GMP+ International

GMO Controlled

GMP+ MI 105

Version EN: 6 August 2018

To be used in combination with:

GMP+ B100 *Feed Responsibility Management System*

GMP+ Feed Certification scheme

Feed Safety Worldwide

gmpplus.org

History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
3-8-2018	New document		After publication

Editorial note:
All changes in this version of the document are made visible. This is how you can recognize:
- New text
- ~~Old text~~
The changes must be implemented by the participant latest at the final implementation date.

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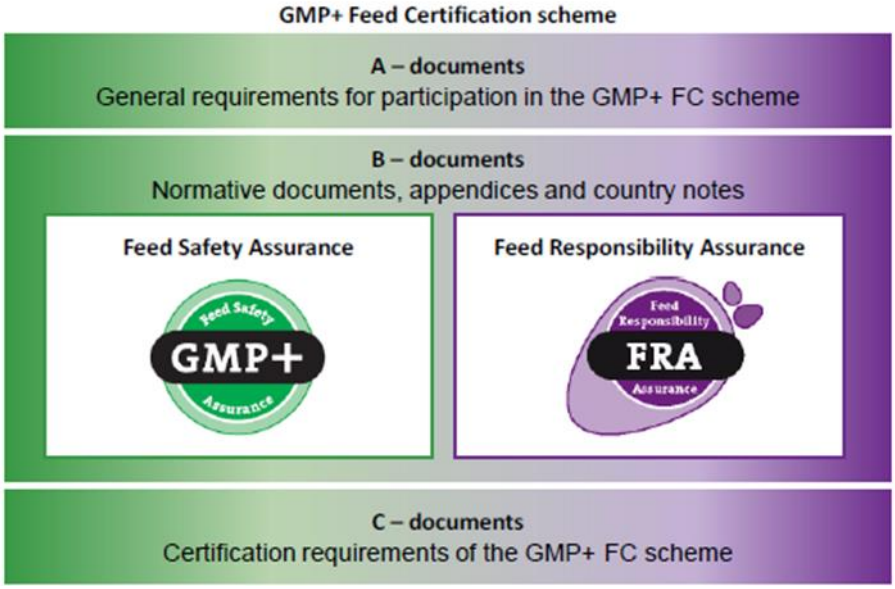
1. Introduction

1.1. GMP+ FRA certification

The GMP+ Feed Certification scheme was initiated and developed in 1992 by the Dutch feed industry in response to various more or less serious incidents involving contamination in feed materials. Although it started as a national scheme, it has developed to become an international scheme that is managed by GMP+ International in collaboration with various international stakeholders.

Even though the GMP+ Feed Certification scheme originated from a feed safety perspective, in 2013 the first feed responsibility standard has been published. For this purpose, two modules are created: GMP+ Feed Safety Assurance (focused on feed safety) and GMP+ Feed Responsibility Assurance (focused on responsible feed).



With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests by GMP+ participants. The animal feed sector is confronted with requests on working responsibly. This includes, for example, the use of soy (including soy derivatives and soy products) and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance. The main goal of the GMP+ Feed Responsibility Assurance module is to facilitate GMP+ participants in meeting these market requirements for responsibly produced feed.

1.2. GMP+ FRA Framework & plugin market initiatives

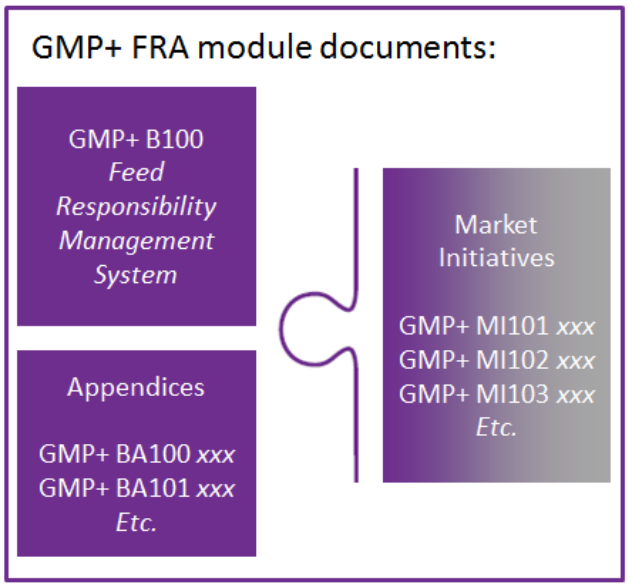
Within the GMP+ Feed Responsibility Assurance module, various market initiatives can be facilitated. GMP+ International created the 'GMP+ FRA Framework' in which these market initiatives can be plugged in.

This basic framework consists of the following elements:

1. *Feed Responsibility Management System*:
   - Management system
   - Prerequisite program
   - Risk assessment and control
   - Purchasing / sourcing
   - A material accounting system for the control of one or more supply chain model.
2. *Certification System*:
   - Third party certification (by approved certification bodies)
   - Qualified auditors
   - Clear rules for audit and certification
   - Supervision (compliance audits) and integrity program.

