SecureFeed
CARING FOR FOOD SAFETY

I-08-03c
Aflatoxin protocol
for maize and maize by-products

Version 12.2
Date: March 28th 2024

Reading guide:

A schematic decision tree is included in the next chapter for participants who want a quick insight into the requirements they have to meet when purchasing maize and by-products.
The decision tree is a schematic overview and leads the reader directly to the applicable part of chapter 15 containing schematically the most important requirements with regard to frequency of analysis, sampling, method of analysis, monitoring, purchase and processing.
The table below it, also contains a hyperlink in the last column to the relevant diagram section.
The decision tree and its diagrams in Chapter 15 can be read separately from the other parts of this protocol.
For the reader who wants to know more, the remaining chapters (6 to 14) offer definitions, background, details, explanations and references.
Below is an overview of the changes made per version. Changes from the previous version are also highlighted in yellow in the text.

Changes from the previous version

Version 9.0 of the Aflatoxin B1 protocol has been considerably modified in comparison with the previous version (version 8.0 of 26 May 2021). The following changes have been made:

1. Layout adjusted to improve readability;
2. Structure modified so that it better matches the structure used by GMP+;
3. Added: Chapter 5: Schematic explanation/decision tree to quickly understand key requirements
4. Definitions added;
5. Batch sizes adjusted to latest insights;
6. Annex 1 added: Assessment framework for the processing protocols used by producers in relation to concentration factors and blending in the production process whereby maize is processed into by-products;
7. The section Revision of Risk Groups from the previous version has been rewritten and included in a separate document (I-08-03c-1 Instruction for revision of country classification D-25).

Version 10 has been modified in comparison with version 9.0. The following changes have been made:

1. In Chapter 12: Reference to F-24a added. This reference was omitted by mistake in version 9.0.
2. In Chapter 14: A reference has been added to form F-34 ‘Cause analysis elevated Aflatoxin B1 levels in dairy cattle feed’

Version 11 has been changed in comparison to version 10:

1. In chapter 7 a sentence has been added to clarify that the first three batches of 'New Harvest' should not only be analysed, but that these results should also be submitted to SecureFeed.
2. Section 8.1 has been added in Chapter 8 making it clear that all analysis done under this protocol must be shared with SecureFeed.
3. In chapter 13, a sentence has been added which refers to this Annex 2.
4. Annex 2 has been added: Handling of maize by-products intended for direct feeding in the event of a minor breach of the SecureFeed norm for Aflatoxine.

Version 12 has been modified from version 11. The following changes have been made:

1. The reading guide and changes overview have been moved forward as "Chapter 0.
2. References to GMP+ scheme 2010 have been replaced with references to the 2020 scheme.
3. In the definitions, the exceptions for some by-products (oils) have been removed so that the protocol now also applies to these by-products. This has been done because GMP+ does not make these exceptions either.
4. The decision tree in Chapter 5 has been simplified; Chapter 15 has been shortened, partly by no longer including the GMP+ (reject) limits in the schemes of Chapter 15.
5. The term 'country of origin' has been changed to 'country of cultivation'. This does more justice to the meaning of the term. Unlike other raw materials, this protocol always refers to the country or region where the maize is grown and not where the feed material is produced.
6. Section 7.2 has been amended so that the mandatory "New Harvest Monitoring" applies only to maize and not to maize by-products.
7. In 8.3, the prescribed frequency of analysis of low-risk products is no longer referred to the SMD, but to its own hazard analysis. Also in table of chapter 9 this has been changed with respect to lot size
8. Sections 8.5 and 8.6 are new. In 8.5 the information obligations between suppliers and buyers are now explicitly written down. In 8.6 an exception is made regarding the information requirements for deliveries between SecureFeed participants.
9. From 12.1.1, the passage regarding the Conditions of Vo 1881/2006 has been moved to its 'own' section 12.5. The name of the regulation has also been updated to Regulation (EU) 2023/915.
10. In the schedules in chapter 15, with regard to rail transport, 'train load' has also been added. This is in line with the provisions of 12.1.2 that also apply to train transport. Train loading was not included in the previous version.

Version 12.2:

1. Added Graindistillers (DDGS) as a product within scope of this protocol.
2. Batchsize of trucks / High risk countries synchronized with GMP+ (2020 TS 1.7) (from 1,500 Mt to 1,000Mt)
3. Batchsize of trains / Medium risk countries synchronized with GMP+ (2020 TS 1.7) (from 1,500 Mt to train size).

1. PURPOSE

This protocol describes special requirements for SecureFeed Participants, for the control of Aflatoxin B1 risks in maize and maize by-products. The requirements are necessary for the control of these aflatoxin risks.

