



## European Feed Ingredients Safety Code

Code of good practice for the monitoring of Mycotoxin in maize and maize co- products (feed materials) derived thereof



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## 1. Introduction

This code of good practice gives requirements for the monitoring of Mycotoxins in batches of unprocessed maize and co- products thereof.

The starch industry needs mandatory to use “food grade” maize which must meet < 2ppb AFL B1 and < 4 ppb sum Aflatoxins after cleaning. Feed materials must meet < 20 ppb AFL B1. The co- products from starch processing make up for 32-35 % of the incoming maize. The food starch is containing only 1-2 % of the incoming Mycotoxin contamination in the raw material and following the concentration is on an average between 2 and 5.

Based on the information coming from the RASSF, surveillance programmes in the primary production, monitoring programmes and supplier information, concerned Starch Europe operators, have strengthened their HACCP based risk assessments on a continuous basis in order to continue guaranteeing safe feed materials to their customers.

Starch manufacturers usually establish multiple raw material/ maize sources so that known “hot” sources/ regions of contaminated lots can be avoided.

Second, starch manufacturers implement monitoring programs designed to detect and reject contaminated lots.

Finally, starch Europe operators produce feed materials as a co- product from starch production. During the wet milling a number of production steps reduce potential high peaks of contamination resulting in food grade starch and feed materials where the contamination of Mycotoxins in general and Aflatoxin more specifically is homogenised. For co- products, the risk analysis and the related analytical control plan for Mycotoxins should however also focus on the production process and possible concentration factor (recycling, use of water fractions in by- products, etc.).

All these measure should reduce significantly the risk of contamination of the feed materials with Mycotoxins and ensure a safe feed material to the customer.

In order to strive for a harmonised EU implementation, this Code of good practice provides sampling and monitoring requirements for Mycotoxin in maize and the co- products of maize processing thereof.

For EFISC-certified maize processing manufacturers the requirements in this Code are mandatory.

## 2. Duration

This protocol is valid and applicable only for a limited period of time. The decision to end the implementation of this protocol will be made on the basis of a risk assessment and in co- decision by EFISC, Starch Europe, FEFAC and other certification schemes.

### 3. EU legal requirements and recommendations

#### 3A. For Food (incoming unprocessed maize):

- [Regulation \(EC\) 1881/2006 setting maximum levels for certain contaminants in foodstuffs](#)
- [Regulation \(EC\) 401/2006 on the official control of the levels of Mycotoxins in foodstuffs](#)
- [Recommendation 2013/165/EU on T-2 and HT 2 in cereals and cereal products](#)

#### EU food limits for Aflatoxin

(As per amended version of Regulation (EC) No 1881/2006)

- Maize to be subjected to sorting or other physical treatment before human consumption or use as an ingredient in foodstuffs. Maximum limits ( $\mu\text{g}/\text{kg}$ ) of 5ppb for Aflatoxin B1 and 10 ppb for sum of Aflatoxins B1+B2+G1+G2. Maize consignments with levels between 2 and 5 ppb Aflatoxin B1 AND 4 to 10 ppb for sum of Aflatoxins B1+B2+G1+G2 clearly need to be labelled as such. Through sorting or other physical treatments the levels should be brought to 2 ppb for Aflatoxin B1 and 4,0 ppb for sum of Aflatoxins B1+B2+G1+G2 before production of foodstuffs.

For maize and all products derived from maize, including processed maize products, maximum limits ( $\mu\text{g}/\text{kg}$ ) of 2 ppb for Aflatoxin B1 and 4 ppb for sum of Aflatoxins B1+B2+G1+G2 are set.

**EU food limits for Deoxynivalenol, Zearalenone, Ochratoxin A, and Fumonisin (with the exception of unprocessed maize intended to be processed by wet milling):**

<b>Ochratoxin A</b>	Unprocessed maize,	5 ppb
<b>Deoxynivalenol</b>	Unprocessed maize,	1750 ppb
<b>Zearalenone</b>	Unprocessed maize,	350 ppb
<b>Fumonisin</b>	Unprocessed maize,	4000 ppb
<b>T2 and TH2</b>	Unprocessed maize	200 ppb

#### 3B. For feed:

[Directive 2002/32/EC](#)

[Commission recommendation of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisin in products intended for animal feeding \(2006/576/EC\)](#)

[Recommendation 2013/165/EU on T-2 and HT 2 in cereals and cereal products](#)

**The EU feed limits for Aflatoxin (based on a moisture content of 12 %):**

- Feed materials 20 ppb for Aflatoxin B1
- Complementary and complete feed 10 ppb for Aflatoxin B1
- Compound feeds for dairy and young animals have to comply with 5 ppb for Aflatoxin B1
- Compound feeds for general not already mentioned categories - 20 ppb for Aflatoxin B1