The several market initiatives of chain partners regarding responsible feed production can be integrated in ('plugged in') this GMP+ FRA framework and together it will form a full standard with several scopes.

Below a visual of how the GMP+ FRA framework in combination with market initiatives is organised in documents in the GMP+ FRA module:



The GMP+ B100 *Feed Responsibility Management System* contains the requirements for the Feed Responsibility Management System and is used to control the requirements of a market initiative in one (or more) of the GMP+ MI documents. The GMP+ MI documents therefor contain a reference to the GMP+ B100 *Feed Responsibility Management System* and contain the scope(s).

All these documents are available via the website of GMP+ International (www.gmpplus.org).

This document is referred to as GMP+ MI105 *GMO controlled* and is part of the GMP+ FRA module.

1.3. GMP+ MI 105 GMO controlled

1.3.1. GMP+ MI 105 GMO controlled

As a result to the market demand for non-GMO feed within the European Union (EU) GMP+ International has created the GMP+ MI105 *GMO controlled* standard. This in order to facilitate feed companies to comply with the market demand.

Consumer perception plays an important role in the demand for non-GMO food (and feed). At present many (inter)national non-GMO standards are applied in the feed sector. The German VLOG standard has set a standard for the food and feed sector in parts of Europe. Therefore, GMP+ International has chosen to collaborate with VLOG to be able to facilitate the demand especially in Europe.

Legislation has been published in various countries, including Germany and France, to label products from animal origin (meat / milk / egg) as non-GMO. Such labelling also means that specific requirements are imposed on the chain upstream, including the animal feed industry. Conditions

relating to the production of non-GMO food from animal origin require the use of GMO controlled feed. To provide animal feed suppliers with the opportunity to supply GMO controlled feed to farmers who deliver non-GMO end products (meat / milk / egg) to markets where legislation allows such labelling, the GMP+ MI105 *GMO controlled* standard was developed.

1.3.2. Regulations (EC) No. 1829/2003 and 1830/2003

The VLOG Standard is based on the GMO labelling provisions of Regulations (EC) 1829/2003 and 1830/2003. Contamination with GMOs permitted in the EU by law does not require labelling according to Regulations (EC) No. 1829/2003 and No. 1830/2003 provided that two requirements are fulfilled:

· The threshold value of the GMO content of 0.9% per feed material is not exceeded and
· The presence of the GMO content is "adventitious or technically unavoidable".

Contamination with approved GMO content < 0.1% are generally considered as technically unavoidable or adventitious. Contamination present in quantities from 0.1% to 0.9% is considered as labelling-compliant if the business has installed and demonstrably implemented organizational measures to avoid introduction of GMO material.

1.3.3. Verband Lebensmittel ohne Gentechnik (VLOG)

VLOG - Verband Lebensmittel Ohne Gentechnik provides a non-GMO standard which includes requirements for the production of products from animal origin without the use of GMO feed ingredients. The VLOG standard supports production facilities in the implementation of the German legal requirements of non-GMO labelling and establishes uniform inspections for certification companies. It is based on the German EC Engineering Act (EG-GentDurchfG).

GMP+ International worked together with Verband Lebensmittel ohne Gentechnik (VLOG) on the GMP+ MI 105 *GMO controlled*.

1.3.4. Scope

Within this standard the following scope is defined:

"GMO controlled"

This standard can be used for:

- the production of GMO controlled compound feed and feed materials
- the trade of GMO controlled compound feed and feed materials
- the storage and transshipment of GMO controlled compound feed and feed materials
- the transport of GMO controlled compound feed and feed materials

1.3.5. Application

The GMP+ MI 105 *GMO controlled* must be used in combination with the GMP+ B100 *Feed Responsibility Management System* document. The two documents together contain all the necessary requirements to comply with the scope mentioned in 1.3.4. More information about this combination can be read in paragraph 1.2.

Guidance:
Although, as stated above, stand-alone certification as 'GMP controlled' is possible based on application of the standards GMP+ B100 Feed Responsibility Management System and *GMP+ MI105 GMO controlled, for most feed companies certification as 'GMP controlled' will be additional to certification for scopes of the Feed Safety Assurance (FSA) module.*

To facilitate this multiple certification, GMP+ International has integrated certification for both feed safety assurance and feed responsibility assurance in a single certification scheme (the GMP+ Feed Certification scheme). This prevents overlap of requirements, ensures uniformity in standards and conditions and allows for limiting the (administrative) burden of audits and certifications. One (successful) audit can result in certification of multiple scopes.

A feed company, already GMP+ certified for one or more of the feed safety assurance scopes, can apply this GMP+ MI105 standard in combination with one of the standards of the GMP+ Feed safety Assurance module.
However, it is the responsibility of the feed company to identify the overlap between the GMP+ FSA standard and the GMP+ B100 standard, and to implement all relevant conditions into one management system which ensures both compliance with the feed safety standards and the GMP+ MI105 GMO controlled.
Compliance will be verified during the audit.