2. PROCESS OWNER

Programme Manager Conformity Assessment (PM-C)

3. REFERENCES

- P-11 Reporting and assessment of exceedances, deviations and threats
- P-13 Calamity control
- I-08-01 Selection Laboratories
- I-08-03c-1 Instruction on revision of country classification D-25
- D-01 Action and rejection limits
- D-25 Country risk classification Aflatoxin B1 in maize and maize (by-)products
- D-28 Participants verification Aflatoxin B1 in dairy cattle feed
- F-23 Verification of Aflatoxin in dairy cattle feed
- F-24 Results Monitoring Aflatoxine en Mycotoxines
- F-34 Cause analysis elevated Aflatoxin B1 levels in dairy cattle feed
- GMP+ (2010) BA4 / GMP+ (2020) TS 1.7 Monitoring
- GMP+ (2010) BA13 / GMP+ (2020) TS 1.6 Sampling guidelines
- Regulation. (EC) No 183/2005, Annex II
- Regulation (EU) No 1881/2006
- Regulation (EU) No 2023/915
- Regulation (EC) No 152/2009, including the amendments from Regulation (EU) No 691/2013
- GAFTA Sampling Rules No.124

4. SCOPE

This protocol describes requirements regarding frequency of analysis, sampling, method of analysis, monitoring, purchase and processing of maize and maize by-products[1] intended for direct delivery to livestock farmers or for the production of compound feed.

Depending on the animals for which the maize or the by-product is intended, the requirements differ.

More and more stringent requirements are imposed on feedstuffs for dairy cattle than on feedstuffs for other animals. This is expressed in this protocol. See also the decision tree in Chapter 5.

4.1. Dairy cattle

This protocol applies to maize and by-products intended for dairy cattle (feed). The measures prescribed in this protocol supplement GMP+ (2020) TS 1.7 Monitoring Chapter 2[2] "Aflatoxin protocol[3]" as regards application in dairy cattle feed.

4.2. Non-dairy cattle

For the purchase and processing of maize and by-products intended for animals other than dairy cattle, the requirements apply as included in GMP+ (2020) TS 1.7 Monitoring Chapter 2[2], with the proviso that the SecureFeed country classification applies as indicated in handbook document D-25 and that participants must report exceedance of action and rejection limits based on the SecureFeed standards as included in handbook document D-01.

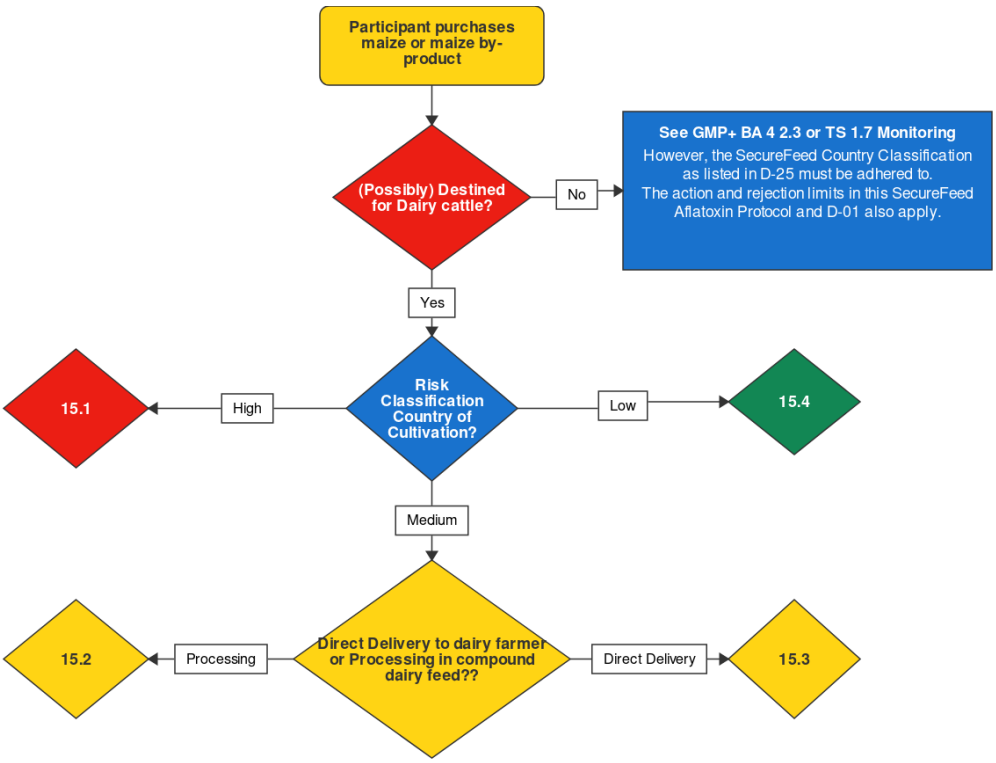
[1] For the sake of readability, in the rest of the document the term "maize by-products" is shortened to "by-products".