**The EU guidance limits for deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins (based on a moisture content of 12 %):**

■ Deoxynivalenol	Maize by-products	12000 ppb
■ Zearalenone	Maize by-products	3000 ppb
■ Ochratoxin A	Cereals and cereal products	250 ppb
■ Fumonisin A & B	Maize by-products	60000 ppb
■ T-2 and HT-2	Maize by- products	500 ppb

**4. Sources of Mycotoxins**

Contamination of maize with mycotoxins can occur at two levels. The first source of contamination is infection of the crop in the field by mycotoxin producing moulds. Field and weather conditions like temperature and humidity are key factors for mould growth and mycotoxin production. However, these conditions are very difficult to control and a thorough monitoring of the crop should be applied to detect and prevent these moulds.

After harvest, a second contamination with mycotoxins can take place by infection of the harvested and processed maize with storage moulds, for example by *Aspergillus* or *Penicillium* species. Infection with storage moulds occurs when storage and/or drying conditions are not optimal. Of these storage conditions, temperature and humidity are the most determining factors for mould growth and mycotoxin production. Also the moisture content of the maize plays a crucial role. Storage conditions should be very well fine-tuned to avoid mould growth.

Table 1: An overview of the main Mycotoxin producing moulds for maize during field and during storage and the mycotoxins they can produce.

FIELD		STORAGE	
Species	Mycotoxins	Species	Mycotoxins
Fusarium spp	Trichothecenes Zearalenone Deoxynivalenol Fumonisin	Aspergillus spp	Aflatoxins Ochratoxins
Aspergillus spp	Aflatoxins		
		Penicillium spp	Ochratoxins

**5. Scope of application**

This code is applicable to all incoming maize and the co- products from starch manufacturing thereof. It is applicable to all defined regions of origin (region/province where the maize was cultivated). If the information by region is not available a risk assessment by country shall be in place

## 6. Risk assessment

In order to define the risk level of a given region the operator shall perform a risk assessment by region (province) of origin as described in the [European code for the industrial manufacturing of safe feed materials](#), the [sector document on starch processing and this protocol](#). (EFISC Code 4.4.3 Inspection, sampling and analysis).



The operator will define the risk level for each defined delivery, based on the relevant information coming from, amongst other:

- The RASFF (previous years)
- Historical data of the three previous years
- Surveillance programs in the primary production by region ( information on GAP (choice of variety, crop rotation, crop planning, soil and crop management, harvesting practices and weather monitoring))
- Pre-harvest information
- Information on GHP at collection, storage and transport
- Sector organisations data collection program
- Traders
- Supplier evaluation
- Incoming product specifications
- Customer product specifications
- Monitoring programme results
- Defined processing factors (based on [literature](#) and/ or plant testing results)

The risk assessment will be documented and auditable.

### 6.1 Defining risk levels of the maize (pre-harvest assessment primary production/ collector)

Following the operator will define the risk level for the maize by region as high, medium or low.

The following criteria apply for defining the risk level by region for:

- 1) Incoming maize for starch production and feed co- products (table 2 a and b)
  - a. Aflatoxin B1 and sum of Aflatoxin
  - b. Other Mycotoxins

The risk assessment results in a list of regions and suppliers with their risk status

**Table 2 a: Pre-harvest assessment- risk levels by region/ incoming maize for starch production and feed co- products- Aflatoxin B1 and sum of Aflatoxins B1+B2+G1+G2.**

<b>Risk level by region</b>	Maize must be treated by physical sorting before it will be used for the production of foodstuffs
<b>High</b>	Origin is unknown Harvest year is unknown Aflatoxin detected above MRL in historical crops or the current crop Aflatoxin B1 Pre harvest monitoring n = 20, m < 8 ppb, M = 10 ppb, c = 10% Sum of Aflatoxins B1+B2+G1+G2 n = 20, m < 8 ppb, M = 10 ppb, c = 10% For feed co products- basis highest accumulation of the Aflatoxin B1
<b>Medium</b>	Origin is known Harvest year is known Regularly Aflatoxin detected in historical crops or the current crop, below MRL Aflatoxin B1 Pre harvest monitoring n = 20, m < 5ppb, M = 8 ppb, c = 10% Sum of Aflatoxins B1+B2+G1+G2 n = 20, m < 6 ppb, M = 8 ppb, c = 10% For feed co products- basis highest accumulation of the Aflatoxin B1
<b>Low</b>	Origin is known Harvest year is known Low detection of Aflatoxin in historical crop or the current crop Always below 2 ppb Aflatoxin detected in corn of the historical crop or the current crop Aflatoxins B1 Pre harvest monitoring n = 20, m < 2 ppb, M = 4 ppb, c = 10% Sum of Aflatoxins B1+B2+G1+G2 n = 20, m < 4 ppb, M = 6 ppb, c = 10% For feed co products- basis highest accumulation of the Aflatoxin B1