Finally, a feed company may also apply the GMP+ MI105 GMO controlled in combination with other standards. Also in this situation, the feed company is responsible for compliance with all relevant conditions.

Storage and transshipment companies and transport companies can only use the standards GMP+ MI 105 *GMO controlled* and GMP+ B100 *Feed Responsibility Management System* in combination with GMP+ FSA certification for the scopes storage and transshipment and transport respectively.

Guidance:
In this GMP+ MI105 GMO controlled there are no additional, specific storage and transshipment and transport requirements regarding non-GMO assurance given. The rationale behind this is that the requirements for storage and transshipment and transport in the VLOG-standard are already fully covered.

- *Internal storage/transport: The GMP+ B100 Feed Responsibility Management System, which is the core standard with requirements for a management system, requires already that any internal storage or transport must be covered under the scope of the management system.*
  - *See for this GMP+ B100 Feed Responsibility Management System, article 4.1.3.*
  - *See guidance above for application of the GMP+ MI105 GMO controlled in combination with GMP+ B100.*

- *External storage/transport: GMP+ FSA certification for the scopes storage and transshipment and transport assure that the storage and transport requirements of the VLOG-standard are met.*

1.3.6. How to read this document

The GMP+ MI 105 *GMO controlled* gives only additional requirements to the requirements of the GMP+ B100 *Feed Responsibility Management System*. These requirements are relevant for the scope of the GMP+ MI105 *GMO controlled*.

The structure of this GMP+ MI105 *GMO controlled* follows the same structure as the GMP+ B100 *Feed Responsibility Management System*. Only when there is an additional requirement to a certain paragraph of the GMP+ B100 *Feed Responsibility Management System*, this is added in the GMP+ MI105 *GMO controlled*. For convenience, the numbering and names of the paragraphs of this GMP+ MI105 *GMO controlled* correspond with the relevant paragraphs in the GMP+ B100 *Feed Responsibility Management System*. These additional requirements are extracted from the VLOG standard.

3 Terms and definitions

In addition to the terms and definitions mentioned in GMP+ A2 *Definitions and Abbreviations* of the GMP+ FC scheme the following terms are used in this document:

Term	Description
At risk feed	Feed which, based on the participant's risk assessment, has an increased risk of GMO content.
Feed exempt from mandatory labelling	Feed which, according to Regulations (EC) No. 1829/2003 or 1830/2003, is not subject mandatory labeling as genetically modified.
Feed subject to mandatory labelling	Feed which, according to Regulations (EC) No. 1829/2003 or 1830/2003, has to be labelled as genetically modified.
GMOs	Genetically modified organisms; according to Regulation (EC) No. 2001/18 these are organisms in which the genetic material has been modified by means of molecular biological methods in a way that naturally is not possible by interbreeding and/or recombination.
GMO controlled feed	Feed which is produced and/or traded in compliance with the requirements of this GMP+ MI 105 *GMO controlled* standard.
Market initiative	A market party that laid down in a GMP+ MI document (sector specific) requirements regarding responsible feed. These market initiative requirements are assured via the GMP+ B100 *Feed Responsibility Management System*.
Non-compliant products	Feed materials and/or compound feed which are subject to mandatory labelling according to Regulations (EC) No. 1829/2003 or 1830/2003
Segregation	A supply chain model where the certified responsible feed is kept physically separate from the uncertified feed throughout the entire supply chain.

4 System requirements

4.1 Management system

These requirements are in addition to the GMP+ B100 *Feed Responsibility Management System*.

4.1.3 Requirements for the management system

The participant determines and documents which feed materials and/or compound feed are covered within the scope of the management system.

Guidance:
The GMP+ B100 Feed Responsibility Management System requires a supply chain model to be included in documentation. This is not applicable as segregation is the only supply chain model that can be used in the GMP+ MI105 GMO controlled.

4.2 Prerequisite programme

These requirements are in addition to the GMP+ B100 Feed Responsibility Management System.

4.2.1 Personnel

The participant performs the required training at least once per year and in any case before the relevant employee starts with the activities which may have an influence on the production and/or trade of GMO controlled feed.

4.2.3 Recall

The participant has a written recall procedure which can be used within the framework of handling positive results and complaints.

4.3 Risk assessment

These requirements are in addition to the GMP+ B100 Feed Responsibility Management System.

4.3.1 Additional requirements for trade

The participant who buys a feed material from a non-certified supplier in which genetic modification can be technically detected through PCR tests and sells this feed material as GMO controlled must also comply with the requirements in 4.3.2.

4.3.2 Additional requirements for production

The participant is required to make an individual, batch-specific risk assessment of risk/ not at risk feed materials, which are used within the scope of GMO controlled feed.