[2] or GMP+ (2010) BA4, 2

[3] Or the GMP+ protocols recognised as equivalent to GMP+ (2020) TS 1.7

5. DECISION TREE

The decision tree below provides a quick insight into which measures are applicable in the context of this protocol.



The table below shows schematically whether a positive release applies to a certain stream; what the relevant limits are and, via a hyperlink, which section of Chapter 15 applies.

Overview table:

Product	Processing or Direct Delivery?	Risk classification Country of Cultivation	Positive Release?	Rejection Limit	Action Limits	LINK
Maize	Processing	High	Yes	1 ppb	-	*15.1*
Byproduct	Processing	High	Yes	1 ppb	-	
Maize	Delivery	High	Yes	1 ppb	-	
Byproduct	Delivery	High	Yes	1 ppb	-	
Maize	Processing	Medium	Yes	20 ppb**	2.5 ppb	*15.2*
Byproduct	Processing	Medium	Yes Or Protocol*	20 ppb**	2.5 ppb	
Maize	Delivery	Medium	Yes	2.5 ppb	2 ppb	*15.3*
Byproduct	Delivery	Medium	Yes Or Protocol*	2.5 ppb	2 ppb	
Maize & Byproduct	Delivery	Low	No	2.5 ppb	2 ppb	*15.4*
Maize & Byproduct	Processing	Low	No	20 ppb	2.5 ppb	

*Protocol as mentioned in Annex 1

**20 ppb is the legal rejection limit for processing in compound feed. SecureFeed also permits the use of compound feed at these high levels, but explicitly draws the participants' attention to their own responsibility for guaranteeing the much lower levels (2 ppb) in compound feed delivered to the farmer!

6. DEFINITIONS:

For the purposes of this Protocol, the following terms and definitions shall apply.

maize
unprocessed maize and processed maize, whether dry or wet, organic or conventional, including in any case the following products:

1. Maize (incl. crushed)
2. Maize, broken
3. Maize, heat treated
4. Maize, acidified
5. Maize (moist)
6. Maize: Corn Cob Mix (CCM)
7. Maize flour

Note on definition: these products are **not within the scope of** this Protocol:

8. Maizecobs silage
9. Maize silage

maize by-product[4]
product containing maize, including at least the following products:

10. Maize moist distillers grain
11. Maizedistillers (DDGS)
12. Graindistillers (DDGS)[5]
13. Maize gluten 60%
14. Maize gluten feed
15. Maize germs
16. Maize germ expeller
17. Maize-germ meal
18. Maize fibre
19. Maize flakes
20. Maize feed meal
21. Maize steep liquor
22. Maize starch
23. Maize screenings

batch
identifiable quantity of a product, establishing common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling; and in the case of a production process, a unit of production of a company using uniform parameters in its production or a number of such units, produced in immediate succession and stored together. (Reg. (EC) No 183/2005, Annex II).

dairy farm
The keeping of mammals for the purpose of obtaining milk from their mothers for human consumption. Apart from cows, (water) buffaloes, sheep, goats, horses and camels are also kept for milk.

[4] For the sake of readability, the term 'by-product' used in this protocol means 'by-product of maize'.

[5] If (among other things) maize is used as a feedstock for the DDGS, the product must comply with the aflatoxin protocol

7. COUNTRIES OF CULTIVATION

The countries of cultivation[6] of maize are divided into 3 risk categories: **High**, **Medium** and **Low**.

7.1. Current country classification

In D-25 "Risk classification countries maize and maize by-products", the current risk classification for maize and maize by-products of the different countries is shown for the current harvest year (and previous harvest years if applicable).

By-products refer to the country where the maize, from which the by-product was produced, was grown. This country of cultivation is the country of origin.

If a batch of maize comes from several origins, the highest country classification shall apply.
If there are doubts about the cultivation country (cultivation country is unknown or not certain), the highest category applies.

7.2. Revision of country classification

SecureFeed determines, at least annually, at the beginning of the new harvest season whether maize and/or by-products from a certain country of origin are classified in the correct risk country group. Based on signals, interim adjustments to the risk country classification may be necessary.

Therefore, each new harvest season, participants should have a good sample of each of the first three batches of maize or by-products[7] analysed for aflatoxin B1 and should submit these to SecureFeed. The procedure for this is described in detail in the manual document "I-08-03c-1: Instruction for the revision of the risk classification countries Aflatoxin B1 in maize and by-products".

8. FREQUENCY OF ANALYSIS

8.1. Mandatory sharing of analyses with SecureFeed

All analysis results under the Aflatoxin protocol should be shared with SecureFeed.

