rejection boundaries](#).

REPORTING OF ANALYSIS RESULTS

Feed and raw materials with an analysis result above the indicated action and rejection limits must be reported immediately to SecureFeed in accordance with [P-11 Reporting and assessment of exceedances, nonconformities and threats](#). (See also document: [P-13 Calamity control](#).)

All other aflatoxin B1 analysis results from maize resulting from the participant's own monitoring, received from third parties within the framework of the GMP+ FSA (and equivalent certification schemes) aflatoxin protocols or this protocol, should be reported at least monthly by e-mail to the secretariat (monitoring@securefeed.eu). Preferably the participant should make use of form F-24 Results of [aflatoxin](#) and [mycotoxin](#) monitoring.

REVISION OF RISK GROUPS

1. Definition 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 are classified in the correct risk group.

For this, information needs to be collected at the start of the new harvest.

Working method:

- As long as there is no new classification of risk groups, the country classification of the previous harvest year applies;
- The starting point for the classification into risk groups of countries of origin for a new harvest year is the classification as established by GMP+ FSA in its Aflatoxin Protocol for Maize for the harvest year in question;
- Shippers of maize are asked to share information about countries of origin with SecureFeed;
- Participants are obliged to sample the first three deliveries per country of origin and have them analysed for aflatoxin B1. The participant has to make sure that these three deliveries do not originate from the same barge. For details on sampling and analysis, see section "SAMPLING AND ANALYSIS MAÏS, 2";
- SecureFeed's own risk classification is equal to or higher than the GMP+ FSA classification, never lower;
- Countries are classified according to the following criteria:

Risk classification	% of analyses by country	Analytical result (x)
High	> 1% > 10%	> 0,020 mg/kg; OR 0,010 mg/kg < x ≤ 0,020 mg/kg
Middle	Percentages of analysis results not specified under risk classification "High" or "Low" are classified under risk classification "Medium"	
Low	> 95% Remaining	< 0,001 mg/kg; AND ≤ 0.005 mg/kg

- For revaluation of countries, at least the following amount of analyses are necessary:
 - Increase risk classification:*
 - At least one analysis
 - Reducing 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 above analyses, where every 10 analyses of trucks are equivalent to one lighter (4 analyses/lighter) / train
- SecureFeed assesses the provided analysis results and determines the desired SecureFeed risk group of a

country of origin;

- i. If the assessment of the analysis results gives cause to determine a lower risk group classification than the GMP+ FSA risk group classification, then GMP+ International will be informed of this. When GMP+ FSA Maintains its original risk group classification, SecureFeed will not deviate from this.
- j. Countries that are "downgraded" from MIDDLE to LOW are followed. SecureFeed analyses 5 samples/month from these countries (= 5 lighters; = 50 trucks, or a combination thereof, where 10 analyses of a trucked batch are equated to an analysed lighter (4 analyses/lighter)).

2. Revision of risk group classification during the year

As soon as maize or maize (by-)products from a certain country of origin are analysed to find a value $\geq 0,0025$ mg/kg aflatoxin B1, this is a reason for alertness.

SecureFeed evaluates reports of elevated levels and updates this Aflatoxin protocol based on these reports.

SCHEMATIC SUMMARY

The diagram "Overview of the application of maize and maize (by-)products" summarises the control measures described above. The basic condition is of course that SecureFeed participants always comply with the conditions in legislation and regulations and GMP+ FSA, and that they establish control measures based on their own company HACCP plan.

Overview of the use of maize and maize by-products

Product	Dairy feed application	Application to animal groups other than dairy cattle
General	Weekly / monthly verification of dairy cattle feed per production location (final feed for dairy cattle) for presence of aflatoxin B1 (see section "Verification on dairy cattle feed, production of dairy cattle feed" for details). For purchased dairy cattle feed, see section "Verification on dairy cattle feed, purchase of dairy cattle feed".	N/A
Maize from <i>column SF Low risk</i>	Application permitted.	Application permitted.
Maize from <i>column SF Medium risk</i>	Application allowed, provided that sampling and analysis are carried out as described in this protocol. Analysis results must be known to/available to participants prior to processing into dairy feed / delivery to dairy farmer.	Application permitted subject to sampling and analysis as described in this protocol. When delivered by barge, analysis results must be known prior to processing/delivery. The results of the analyses of maize by truck do not have to be known prior to processing/delivery.
Maize from <i>column SF High risk</i>	Application prohibited, unless the aflatoxin B1 levels in the hold analysis and the 4 analyses of the lighter/barge/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 containing maize from <i>column SF Low risk</i>	Application permitted.	Application permitted.
Maize (by-)products containing maize from <i>column SF Medium risk</i>	Application permitted subject to sampling and analysis as described in this protocol. For direct delivery to dairy farmers, the SecureFeed participant must ensure, prior to delivery, an analysis result of the maize (co-	Application permitted, provided that sampling and analysis of the Maize (by-)products are as described in this protocol.

	<p>)product that demonstrates that the Aflatoxin B1 content of the batch is < 0,0025 mg/kg.</p> <p>Or:</p> <p>The supplier or producer of the maize (by-)products works on the basis of a protocol demonstrably approved by SecureFeed.</p>	
<p>Maize (by-)products containing maize from <i>column SF High risk</i></p>	<p>Application permitted, subject to sampling and analysis as described in this protocol. For direct delivery to dairy farmers, the SecureFeed participant must ensure, prior to delivery, an analysis result of the maize (co-)product that demonstrates that the Aflatoxin B1 content of the batch is < 0,0025 mg/kg</p>	<p>Application permitted, provided that sampling and analysis of the Maize (by-)products are as described in this protocol.</p>

Wherever reference is made to "GMP+ protocol", reference is made to the current version of the GMP+ (2010) FSA BA4, par. 2.3. or GMP+(2020) TS 1.7 Monitoring chapter 2 and 3.

NB: In the case of permitted application, the product must also always comply with the see document: [action and rejection limits of SecureFeed \(D-01\)](#)

SECUREFEED PARTICIPANT

The participant guarantees that the purchased maize or maize (by-)products meet the set requirements.

DURATION, MANAGEMENT AND EVALUATION OF THE PROTOCOL

This protocol and amendments to this protocol shall apply with immediate effect. SecureFeed evaluates this protocol at least once a year, prior to the new European maize harvest season.