n= number of batches, m= limit in ppb, M= max limit in ppb

c=maximum amount of samples which can be over m, but under M

**Table 2b: Pre-harvest assessment- risk levels by region/ incoming maize for starch production and feed co- products- other mycotoxins.**

<b>Risk level by region</b>	Risk levels set for unprocessed maize before <b>first-stage processing</b> . [Cleaning, sorting and drying procedures are not considered as first-stage processing insofar as no physical action is exerted on the grain kernel itself]. See §3b for the EU guidance limits for deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in feed
<b>High</b>	Origin is unknown Harvest year is unknown Frequently other mycotoxins detected in historical crops or the current crop Frequently other mycotoxins detected in historical or current maize co-products Other mycotoxins n = 20, m < 85 % EU maize by-products guidance feed limit, M = 100%, c = 10% For feed co products - basis highest accumulation of each mycotoxin
<b>Medium</b>	Origin is known Harvest year is known Regularly other mycotoxins detected in historical crops or the current crop Regularly other mycotoxins detected in historical or current maize co- products Other mycotoxins n = 20, m < 75 % EU maize by-product guidance feed limit, M = 85 %, c = 10% For feed co products - basis highest accumulation of each mycotoxin
<b>Low</b>	Origin is known Harvest year is known Low detection of other mycotoxins in historical crop or the current crop Low detection of other mycotoxins in historical or current maize co- products Other mycotoxins n = 20, m < 50 % EU maize by-product guidance feed limit, M = 75%, c = 10% For feed co products- basis highest accumulation of each mycotoxin

n= number of batches, m= limit in ppb, M= max limit in ppb

c=maximum amount of samples which can be over m, but under M



## 6.2 Verification of the risk status at the start of the harvest

In order to verify the risk classification by mycotoxin by region and monitor its development in time, the operator shall monitor the incoming batches in line with the requirements in table 3 and evaluate the risk status accordingly.

**Table 3: Verification risk level by region/ mycotoxin levels in incoming maize for food starch**

Risk level by region	1. Criteria for defining the risk level of Aflatoxin B1, sum of Aflatoxins and other mycotoxins in maize purchased for starch production by region.
High	Period of 10 weeks and/ or n=30, m &M= see table 2a &b, c=10%
Medium	Period of 10 weeks and/ or n=15, m &M= see table 2a &b, c=10%
Low	Period of 10 weeks and/or n=10, m &M=see table 2a &b, c=10%

If more than 10 % of the analysis are above the defined risk level the region moves to the appropriate, higher risk level.

If 90% of the analysis fall within the lower risk level the region moves to the appropriate, lower risk level.

n= number of batches, m= limit in ppb, M= max limit in ppb

c=maximum amount of samples which can be over m, but under M

Flow diagram 1 risk assessment maize Aflatoxin B1/ Mycotoxins in general for feed & food



## 7. Monitoring

Based on the defined risk level the operator shall follow the following monitoring frequency:

**Table 4: Monitoring frequency**

High	100 % monitoring
Medium	25 % Monitoring: a) one out of four batches* analysed or b) one composite sample out of four batches*
Low	Based on the operators risk assessment, in line with the monitoring requirements as given in the Starch Europe sector document

\*see definition batch in §8- same origin, year

Based on the monitoring results the defined risk level/ monitoring frequency can be adapted. This process will be documented.

The precautionary principle must always prevail. In case of doubt, the company must always apply 100 % monitoring as described in this code of good practice.

## 8. Sampling and analysing

Incoming maize has to be sampled and analysed by batch in line with the risk classification and the defined monitoring frequency, sampling and analysis protocols (number of incremental samples by batch, aggregated sample, lab sample) as defined in this protocol in order to verify the safety of the product.

A **batch** is an identifiable quantity of maize or maize co- products, determined to have common characteristics; and in case of a production process 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 (Regulation 767/2009/EC amended).

Based on the above the batch is to be defined by the operator based on the physical hold (sea ship compartment) or a combination of holds (inland waterway, train, truck). The following batch sizes apply:

**Table 5 Batch sizes**

Seagoing vessel	Tonnage as transported by hold
Inland waterway transport	Tonnage as transported by inland waterway vessel or coaster
Train	Total volume of the entire train
Road transport*	Up to 80 trucks (2000T) can be handled as one batch

Feed materials intended for the dairy industry (see §2), will be monitored in line with the requirements under §8b and customer specification (business to business).