Guidance:
An "Assessment Aid – At Risk Feed" is available on the VLOG homepage (under 'Further Documents / Instructions) to assist the feed business. This document includes a table which provides an overview of where growing genetically modified plants is allowed and thus possible at-risk feed origin.

Note: According to the VLOG standard livestock farmers are required to classify feed containing the following feed materials as "at risk": soya, corn, rapeseed oil and cotton. Sugar beet is to be considered as "at risk" under specific circumstances. These circumstances are explained in the document "Risk Grading Sugar Beet, which is available on the VLOG homepage (under 'Further Documents / Instructions).

4.4 Purchasing requirements

These requirements are in addition to the GMP+ B100 Feed Responsibility Management System.

4.4.1 Selection of suppliers

The participant must purchase feed and/or services from a supplier according to the below specifications:

Purchase of	Accepted certificates - scopes:	Additional requirements
Feed materials	GMP+ MI 105	-
	VLOG – Ohne Gentechnik	-
	Certificates accepted by VLOG as equivalent	-
	As an exception to the requirement that suppliers must be selected with an accepted certificate, it is allowed to select a supplier who has no accepted certificate.	As long as the participant has a confirmation from the supplier of the non-GMO status of the purchased feed material.
Compound feed	GMP+ MI 105	-
	VLOG – Ohne Gentechnik	-
	Certificates accepted by VLOG as equivalent	-
	As an exception to the requirement that suppliers must be selected with an accepted certificate, it is allowed to select a	As long as the participant has a confirmation from the supplier of the non-GMO

	supplier who has no accepted certificate.	status of the purchased compound feed.
Storage and transshipment	GMP+ MI 105	-
	GMP+ B1/B3 - storage and transshipment of animal feed (or equivalent)	-
	VLOG – Ohne Gentechnik	-
	Certificates accepted by VLOG as equivalent	-
	As an exception to the requirement that suppliers must be selected with an accepted certificate, it is allowed to select a supplier who has no accepted certificate.	As long as the purchase of storage and transshipment is in accordance with the requirements as stated in the GMP+ FSA BA10 Annex 10
Transport	GMP+ MI 105	-
	GMP+ B4 - transport of animal feed (or equivalent)	-
	VLOG – Ohne Gentechnik	-
	Certificates accepted by VLOG as equivalent	-
	As an exception to the requirement that suppliers must be selected with an accepted certificate, it is allowed to select a supplier who has no accepted certificate.	As long as the purchase of transport is in accordance with the requirements as stated in the GMP+ FSA BA10 Annex 9.
Production or processing on contract basis	GMP+ MI 105	-
	VLOG – Ohne Gentechnik	-
	Certificates accepted by VLOG as equivalent	-

Guidance:

The standards, which VLOG has recognized as equivalent to the VLOG – Ohne Gentechnik standard are available on the VLOG homepage (under 'Further Documents / Instructions).

Feed can only be labelled and sold as GMO controlled feed by a company that is certified in compliance with the requirements in this standard.

For packaged GMO controlled feed it is not an obligation to purchase certified transport, certified storage and/or certified transshipment.

The participant may purchase feed materials and/or compound feed from a non-certified supplier and place it on the market as GMO controlled in compliance with the requirements of this standard.

4.4.2 Verification of incoming goods

4.4.2.1 Additional requirements for production

For each feed material classified as 'at risk' in the risk assessment, a confirmation of the non-GMO status from the supplier is required. This may be done by one or more of the following examples:

- A valid certificate in accordance with the GMP+ MI 105 *GMO controlled* (or equivalent) standard together with a declaration about the non-GMO status of the batch/lot being delivered.
- A test result according to the requirements of the GMP+ MI 105 *GMO controlled* (or equivalent) standard proving the non-GMO status of the batch/lot being delivered.
- An additional indication on the delivery slip declaring the products to be exempt from mandatory labelling.
- A clear contractual agreement regarding the delivery of feed exempt from mandatory labelling.

Furthermore, for feed additives and processing aids, to be processed in GMO controlled compound feed and feed materials it must be documented in writing that they are not subject to mandatory labelling obligations.

Guidance:
The participant should verify that the incoming goods are exempt from mandatory labelling in accordance with Regulations (EC) 1829/2003 and 1830/2003.

Compound feed producers may apply the above mentioned requirements for their trading activities.

4.4.3 Services

In case of outsourcing activities to third parties (for example subcontracts for storage, transport or other services), the participant:

a. ensures that this activity is purchased in compliance with the purchasing requirements in 4.4.1., and
b. provides the third party with written instructions to ensure compliance with the requirements in this standard.

4.5 Informing the customer & delivery requirements

These requirements are in addition to the GMP+ B100 Feed Responsibility Management System.

4.5.1 Inform the customer about the status of the feed

Guidance
An additional option for the participant to demonstrably inform about the status of the feed is by using the wording "GMO controlled" for the feed materials and/or compound feed assured under his GMP+ feed responsibility management system.

