

Annex 8.5 Additional control plans

Additional control plan Aflatoxin B1

Fundamentals

The additional control plan must be adhered additionally to the annual analyses which are required within the QS scheme according to the **Guideline Feed Monitoring**.

Scope

The additional control plan has to be followed by

- premix producers (production scope 70; to be applied from 01.01.2025),
- compound feed producers (production scope 71),
- feed material producers, (production scope 72),
- small scale feed material producers (production scope 73),
- private labeller (production scope 74) and
- traders (including delivery trading; production scope 76)

if they trade or process maize or processed maize.

Responsibilities

Each QS certified company, which receives maize or processed maize (feed material), has to fulfil this additional control plan, unless the supplier already complies with this or with a recognized additional control plan of another standard owner.

QS recognizes the additional control plans of the following standard owners:

- GMP+ International
- OVOCOM
- AIC
- EFISC-GTP

However, the QS-certified company requires the supplier's analysis result(s) for products in the "High" or "Medium" risk classifications, irrespective of the supplier's certification scheme.

Requirements

Risk classification for countries of cultivation

The countries of cultivation are classified in different categories (high, medium and low risk). If required, a country can be divided into different regions.

Table 1: Risk classification for countries of cultivation

High	Medium	Low
<ul style="list-style-type: none"> • Romania • Serbia 	<ul style="list-style-type: none"> • all other countries which are not mentioned under 'high' or 'low' 	<ul style="list-style-type: none"> • Austria • Belgium • Denmark • Estonia • Finland • France • Germany • Iceland • Ireland • Latvia • Lithuania

High	Medium	Low
		<ul style="list-style-type: none"> Luxembourg Netherlands Norway Poland Sweden UK

The country of cultivation of the maize should always be known. If the country of cultivation is not known, classification as high risk is applicable.

In addition to the classification made by the standard owner, the precautionary principle always prevails. This means that a company always has to consider and calculate the possible risk of Aflatoxin B1 in maize or processed maize from a country of cultivation as well as the storage conditions until receiving or processing the products. If necessary, the products have to be analysed.

Sampling

The requirements for sampling depend on the risk classification for the country of cultivation, means of transport and storage of the products. For high and medium risk, the sampling has to be done in accordance with the **Regulation (EC) No 152/2009** (respectively valid successor regulation) as regards methods of sampling and analysis. For low risk the sampling has to be done in accordance with the **Guideline Feed Monitoring**.

The company applying this additional control plan sends at least 4 kg of sample material (maize/ by-product) to the laboratory for preparation and analysis. The preparation and analysis by the laboratory are in accordance with the following conditions:

- The at least 4 kg of sample material from the sampling is completely grinded and homogenized.
- At least 500 g are taken from the homogenized quantity as a final sample.
- The sample for analysis is prepared from the final sample.
- The remains of the final sample are retained for potential re-analysis.

The sampling of the raw material must always be related to the batch. This means, the sample to be analysed must be taken from one batch of the same origin (country of cultivation). Two or more different origins must not be mixed. If the mixing of products from two different countries of origin cannot be avoided, the entire batch is sampled according to the country of origin that is categorised as the higher risk. A batch (according to **Regulation (EU) 767/2009**) means an identifiable quantity of feed determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling. In the production of processed maize, a "batch" or "lot" is defined as a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together.

Table 2: Overview of requirements for sampling

Means of transport	Requirements regarding	Risk classification		
		High	Medium	Low
Seagoing vessel	Samples per batch	1 sample per hold (max. batch size 2,000 t) ¹	1 sample per hold	Risk-oriented according to Guideline Feed Monitoring on HACCP basis

Means of transport	Requirements regarding	Risk classification			
		High	Medium	Low	
All other transportation and storage sites	Location of sampling	port of loading or port of unloading			
	Sampler	Sampler of an independent superintendent organization accredited according to ISO 17020 or ISO 9001 or GAFTA certification		According to Guideline Feed Monitoring	
	Samples per batch	Truck: 1 sample per batch (max. batch size 1.000 t) ²	Truck: 1 sample per batch (max. batch size 2.000 t) ²		
		Train: 1 sample per batch (max. 1 block train)			Risk-oriented according to Guideline Feed Monitoring on HACCP basis
		Inland waterway vessel or coaster: 1 sample per inland waterway vessel or coaster			
		Silo/storage site: 1 sample per batch (max. batch size 1,000 t) ³	Silo/storage site: 1 sample per batch (max. batch size 2,000 t) ³		
	Location of sampling	Truck: Country of cultivation or destination			No specification
		Train and Inland waterway vessel or coaster: Country of cultivation (place of loading)			
		Storage site			
		Sampler	According to Guideline Feed Monitoring		

¹ One sample has to be analysed per hold. Pooling of the contents of several holds, which belong to one batch, is possible (max. 2,000 t). If the hold contains more than 2,000 t, several samples must be taken accordingly.

² One sample has to be analysed per truck; pooling of several truck supplies, which belong to one batch, is possible (max. 1.000 t or 2.000 t)

³ One sample per batch (max. 1,000 t or 2,000 t) must be analysed per silo/storage site. If the storage site/silo contains more than 1,000 tonnes or 2,000 tonnes, several samples must be taken accordingly.

Feed material producers which process maize are also allowed to conduct the analysis exclusively in the final products.

In case the sampling dates back more than 3 months a new sampling is required.