8.2. High- and medium-risk countries

Each[8] batch of maize or batch of maize by-products from **high-** and **medium-risk countries shall be** analysed.

8.3. Low-risk countries

For batches originating from **low-risk countries**, the participant should apply the analysis frequency as described in the collective SecureFeed Monitoring Plan Animal Feeds (SMD).
A different analysis frequency also applies at the start of a new harvest year (see 7.2 of this protocol).
In addition, extra monitoring requirements apply to by-products originating from **low-risk countries** and delivered directly to the dairy farmer. For these by-products, the participant delivering the by-product must analyse a batch every month, or have it analysed, in accordance with this protocol.

8.4. Further provisions

If a batch of maize or a by-product has already been analysed by a GMP+ certified supplier[9], then this batch does not have to be analysed again if the following conditions are demonstrably met:

- The analysis results are available.
- There must be a clear link between the batch delivered and the certificate of analysis;
- The batch size is the same as the one described in chapter 0 described in chapter 1;
- Sampling and analysis was carried out as described in this protocol.
- The analysis was carried out within a maximum of 3 months prior to the date of unloading/delivery to the participant. If this is not the case, a new analysis[10] must be carried out.
- In case of re-analysis, the highest value of all measured aflatoxin B1 results applies. All analytical results of the batch (including the expired results) have to accompany the batch.

[6] If applicable, a country may be divided into several regions.

[7] This obligation **does not apply** to batches of CCM from low-risk countries.

[8] Unless otherwise specified in this document for certain products.

[9] This also applies when the supplier participates in another accepted feed safety assurance scheme

[10] A new analysis means that a new sample must always be taken. A second analysis on a previously taken sample does not count as a new analysis.

8.5. Obligations regarding the provision of information to buyers

- Information about harvest year and country of cultivation of the batch of maize or batch of by-products should always be known to each link in the supply chain.
- In case of Positive Release, the batch of maize or batch of by-products should always be accompanied by the analysis results for the batch.
    - These data must show that the sampling was carried out no longer than 3 months prior to the delivery date.
    - For stored lots and re-analysis after 3 months, the highest measured Aflatoxin B1 value (of all sampling times) is leading, since it is not likely that the Aflatoxin B1 level could decrease over time.
    - All analytical results applicable to the lot (including expired results) should accompany the lot.
    - In the case of maize by-products, the food company, as referred to in Section 12.5, must certify in writing that it has applied the protocol to the incoming stream of maize.
- In order to properly apply the obligations of this protocol, this information should be known to the purchasing SecureFeed participant prior to processing or delivery. If necessary, this information should be actively requested from the supplier.

8.6. Further provisions regarding cross-deliveries of maize by-products between SecureFeed participants

If a batch of by-product is delivered by a SecureFeed participant to a Securefeed participant, the receiving SecureFeed participant will not be bound by the provisions of section 8.5, if and to the extent that the following conditions are demonstrably met:

- The analysis results of the batch in question are reported to SecureFeed by the supplying SecureFeed participant;
- Analysis certificate(s) is/are available to the receiving SecureFeed participant upon request;
- The delivering and receiving SecureFeed participant have demonstrably agreed with each other that the delivering SecureFeed participant guarantees that the lots to be delivered meet the standards for dairy cattle feed.

9. SIZE OF BATCHES

The size of a batch to be sampled and the corresponding minimum number of samples to be analysed are related to the means of transport and the origin.

In deviation from the provisions in GMP+ (2020) TS 1.7 Monitoring Chapter 2[11] and in deviation from the provisions in Regulation (EC) No. 152/2009, including the amendments in Regulation (EU) No. 691/2013, and in deviation from GAFTA sampling rules No. 124, the maximum batch size in accordance with Table 1 shall apply for the application of this protocol.

Table 1: Maximum batch size

Means of transport	**High-risk countries**	**Medium risk countries**	**Low-risk countries**
Seagoing vessel or Coaster	Max. 2,000 mt	Max. 5,000 mt	Collective SecureFeed SMD terms
Inland waterway vessel Lighter/barges	Inland waterway vessel Lighter/barges	Inland waterway vessel Lighter/barges	
Train	Max. 1,500 mt	Train	
Truck, ex Storage/warehousing, production site or collection point	Max. 1,000 mt	Max. 2,000 mt	

10. PLACE OF SAMPLING

Batches should be sampled during loading (country of cultivation) *or* unloading (country of destination). If the protocol is applied during *unloading*, the batch (size) is determined by *the means of transport in which* the maize or maize by-product *is* subsequently *loaded*.

11. SAMPLING AND ANALYSIS OF MAIZE AND BY-PRODUCTS FROM LOW-RISK COUNTRIES

Maize and by-products from low-risk countries of origin should be sampled and analysed in the way prescribed in the general GMP+ FSA requirements (GMP+ (2020) TS 1.6 Sampling guidelines)[12].