Note: According to the VLOG standard livestock farmers demand a statement from their feed suppliers about the non-GMO status of the feed they receive.

The system must assure that feed materials and/or compound feed which are subject to mandatory labelling are labelled in accordance with Regulations (EC) 1829/2003 or 1830/2003.

Note: For the use of logo's and trademarks, see GMP+ A3 *GMP+ Logo's and/or Trademarks*.

Guidance
The VLOG document "Guideline for monitoring GMOs in feed" gives examples of situations where mandatory labelling is required or not. This guideline is available on the VLOG homepage (under 'Further Documents / Instructions) to assist the feed business.

4.6 Verification and improvement

These requirements are in addition to the GMP+ B100 Feed Responsibility Management System.

4.6.1 Complaints

Guidance
Measures to be taken as a result of the complaint may include the labelling and blocking of products.

5 Supply chain models

These requirements are in addition to the GMP+ B100 Feed Responsibility Management System.

Guidance:
Only 5.2.1 and 5.2.2 of the GMP+ B100 Feed Responsibility Management System are relevant and can be applied for the scope of the GMP+ MI 105 GMO controlled.

5.2 Segregation

Vehicles must be demonstrably dry cleaned after transporting bulk raw materials or feed labelled as genetically modified pursuant to Regulations (EC) No. 1829/2003 and 1830/2003.

Guidance:
This requirement for cleaning after transport of agricultural products is already included in the GMP+ FSA certification.

6 Sampling and testing

6.1 General

Sampling is done in compliance with relevant EU legislation and/or already accepted sampling standards.

Guidance:
Accepted sampling standards are for example GAFTA and FOSFA.

6.2 Monitoring plan

6.2.1 Feed in which genetic modification cannot be detected

If the participant only uses feed in which, due to technical limitations, genetic modification cannot be detected through PCR tests, no sampling/GMO test is necessary. This should be concluded from the risk assessment.

Guidance:
The VLOG document The VLOG document "Suitability of GMO Analysis for Feed and Raw Materials" explains which in products GMOs can and cannot be detected. This document is available on the VLOG homepage (under 'Further Documents / Instructions)

6.2.2 Feed in which genetic modification can be detected

The participant must have a monitoring plan that describes the sampling and testing procedure. This plan must be carried out annually. The monitoring plan must at least contain:

1. Requirements to sample takers
2. Sampling method
   - Product to be sampled
   - Place of sampling
   - Method of taking final samples and retained samples
   - Sample size and number of samples
   - Sealing and identification
3. Storage duration of samples
4. Recording of samples
5. Sampling frequency

6.2.2.1 Requirements to sample takers

The sample taker complies with the requirements for samplers as laid down in GMP+ BA13 *minimum Requirements for Sampling*.

6.2.2.2 Storage duration of samples

The storage duration of samples matches the use and shelf life of the sampled product.

6.2.2.3 Sampling and testing frequency

The frequency of sampling and testing is based on the participant's' individual risk assessment and is in compliance with the requirements in Annex 1. For each outgoing batch, at least one retained sample is taken.

A trader may make use of representative samples and testing results from the producer (supplier).

Each final sample is tested.

Guidance:
The auditor is authorized to take additional samples and/or carry out additional GMO tests on a risk-targeted basis or in suspicious cases.

6.2.2.4 Sample preparation and analysis until January 1st 2019

The participant is responsible for instructing the laboratory that carries out the testing on GMOs. The preparation and analysis by the laboratory are in accordance with the following conditions:

a. Milling

Depending on the sample matrix, the following minimum amounts of sample material are to be completely milled in each case:

- Feed: min. 400 g, max. 1 kg, entirely milled
- Raw materials (whole maize/corn kernels, soy beans or rapeseed/canola grains, among other): at least 3000 grains or approx. the respectively corresponding sample amount (maize/corn at least 1000 g; soy at least 700 g, rapeseed/canola at least 60 g), entirely milled

Guidance:
The sample size as required in the GMP+ MI 105 GMO controlled is larger than the sample size as required under GMP+ FSA certification as stated in the GMP+ BA13 Minimum Requirements for Sampling.

b. DNA extraction

At least two DNA extractions from each sample will be carried out after every milling/homogenization. The required weight of each sample is at least 2000 mg for feed, seeds and materials that are suspected of being not being homogenously distributed. In exceptional cases (for otherwise non-extractable material), the weight may be only 500 mg.

c. Analysis

The sample for testing is tested on GMOs in compliance with the requirements in Annex 2.

d. Laboratory

The testing is carried out by a laboratory accredited for ISO 17025 with GMO testing covered under the scope of the accreditation.

6.2.2.5 Sample preparation and analysis after January 1st 2019

The testing on GMOs is carried out by a laboratory recognized by VLOG.