For all other feed materials the operator shall formulate a monitoring plan, based on his risk assessment.

The following sampling situations apply:

**a) Incoming product (food grade)**

For the incoming maize the following sampling methods are accepted at loading <sup>1</sup> or unloading of the product:

- Regulation (EC) 401/2006 laying down the methods of sampling and analysis for the official control of the levels of Mycotoxins in food stuffs.
- Regulation (EC) 691/2013, amending Regulation (EC)152/2009,laying down the methods of sampling and analysis for the official control of feed

The following method has proven to produce reliable results and can be used as an alternative by the operator:

- GAFTA 124, rules for sampling and analysis instructions for grain, feeding stuff raw materials, cereal by- products, pulses, seeds and rice

**b) The finished feed materials (co- products from maize starch processing)**

The operator shall formulate a monitoring plan for the finished feed material (such as feed materials with the numbers 1.2.2 to 1.2.17 in the European Catalogue of feed materials) based on the operators risk assessment in line with the EFISC code §4.4.3. As part of the risk assessment the operator will define the processing factor for each specific maize co- product and type of mycotoxin, based on literature and his processing line and process characteristics.

### **8.1 Sampling requirements**

The operator has to ensure that the final samples taken can be considered as representative of the batch and are taken in accordance with the sampling and analysing methods given in §8 §a)or b) as applicable.

The samples will be taken by an independent sample taker from an organization which is certified for ISO 17020 or alternatively, ISO 9001 in combination with GAFTA (GTAS).

\*Trucks can be sampled by a trained sample taker at location, trained and experienced in the relevant protocol as given above, in line with the requirements in the EFISC Code §4.4.3.1.

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<sup>1</sup> Analysis performed in line with this protocol within a period of three months before de- loading at the processing facility (See §7)

#### **Guidance sampling incoming maize (food grade)**

- The number of incremental samples will vary with the size of the sampled batch in line with §8
- Each aggregated sample shall give the final sample.
- The total weight of the incremental samples making up each aggregated sample shall be 10 kgs.
- This aggregated sample is milled and homogenised to provide for at least one 2 Kg sample of milled crude maize that is homogenized.
- This sample is reduced to about 1 Kg and then milled again and homogenized.
- From this sample two 500 gram samples are taken to use as: (1) a basic sample to extract the lab sample and (2) reference sample
- These samples shall be packed and sealed without delay. The reference sample will be kept in adequate storage for the period of three months in line with the EFISC Code § 4.4.3.1 Sampling.
- The EFISC certified operator will communicate these requirements on sample preparation to the sampler and the laboratory performing the analysis.
- The laboratory shall preferably make use of slurry homogenising (wet milling) instead of dry milling and homogenising, in order to further improve the reliability of the test results.

## 8.2. Analysis

The final sample will be analysed by an ISO 17025 accredited laboratory or internal lab, in line with the EFISC Code §4.4.3.3

The appropriate analyse method will be chosen, appropriate to the level of contamination (ELISA, HPLC, LC-MS/MS).

The remainder of each final sample should be sealed, labelled and stored.

The collected data will be sent by the operator to the European sector organization Starch Europe, in line with the requirements of the sector monitoring program.

The monitoring data can be shared with the customer on request.

## 9. Exceptions

If the operator purchases maize which has already been sampled and tested the fulfilment of sample requirements of this code is not required and the operator should apply the entry check program as described in the EFISC Code.

The situation is applicable if the supplier has conducted the sampling and analysis according to one of the recognized protocols as mentioned in §8. The analyse report on Mycotoxin for the respective batch has to be provided to the operator and should not be older than three months before arrival of the batch at the production facility (date of analyse results).

The batch number should be indicated on the certificate and traceability of the batch should be given at all times. If this is not the case or there is reason to suspect the transport and/ or storage conditions/ management the analysis has to be redone.

## 10. Related documents

- Regulation (EC) 401/2006- laying down the methods of sampling and analysis for the official control of the levels of Mycotoxins in food stuffs.
- Regulation (EC) 152/2009- laying down the methods of sampling and analysis for the official control of feed
- Regulation (EC) 691/2013 amending (EC) 152/2009 as regards methods of sampling and analysis (as of 1 January 2014)
- GAFTA 124- rules for sampling and analysis instructions for grain, feeding stuff raw materials, cereal by- products, pulses, seeds and rice