There is one exception to this: For by-products delivered directly to the dairy farmer from **low-risk countries**, the participant delivering the by-product must analyse a batch each month, or have it analysed, in accordance with this protocol.

[11] or GMP+ BA4, 2.3
[12] or (GMP+ (2010) BA13)

12. SAMPLING AND ANALYSIS OF MAIZE AND BY-PRODUCTS FROM HIGH AND MEDIUM RISK COUNTRIES

12.1. Sampling method

12.1.1 General

The sampler should take representative samples in accordance with the method described in

- Regulation (EC) No 152/2009, including amendments from Regulation (EU) No 691/2013);
  or
- GAFTA Sampling Rules No. 124;

..under the following conditions:

- The sampling methods permitted by SecureFeed are also observed.
- Sampling should be carried out on the entire batch. Sampling of only part of the batch is not acceptable within the framework of this protocol. In case the whole batch is not accessible for sampling in the (flat) warehouse, a sampling plan shall be drawn up and documented covering the accessible part of the batch. The part of the batch not yet sampled and analysed should be sampled as soon as possible and as soon as access is safe.
- When maize is stored in a silo for more than three months and is not accessible for sampling prior to delivery to the customer, sampling may be carried out during the loading process. The results should be available prior to unloading at the customer's premises or at least prior to the next processing step or feeding (if there is a written agreement between the seller and the customer).
- A Participant may agree with its supplier to use Aflatoxin B1 test results provided by the supplier.
- The analysis may be carried out in the country of origin, so that the result is known to the customer before the batch is processed.

12.1.2 Supply of maize by water and train

In the case of transport of maize[13] by water and/or by rail, the following conditions shall apply:

- At least 4 aggregate samples per batch shall be taken and submitted to the laboratory for analysis,
- For each quarter of the sampled batch an aggregate sample is taken.
- Each of these aggregate samples shall be made:
  - at least 10 incremental samples of 1 kg resulting in an aggregate sample of at least 10 kg[14] or at least 4 Kg

  Or
  - at least 20 incremental samples resulting in aggregate samples of at least 4 Kg.

12.2. Sampler

Each batch shall be sampled by an independent monitoring organisation accredited in accordance with ISO 17020 for an applicable scope, or in accordance with ISO 9001 for an applicable scope in combination with a GAFTA[15] approval as inspector for sampling in a relevant field of application (such as animal feed).

12.2.1 Sampler in case of supply by truck

In the case of direct delivery by truck of batches that have not yet been sampled and analysed in accordance with this protocol, the following shall apply:

- From countries with risk class **High**, sampling should be carried out and supervised by a sampler complying with the provisions in 12.2.
- Sampling from countries with risk class **Medium** should take place in accordance with GMP+(2020) TS 1.6 Sampling guidelines[16].

[13] These (additional) conditions do not apply to by-products; 4 analyses per batch has no added value for by-products, as these products are much more homogeneous.
[14] In case of the slurry method
[15] Website GAFTA: http://www.gafta.com/members/superintendents
[16] or GMP+(2010) BA13

12.3. Laboratory and analysis

Samples should be analysed for Aflatoxin B1 values. This analysis should be performed by a laboratory that meets the requirements as outlined in Handbook Document I-08-01 "Selection of laboratories". Semi-quantitative methods, such as thin-layer chromatography (TLC), ELISA and others, may not be used for the analyses referred to in this protocol.

Each final sample must be completely ground up and made homogeneous by the laboratory. See GMP+ (2020) TS 1.7[17] for the conditions relating to sample preparation and analysis by the laboratory.

The certificate of analysis shall mention at least the country of cultivation of the maize, the batch identification (such as batch number, lighter, (sea) boat name and hold), the size of the batch from which the sample was taken and the sampling date.

12.3.1 Certificate of analysis in case of truck delivery

In the case of delivery by truck, the certificate of analysis of the storage in the country of cultivation may be used as a representative for the lorries loaded from it, provided that the storage has been sampled in accordance with this chapter.

12.4. 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, deviations and threats and see document: P-13 Calamity control.

All other aflatoxin B1 analysis results from maize resulting from the participant's own monitoring or 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 Monitoring Aflatoxine en Mycotoxines.

12.5. Food producing companies purchasing and processing maize under the conditions of Regulation (EU) 2023/915[18]

If the supplier (or participant) is the producer or trader of a by-product, it should apply this protocol to the by-product being supplied.

Food producing companies that purchase and process maize grown in a medium-risk country under the conditions of Regulation (EU) No. 2023/915, may apply the protocol to the influx of maize, if they demonstrably work with a processing protocol that meets the requirements as included in Annex 1: "Assessment framework assurance protocols aflatoxin risks".