> *Guidance:*
> *The sample size as required in the GMP+ MI 105 GMO controlled is larger than the sample size as required under GMP+ FSA certification as stated in the GMP+ BA13 Minimum Requirements for Sampling.*

When commissioning a laboratory, the following information must be indicated in the order or other documents having similar effect, and submitted to the laboratory:

· Order of GMO tests according to the VLOG requirements for laboratories as stated in the VLOG standard

· Composition of the sample:

If containing soy, maize/corn, rapeseed/canola and/or rice feed material or ingredients, it must be indicated in what form these are contained (e.g. maize/corn as maize/corn mash, soy as soy extraction meal) and the composition of the compound feed.

Upon receipt of the test results, the laboratory is still recognized by VLOG.

6.3 Handling of positive test results

The participant must establish a system for handling positive test results. This shall include appropriate measures like the labelling/blocking of non-compliant products and a recall procedure.
In case of contamination, appropriate corrective action must be initiated and documented. The effectiveness is to be reviewed as part of self-monitoring.

Positive test results are to be handled according to Annex 3.

Annex 1 Sampling and testing

The tables below specify the sampling frequency for GMO controlled feed materials and compound feed. The sampling frequency applies only to the products that fall under the scope of this standard.

The sampling frequency is calculated based on 88% dry matter content.

The sampling frequency is to be implemented by participants producing and/or trading GMO controlled feed materials and/or compound feed.

1. Producing companies

The table below provides the sampling frequency for participants producing GMO controlled feed material and compound feed.

	Incoming goods	**Outgoing goods**
Production activity on location participant	**- Feed material**	**- GMO controlled feed material* - GMO controlled compound feed**
Production completely exempt from mandatory labelling	1 sample of every batch of at risk feed material	< 10,000 t/year: 1 sample ≥ 10,000 to 50,000 t/year: 2 samples ≥ 50,000 to 100,000 t/year: 4 samples ≥ 100,000 to 200,000 t/year: 6 samples ≥ 200,000 to 300,000 t/year: 8 samples For every additional 100,000t/year: 2 additional samples
Production of GMO controlled feed and non-GMO controlled feed subject to mandatory labelling	1 sample of every batch of at risk feed material	< 2,000 t/year: 1 sample ≥ 2,000 to 5,000 t/year: 3 samples ≥ 5,000 to 10,000 t/year: 5 samples ≥ 10,000 to 50,000 t/year: 10 samples ≥ 50,000 to 100,000 t/year: 15 samples ≥ 100,000 to 200,000 t/year: 20 samples ≥ 200,000 to 300,000 t/year: 25 samples For every additional 100,000 t/year: 5 additional samples.

* Participants who only produce feed materials not subject to mandatory labelling can dispense with sampling of the outgoing feed materials if corresponding test was performed on the incoming goods.

2A. Trading companies

The table below provides the sampling frequency for participants trading GMO controlled feed material and compound feed.

	GMO controlled feed materials and/or compound feed present on location participant	
	Bulk	**Packaged**
Products present on location participant and/or subcontracted storage location	**Annual minimum number of samples/tests for <u>outgoing</u>**	
<u>Only</u> bulk GMO controlled feed material and/or compound feed	< 10,000 t/year: 1 sample ≥ 10,000 to 50,000 t/year: 2 samples ≥ 50,000 to 100,000 t/year: 4 samples ≥ 100,000 to 200,000 t/year: 6 samples ≥ 200,000 to 300,000 t/year: 8 samples For every additional 100,000t/year: 2 additional samples	No (additional) sampling
Bulk GMO controlled feed material and/or compound feed <u>and</u> bulk feed exempt from mandatory labelling		
Bulk GMO controlled feed material and/or compound feed <u>and</u> bulk feed subject to mandatory labelling <u>and</u> if participant does not know which products are present at the subcontracted storage location	< 2,000 t/year: 1 sample ≥ 2,000 to 5,000 t/year: 3 samples ≥ 5,000 to 10,000 t/year: 5 samples ≥ 10,000 to 50,000 t/year: 10 samples ≥ 50,000 to 100,000 t/year: 15 samples ≥ 100,000 to 200,000 t/year: 20 samples ≥ 200,000 to 300,000 t/year: 25 samples For every additional 100,000 t/year: 5 additional samples	No (additional) sampling

2B. Trading companies converting into GMO controlled feed material

The table below applies to the participant, as meant in paragraph 2.3.2 above, who buys a feed material from a non-certified supplier in which genetic modification can be technically detected through PCR tests and sells this feed material as GMO controlled.

	Incoming goods	Outgoing goods
Trading activity on location participant	**Feed material**	**GMO controlled feed material**
Only bulk GMO controlled feed material which is exempt from mandatory labelling	1 sample of every batch of at risk feed material	< 10,000 t/year: 1 sample ≥ 10,000 to 50,000 t/year: 2 samples ≥ 50,000 to 100,000 t/year: 4 samples ≥ 100,000 to 200,000 t/year: 6 samples ≥ 200,000 to 300,000 t/year: 8 samples For every additional 100,000t/year: 2 additional samples.
Bulk GMO controlled feed material and bulk feed subject to mandatory labelling and, if applicable, bulk feed exempt from mandatory labeling	1 sample of every batch of at risk feed material	< 2,000 t/year: 1 sample ≥ 2,000 to 5,000 t/year: 3 samples ≥ 5,000 to 10,000 t/year: 5 samples ≥ 10,000 to 50,000 t/year: 10 samples ≥ 50,000 to 100,000 t/year: 15 samples ≥ 100,000 to 200,000 t/year: 20 samples ≥ 200,000 to 300,000 t/year: 25 samples For every additional 100,000 t/year: 5 additional samples.