If the whole batch in the warehouse is not accessible for sampling, a sampling plan should be made and documented, that covers the accessible part of the batch. The part of the batch that has not yet been sampled and analysed, should be monitored once it is possible and safe to get access.

In case of stored batches and reanalysis after 3 months, the highest measured Aflatoxin B1 value (from all sampling moments) is leading since it is not obvious that Aflatoxin B1 content could decrease over time. All analysis results applicable for the batch (also those which are older than 3 months) must accompany the batch.

Analysis and data entry

The analyses which are commissioned by QS certified companies as part of this additional control plan, may only be conducted by QS recognized laboratories. Furthermore, these analyses have to be entered into the QS-database in accordance with the requirements described in the **Guideline Feed Monitoring**.

As the sample type "Additional control plan" needs to be selected.

Note: *If a sample has to be taken according to the additional control plan and gate-keeping, sampling according to the additional control plan is sufficient. In this case, "Gate-Keeping" is to be specified as the sample type and the addition "was sampled according to additional control plan" is to be added under remarks.*

Exceeding of limits or guidance values

In the case of an exceedance of the legal maximum value or a QS guidance value (QM-Milk maximum level or QM-Milk action threshold for products intended for feeding dairy cows in QM-Milk dairy farms) for aflatoxin B1, it has to be proceeded according to the Guideline Feed Sector (chapter 2.1.4 Incident and crisis management and chapter 2.8.4 Control of faulty products) as well as to the Guideline Feed Monitoring (chapter 5.1 Incident and crisis management). If the products concerned have already been delivered, the customer of the products (client) has to be informed immediately in the case of an exceedance of the legal maximum level or QM-Milk maximum level.

Handling of analysis results and forwarding to the customer

- High and medium risk of the country of cultivation:
The analysis results must be available before processing or sale and forwarded to the customer (positive release).
For medium risk, the following procedure may be applied: In cases where maize is stored longer than 3 months in a silo and is not accessible for sampling before delivery to the customer, sampling may be carried out during loading. The results must be available before unloading at the customer or at least before the next processing step or feeding (if there is a written agreement between the seller and the customer).
 - For unprocessed maize, the analysis results which can be clearly assigned to the batch, need to be attached to the batch.
 - Feed material producers which process maize are also allowed to conduct the analysis exclusively in the final products. The analysis results need to be clearly assignable to the batch (maize by-products).
 - Feed material producers which process maize and conduct analyses in the raw materials have to confirm in written form to their customer that the additional control plan for the incoming maize was applied. Additionally, the end products have to be analysed by the feed material producer according to an internally determined control plan considering the concentration factors. These results need to be reported to the customer on his request or in the case of values $\geq 3 \mu\text{g}/\text{kg}$ (for direct delivery to QM-Milk participating dairy farms: $\geq 2,5 \mu\text{g}/\text{kg}$).
- Low risk:
When the respective batch is analysed, the analysis result has to be forwarded to the customer on his request.

Reclassification for countries of cultivation

QS reviews the risk classification for countries of cultivation together with the other standard owners on a regular base. A reclassification of the countries in the different categories will be made as soon as a certain number of analyses is available and can be evaluated by the scheme owner. Therefore, the following applies:

- For upgrading a country of cultivation to a higher risk level, the number of samples to be tested is at least 1.
- For downgrading a country of cultivation to a lower risk level, the number of samples to be tested is at least 50 (results of the current harvest).
- A country of origin is downgraded to a lower risk at the earliest 3 months after the current version comes into force.

Analysis results which are available for QS and the recognized standard owners are used for evaluation and reclassification. Other information like RASFF notifications, information about weather/harvest conditions, expert opinions and further relevant sources can also be used for reclassification.

The reclassification is based on the criteria in the following table:

Table 3: Criteria for Reclassification of a country of cultivation

Risk level by country of cultivation	Criteria defining the risk level
High	<ul style="list-style-type: none"> • > 1 % of the available analysis results within the previous evaluation period > 20 µg/kg or • > 10 % of the available analysis results between > 10 µg/kg and ≤ 20 µg/kg
Medium	<ul style="list-style-type: none"> • Percentages of analysis results that are not mentioned under the risk levels 'High' or 'Low' fall under the risk level 'Medium'
Low	<ul style="list-style-type: none"> • < 1 % of the available analysis results between > 5 µg/kg and ≤ 10 µg/kg and • > 90 % of available analysis results < 2 µg/kg and • other available analysis results ≤ 5 µg/kg

The reclassification will result in a revised additional control plan. The scheme participants will be informed by QS about the revised document.

Revision Information Version 18.09.2024

Criteria/requirement	Change	Date of change
Entire document	Change: Editorial changes and restructuring	18.09.2024
Scope	New: Addition of premix producers to the scope, transition period until 01.01.2025	18.09.2024
Risk classification for countries of cultivation	<p>Clarification: If required, a country can be divided into different regions</p> <p>New risk classifications of the following countries of cultivation:</p> <ul style="list-style-type: none"> • Romania from Medium to High • Czech Republic from Low to Medium 	18.09.2024
Sampling	<p>Clarification: If the mixing of products from two different countries of origin cannot be avoided, the entire batch is sampled according to the country of origin that is categorised as the higher risk.</p> <p>New:</p> <ul style="list-style-type: none"> • For sea-going vessels and high risk classification, the maximum batch size is 2,000 t and sampling is possible at the port of loading or unloading. • For sampling in the silo/storage facility and high risk classification, the maximum batch size is 1,000 t, for medium risk 2,000 t. 	18.09.2024