13. CONDITIONS FOR THE PURCHASE AND DIRECT SUPPLY OF END FEED

SecureFeed participants are responsible, when purchasing dairy cattle feed containing maize and/or by-products from third parties, for ensuring that the dairy cattle feed purchased demonstrably meets the requirements of this protocol.
In the event that a dairy feed is delivered by a supplier who is not a SecureFeed participant, the participant must also ensure that this supplier fully complies with this protocol.
If this condition cannot be met, an analysis as referred to in Chapter 12 must be included with each delivery of dairy cattle feed (positive release).
In addition, by-products delivered directly to the dairy farmer are subject to the conditions set out in Annex 2.

[17] Or GMP+ BA4 2.3

[18] The full name of the regulation is: Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in foodstuffs and repealing Regulation (EC) 1881/2006

14. VERIFICATION ON END FEED

14.1. Introduction

SecureFeed considers it necessary that - in addition to the regular monitoring programme - additional verification for aflatoxin B1 takes place in end feed, intended for dairy cattle, in which maize and/or by-products are processed.
This verification should be only be done by participants that produce dairy cattle feed.

14.2. Working method for production sites

14.2.1 Weekly or monthly verification

1) On each site where dairy cattle feed containing maize and/or by-products is produced (irrespective of its origin), one sample must be analysed each week from the dairy cattle feed with the highest percentage of maize and/or by-products blended in.
2) If no new batches of maize or by-products have been processed into dairy cattle feed in a week, another verification of dairy cattle feed is not necessary.
3) If a production location for dairy cattle feed can demonstrate for 6 consecutive months that it only has weekly Aflatoxin B1 verification results ≤ 0.001 mg/kg (**1 ppb**), then this location may reduce the verification frequency from weekly to monthly[19].
4) If during the monthly Aflatoxin B1 verification, results > 0.001 mg/kg (**1 ppb**) are detected, the following shall apply:
   a) If 0.001 mg/kg (**1 ppb**) < Aflatoxin B1 analytical result ≤ 0.002 mg/kg (**2 ppb**)
      i) The verification frequency remains monthly;
      ii) Report immediate to SecureFeed (see 14.2.3 – 3)
   b) If Aflatoxin B1 analysis result > 0.002 mg/kg (**2 ppb**).
      i) The frequency of verification is changed to weekly.
      ii) After another 6 months of exclusively weekly Aflatoxin B1 verification results ≤ 0.001 mg/kg, the verification frequency may be reduced to monthly.

14.2.2 New participants or new production sites

1) New participants/participating production sites always start with the procedure as described under 14.1.

14.2.3 Communication of verification results and cause analysis

1) The participant shares the results of the dairy feed verification with SecureFeed (at least quarterly, preferably monthly):
   a) via the GMP+ monitoring database on the condition that:
      i) the participant registers the result under the product compound feed for cattle: dairy cattle feed; compound feed for goats, compound feed for sheep.
      ii) If the participant produces dairy feed which falls outside these GMP+ product categories, then the participant should inform SecureFeed of the product name under which they will upload the results.
      iii) the participant finalises the registered results and shares them with the SecureFeed group in the GMP+ monitoring database.
      iv) the participant documents in F-23 Verification of Aflatoxin in dairy cattle feed the weeks/months when no sampling was performed, including the reason, and shares this at least quarterly via monitoring@securefeed.eu (if applicable).

   OR
   b) via Excel form F-23 Verification Aflatoxin B1 in Dairy Feed from the SecureFeed handbook.
      i) This form should be emailed to monitoring@securefeed.eu.
2) In case of detected elevations in dairy feed (> SecureFeed action limit), the participant will inform SecureFeed and other participants by return via the notification system in the SecureFeed database.
3) In case the results of the analysis are below the SecureFeed action limit but above the 0,001 mg/kg (1 ppb), the participant needs to set up a cause analysis and share it with SecureFeed using the form F-34 'Cause analysis elevated Aflatoxin B1 levels in dairy cattle feed'. This form should be e-mailed to monitoring@securefeed.eu.
4) The participants of the dairy cattle verification are listed in D-28 Participants in dairy cattle verification.