Annex 2 GMO tests

1. Minimum requirements for raw materials / feed material

1.1. Minimum requirements for soy and soy products

Determination and assessment of the summation value of the most relevant soy GMOs:

- Quantification of GTS 40-3-2 (RRS- 1)
- Quantification of MON89788 (RRS-2)
- Qualitative detection of A2704-12

  In the event of positive result for A2704, the quantity of this GMO can, for example, be estimated using the ΔΔct method or similar method ensuring that sufficient quantities of species DNA are present. For values over 0.1%, a quantification must be carried out.

Alternately, the laboratory may work with screening parameters that detect at least the GMOs mentioned. In subsequent identification / quantification of positive findings, at least all GMOs (if corresponding elements are positive) mentioned here must be quantified.

1.2. Minimum requirements for corn and corn products

1. Screening for 35S Promoter (p35S) and NOS Terminator (tNOS).

Other screening elements can be implemented to narrow the corresponding GMO down.

2. If positive**:** Analysis at least for NK603, TC1507, MON810, MON89034 + RRS-1 (RRS= soy)

If using the positive screening parameters, one or more of these GM corn types can be ruled out, then the same number of commercialized GM corn types that come into question must be searched for instead.

Positive screening results must be clarified; if none of the 4 GM corn types are positive, other GM types must be analyzed.

3. Determining the summation value of the corn GMO

Identified varieties must be quantified if the estimation of the concentration, when using, for example, the ΔΔct method or another similar method ensuring that sufficient quantities of species DNA are present, leads to values over 0.1%.

RRS-1 positive:

Estimating the soy mass and assessing the amount of soy: Is it a relevant amount or minimal traces? If a botanical contamination containing GMO is determined, an assessment according to the official guideline (concerns botanical impurity) must take place.

1.3. Minimum requirements for canola and canola products

1. Triple screening that detects all relevant GM canola varieties (e.g. tNOS, pat gene (or LibertyLink construct), CTP2-CP4epsps (or pFMV))
2. ID depending on positive screening results
· tNOS positive: at least RRS + bar gene for MS8 / RF3 or both directly
· pat gene / LibertyLink positive: at least canola T45
· CTP2-CP4epsps / pFMV positive: at least GT73
3. Determining the summation value of GM canola
Identified GM canola varieties must be quantified if the estimation of the quantity, when using, for example, the ΔΔct method or another method ensuring that sufficient quantities of species DNA are present, leads to values over 0.1%.

Positive screening results must be clarified.

If no canola GMO is detected, the presence of a botanical contaminant containing GMO with soya or corn GMO must be clarified (estimation and assessment of masses). Is it a relevant quantity or minimal traces? If a botanical contamination containing GMO is determined, an assessment according to the official guideline
must take place.

1.4. Minimum requirements for rice and rice products
1. Preparation of laboratory samples:
Two subsamples of at least 250 g each are to be created from the laboratory sample sent, and each is to be analyzed separately (1 extraction, 2 PCRs per subsample:).
2. Element-specific screening:
p35S + tNOS + cry1Ab/cry1Ac sequence
3. Design-specific proof:
Identification, by agreement between the company and the laboratory, of GMO events that cause a positive screening result (see 1).

4. Exclusion of botanical impurities (GMO carryovers from other plant species) from corn, soy, cotton and (naturally occurring) Cauliflower Mosaic Virus

If the element-specific screening yields a positive result, design-specific proof is to be provided as the next step. In combination with the exclusion of botanical impurities and the Cauliflower Mosaic Virus, an investigation is to be made of whether the sample contains genetically modified rice.

5. Evaluation of the PCR results:
If the targeted sequence of genetically modified rice is proven for at least one of the subsamples analyzed, this result is to apply to the entire sample and the batch.

2. Minimum requirements for compound feed

2.1. Minimum requirements for compound feed containing soya

Determination and assessment of the summation value of the most relevant GMOs:

Soy:

· Quantification of GTS 40-3-2 (RRS-1)
· Quantification of MON89788 (RRS-2)
· Qualitative detection of A2704-12

In case of positive result for of A2704, the quantity of this GMO can, for example, be estimated using the ΔΔct method or a similar method ensuring that sufficient quantities of species DNA are present. For values over 0.1%, a post-quantification must be carried out.

In case of limited analyzability of the soya ingredient, the practical LOD must be indicated.