[19] The so-called 6-month rule

15. SCHEMATIC OVERVIEW OF REQUIREMENTS

15.1. Maize and by-products – High Risk - Processing and Direct Delivery

Schematic:

Products	Maize and by-products
Origin of Maize	High-risk country
Destination	Processing and/or Direct Delivery
Conditions for processing	Positive Release & all analyses below the SF rejection limit, including those of the seagoing vessel
Requirements for sampling and analysis:	Sampling in accordance with GAFTA (124) or EC 691/2013 and the additional conditions in chapter 12.1.1 & 12.1.2
Additional sampling requirements in case of delivery of maize[20] by **water and train**	Minimum 10 incremental samples of 1 Kg on each quarter of coaster, barge, lighter or pushed lighter, resulting in at least 4 aggregate samples of at least 10 Kg each to be analysed. **OR** Minimum 20 incremental samples from each quarter of coaster, barge, lighter or pushed lighter, resulting in at least 4 aggregate samples of at least 4 Kg, each to be analysed.
	At least 1 seagoing vessel analysis sampled in accordance with GAFTA 124 or EC 691/2013.
	Sampling by independent sampler
Additional sampling requirements in case of direct delivery by **truck**	At least one analysis per batch (max 1,000Mt) Sampling by independent sampler
SF Rejection Limit	0.001 mg/Kg (**1 ppb**)

[20] These additional sampling requirements do not apply to by-products; see also the footnote in 12.1.

15.2. Maize and by-products – Medium Risk - Processing

Schematic:

Products	Maize and by-products
Origin of Maize	MEDIUM-risk country
Destination	Processing into dairy cattle feed
Conditions for processing	Positive Release Or Participant has established that the food producer has produced the by-product in compliance with a SecureFeed approved protocol for the processing of maize into by-products under the conditions set out in section 12.5
Requirements for sampling and analysis:	Sampling in accordance with GAFTA (124) or EC 691/2013 and the additional conditions in chapter 12.1.1.
Additional sampling requirements in case of delivery of maize[21] by **water and train**	Minimum 10 incremental samples of 1 Kg on each quarter of coaster, barge, lighter or pushed lighter, resulting in at least 4 aggregate samples of at least 10 Kg each to be analysed. **OR** Minimum 20 incremental samples from each quarter of coaster, barge, lighter or pushed lighter, resulting in at least 4 aggregate samples of at least 4 Kg, each to be analysed.
	Sampling by independent sampler
Additional sampling requirements in case of direct delivery by **truck**	At least one analysis per batch (max Mt 2,000)
	Sampling by the GMP+ FSA-certified company in accordance with the general GMP+ FSA requirements (GMP+ (2020) TS 1.6)
SecureFeed Rejection Limit	0.02 mg/Kg (**20 ppb)**

[21] These additional sampling requirements do not apply to by-products; see also the footnote in 12.1.

15.3. Maize and by-products – Medium Risk - Direct Delivery

Schematic:

Products	Maize and by-products
Origin of Maize	MEDIUM-risk country
Destination	Direct delivery to dairy farmer
Conditions for processing	Positive Release Or Participant has established that the food producer has produced the by-product in compliance with a SecureFeed approved protocol for the processing of maize into by-products under the conditions set out in section 12.5
Requirements for sampling and analysis:	Sampling in accordance with GAFTA (124) or EC 691/2013 and the additional conditions in chapter 12.1.1.
Additional sampling requirements in case of delivery of maize[22] by **water and train**	Minimum 10 incremental samples of 1 Kg on each quarter of coaster, barge, lighter or pushed lighter, resulting in at least 4 aggregate samples of at least 10 Kg each to be analysed. **OR** Minimum 20 incremental samples from each quarter of coaster, barge, lighter or pushed lighter, resulting in at least 4 aggregate samples of at least 4 Kg, each to be analysed.
	Sampling by independent sampler
Additional sampling requirements in case of direct delivery by **truck**	At least one analysis per batch (max Mt 2,000)
	Sampling by the GMP+ FSA-certified company in accordance with the general GMP+ FSA requirements (GMP+ (2020) TS 1.6)
SecureFeed Rejection Limit	0.0025 mg/Kg (**2,5 ppb)**

[22] These additional sampling requirements do not apply to by-products; see also the footnote in 12.1.

15.4. Maize and by-products – Low Risk - Processing and Direct Delivery

Schematic:

Products	Maize and by-products
Origin of Maize	Low Risk country
Destination	Processing and/or Direct Delivery
Requirements for analysis frequency	According to the hazard analysis of the GMP+ (og) certified company And additionally in case of maize: At start of Harvest Year: Have first three batches of maize analyzed and send the results to SecureFeed*. And additionally in case of maize by-products: 1) Monthly have at least one batch of the directly delivered by-product analyzed and send the results to SecureFeed. OR 2) Participant has established that the by-product has been produced under conditions as referred to in paragraph 12.5. *Does not apply to batches of CCM.
Requirements for sampling and analysis:	As in GMP+ (2020) TS 1.6 – sampling guidelines
Sampling requirements in case of delivery by **water or train**	X
	X
Sampling requirements in the case of direct delivery by **truck**	
	Sampling by the GMP+ FSA-certified company in accordance with the general GMP+ FSA requirements (GMP+ BA13)
SF Rejection Limit for product to be processed in compound feed	0.02 mg/Kg (**20 ppb**)
SF Rejection Limit for product to be directly Delivered to dairy farmer in compound feed	0.0025 mg/Kg (2,5 ppb)

ANNEX 1: ASSESSMENT FRAMEWORK FOR ASSURANCE PROTOCOLS AFLATOXIN RISKS

Application
SecureFeed uses this assessment framework to assess processing protocols of suppliers / producers of by-products.

These are specifically protocols of suppliers/producers of by-products from **Medium** Risk Countries that are allowed to apply I-08-03c to maize inflows[23].

Purpose of this assessment framework
The aim of this assessment framework is to make it possible to abandon the positive release measure for by-products from **Medium** risk countries by replacing it with a well-secured process for processing maize that focuses on analysing the incoming maize and the concentration factors of its by-products.

This process must be described by the supplier of the by-product in a processing protocol.

That processing protocol must be approved by SecureFeed.

This assessment framework describes the requirements with which the processing protocols drawn up by the suppliers must comply. It also contains guidelines that the supplier/producer may, but is not obliged to, follow.

Working method
Description of the steps of the approval process:
1. Participant requests the protocol from the Supplier;
2. Participant submits it to SF secretariat;
3. SF approves or rejects the protocol with indications for improvement;
4. The suppliers shall process the indications and resubmit the improved protocol.

Requirements for the processing protocol
SecureFeed will only approve a processing protocol as referred to in this annex if it meets the following requirements:
1. Incoming maize is sampled and analysed according to this SecureFeed Aflatoxin protocol.
2. The blend process must be well substantiated in such a way that for each concentration factor <0.0025 mg/Kg (**2.5 ppb***) in the final product for dairy cattle can be guaranteed;

*The 2.5 ppb limit obviously only applies if the end product in question is also intended and/or suitable for direct feeding to dairy cattle.

Guidelines for a processing protocol:
The supplier/producer may consider the following guidelines when drawing up his processing protocol:
1. Work with a detection limit <0.0001 (**0.1 ppb**) mg/Kg;
2. Determine how the concentration factor of a by-product affects the maximum Aflatoxin content of the incoming maize as a basic condition for processing.
    - As an example of such an agreement: In a production process with a concentration factor of 4, **0.5 ppb** in the incoming maize is the basic condition for processing. In the case of higher values, positive release is used.
3. Establish a sound rationale for the concentration factors applied.
4. Use the highest concentration factor found in the calculations / validation / verification.
5. When determining the concentration, use the average of the (4) aflatoxin analyses (and not the highest value);
6. All maize processed in the production process must be included in the blending (think of sievage at the intake before processing);
7. Validate regularly that the applicable standards for the by-products are met;
8. Validate regularly that the concentration factors are sufficient;

[23] See also section 12.5. Food producing companies purchasing and processing maixe under the conditions of Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in foodstuffs and repealing Regulation (EC) 1881/2006).

ANNEX 2: HANDLING OF MAIZE BY-PRODUCTS INTENDED FOR DIRECT FEEDING

Application
This appendix has been added in order to achieve a workable situation in the event of a minor breach of the SecureFeed norm for Aflatoxin B1 in by-products of maize intended for direct feeding.

Purpose of this annex
To create clarity in the handling of by-products of maize intended for direct feeding and which contain a minor violation of the SecureFeed norm on Aflatoxin B1.
By applying the procedure described in this annex, the possibility is given to avoid a recall without jeopardising food safety.

Context
The SecureFeed norm for Aflatoxin B1 in feed materials delivered to dairy farmers for direct feeding is 0.0025 mg/Kg (**2.5 ppb**). This means that when analysis results for delivery give values above this norm, feed materials may not be delivered directly to dairy farms. The GMP+ rejection limit is 0.005 mg/Kg (**5 ppb**).

Procedure
In case there is:
1. A by-product intended for direct feeding;

and

2. ..that has been delivered to the dairy farmer before the results of the analysis of the batch concerned were known;

and

3. the Aflatoxin B1 analysis result of that batch is between 0,0025 mg/Kg (**2,5 ppb**) and 0,005 mg/Kg (**5 ppb**);

..then SecureFeed is allowed to carry out a risk assessment to determine the next steps instead of immediately issuing a recall of the batch in question.

If, for example, by adjusting the feed advice, the concentration of Aflatoxin M1 in the milk remains below the norm of 0,04 µg/litre, no recall needs to take place.
Such a decision will be taken in consultation with the Notification Working Group.

This decision can only be taken if the dairy farmer is notified by the participant of a possible adjusted feed advice based on the analysis results.

If it appears that, after adjustment of the feed advice, there is still a violation of the rejection limit for Aflatoxin M1 in the milk, the participant should be able to demonstrate that the adjusted advice was given.