Guidance: *Summarize the events that are analyzed. Together they should meet the requirements*.

For corn ingredient:

Additional qualitative detection of the 3 commercialized corn varieties: NK603, TC1507, MON810

In case of positive result, the quantity of this GMO can, for example, be estimated using the ΔΔct method or a similar method ensuring that sufficient quantities of species DNA are present. For values over 0.1%, a post quantification of the GMOs detected must be carried out.

In the event of limited analyzability of the corn ingredient, the practical LOD must be indicated.

For canola ingredient:

Additional qualitative detection of GT73

In case of positive identification, quantification of GT73 must take place if the estimation of the quantity using, for example, the ΔΔct method or another similar method ensuring that sufficient quantities of species DNA are present, leads to values over 0.1%.
In case of limited analyzability of the canola ingredient, the practical LOD must be indicated.
Alternately, the laboratory may also work with screening parameters that detect at least the GMOs mentioned (soy, canola, corn). In subsequent identification / quantification of positive results, at least all GMOs (if corresponding elements are positive) mentioned here must be identified and, if necessary, quantified.

2.2. Minimum requirements for soy-free compound feed

Determination and assessment of the summation value of the most relevant GMOs:

Estimating the soy mass:

In a first step, the mass of soy in the feed is estimated. For quantities over 0.9%, the quantity of soy GM must be determined (cf. Minimum requirements for feed containing soy) and an assessment according to the official guideline must take place.

For canola ingredient:

Qualitative evidence of canola GT73 + canola MS8 or canola RF3 (or bar gene)

In the event of positive identification, quantification of GMO or GMOs found must take place if the estimation of the quantity when using, for example, the ΔΔct method or another similar method ensuring that sufficient quantities of species DNA are present, leads to values over 0.1%.

In the event of limited analyzability of the corn ingredient, the practical LOD must be indicated.

For corn ingredient:

Qualitative evidence of 3 corn varieties used commercially: NK603, TC1507, MON810

In the event of positive identification, quantification of GMO or GMOS found must take place if the estimation of the quantity when using, for example, the ΔΔct method or another similar method ensuring that sufficient quantities of species DNA are present, leads to values over 0.1%.

In the event of limited analyzability of the corn ingredient, the practical LOD must be indicated.

Alternately, the laboratory may work with screening parameters that detect at least the GMOs mentioned (soy, canola, corn). In subsequent identification / quantification of positive results, at least all GMOs (if corresponding elements are positive) mentioned here must be identified and, if necessary, quantified.

3. Other products / raw materials

The strategies for analyzing GMOs in other feed materials and compound feedmust continue to be agreed upon with the commissioned laboratory, taking into account the composition and origin of the products.

Annex 3 Evaluation of test results and measures to be taken

Second or third analyses of the sampled batch are permitted, but must be performed immediately (express analysis). If two test results with different conclusions are obtained for a single sample, the following procedure is to be undertaken, resulting in a final finding:

- If the results overlap, taking into account the expanded measurement uncertainty, the average value of the two test results is used.
- If the results do not overlap, taking into account the expanded measurement uncertainty, a third test of the batch is ordered.

The customer is informed (on request) periodically about positive test results related to the delivered batches and receives a summary or overview of the results.

In the event of inaccurately labelled delivered feed or food product, the producer's customers and certification body must be notified with at least the information as mentioned in the table below.

The internal auditor examines whether the analytical test results were evaluated correctly and any necessary (corrective) measures were properly implemented.

In case the test result of a feed material or compound feed is between 0.1% and 0.9% GMO (0.1% GMO < x ≤ 0.9% GMO), then the participant

a. Informs the (feed) supplier
b. takes the measures for improvement and validation The results of the validation are documented and are available upon request.

In case the test result of a feed material or compound feed is above 0.9% GMO, then the participant undertakes the following actions:

a. inform the (feed) supplier, and
b. in the case of rejection, notice to producers of „ohne Gentechnik" food products of animal origin

Guidance *With 'producers of „ohne Gentechnik" food products of animal origin' is meant the livestock farmer.*

The participant must provide his (feed) supplier and/or producers of „ohne Gentechnik" food products of animal origin with at least the information as mentioned in the table below.

Feed (exact name)	☐ Compound feed ☐ Feed material
Delivery date	
Batch identification number	
Number of delivery slip, if applicable	
Date of delivery slip, if applicable	
Date sample taken	
Place sample taken	
Unique sample identification (e.g. SampleID)	
Date of test report	
Species with finding of GMO content (e.g. soy, maize/corn, ...)	
Test result (PCR)*	Species: GMO positive, >0.9%; exact value: % of which Event 1 % Event 2 % Species: GMO positive, >0.9%; exact value: % of which Event 1 % Event 2 %
In the case of compound feed: Species with finding of GMO content declared as compound feed component?	☐ Yes If declared: Quantity of species: % ☐ No Quantified amount of species: %
Customer(s) affected, if applicable	

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