CR 3.0 Assessment and Certification of additional scopes

CR 3.0 Final Draft

Version EN: July 2020

GMP+ Feed Certification scheme 2020
Index

WELCOME .................................................................................................................. 4

1. SCOPE .................................................................................................................. 4

2. NORMATIVE REFERENCE(S) .............................................................................. 4

3. TERMS AND DEFINITIONS ................................................................................... 4

4. PROCESS REQUIREMENTS .................................................................................... 5
   4.1. PRE-CERTIFICATION ACTIVITIES .................................................................... 5
       4.1.1. Application .................................................................................................. 5
       4.1.2. Application review ..................................................................................... 5
       4.1.3. Certification agreement .............................................................................. 5
       4.1.4. Audit/Inspection team assignment .............................................................. 5
       4.1.5. Rotation of auditors/inspector .................................................................... 5
       4.1.6. Audit plan ................................................................................................... 6
   4.2. CERTIFICATION PROCESS ............................................................................. 6
       4.2.1. Audit/Inspection ......................................................................................... 6
           4.2.1.1. General .................................................................................................. 6
           4.2.1.2. Initial certification audit/inspection .......................................................... 7
           4.2.1.3. Temporary acceptance .......................................................................... 7
           4.2.1.4. Surveillance audits ................................................................................ 7
           4.2.1.5. Announced surveillance audits ............................................................... 7
           4.2.1.6. Unannounced surveillance audits ......................................................... 7
           4.2.1.7. Recertification audit .............................................................................. 7
           4.2.1.8. Expansion audits ................................................................................. 8
       4.2.2. Special audits / Inspections ....................................................................... 8
           4.2.2.1. Stricter supervision ............................................................................... 8
           4.2.2.2. Repeat audit / Inspection ..................................................................... 8
       4.2.3. Extraordinary events ................................................................................ 8
       4.2.4. Identifying and recording Audit/Inspection findings .................................. 9
       4.2.5. Audit report ................................................................................................ 9
       4.2.6. Review ....................................................................................................... 9
       4.2.7. Certification decision ................................................................................ 9
       4.2.8. Certificate/temporary Acceptance/Statement ........................................... 9
           4.2.8.1. Certificates .......................................................................................... 9
           4.2.8.2. Temporary acceptance ......................................................................... 10
           4.2.8.3. Certificate/temporary Acceptance Templates: .................................... 11
   4.3. SUSPENSION OR WITHDRAWAL OF A CERTIFICATE/TEMPORARY ACCEPTANCE .......... 14
   4.4. TRANSFER TO ANOTHER CERTIFICATION BODY ........................................ 14
       4.4.1. Pre-transfer review ................................................................................... 14
4.4.2. Certification process during transfer ................................................................. 14

5. EXCLUSION OF GMP+ INTERNATIONAL LIABILITY .............................................. 14

6. TARIFF ......................................................................................................................... 14

7. DISPUTES BETWEEN CERTIFICATION BODIES AND GMP+ CERTIFIED COMPANIES ...... 15

ANNEX 1: FREQUENCY AND AUDITS/ INSPECTION DURATION: ........................................ 16

ANNEX 2: FEED RESPONSIBILITY ASSURANCE (FRA) MULTI-SITE CERTIFICATION ........... 19

ANNEX 3: RELATED DOCUMENTS .................................................................................. 20
Welcome

This Feed Certification Scheme document helps you to provide feed safety worldwide. By meeting the requirements set by GMP+ International together with our GMP+ Community, we aim to help you get the feed certification you need. Please read the information in this document carefully.

Let’s make this work together!

1. **Scope**

This document contains assessment and certification/inspection criteria for:
- Feed Responsability Assurance Module (FRA) module,
- Inlandwaterway transport and short sea shipping of feed (based on ISO/IEC17020),
- Laboratory testing and registered laboratories (based on ISO/IECISO17025).

2. **Normative reference(s)**

The following documents, in whole or in part, are normatively referenced in this document and are mandatory to comply with. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- ISO/IEC 17021-1:2015 Conformity assessment – requirements for bodies providing audit and certification of management systems.
- NPR-ISO/TS 22003:2013 Food safety management systems – requirements for bodies providing audit and certification of food safety management systems.
- F 0.1 Rights and Obligations.
- F 0.3 Scope of certification.
- CR 1.0 Acceptation requirements.
- CR 2.0 Assessment and Certification.

3. **Terms and Definitions**

For GMP+ definitions see F 0.2 Definition list. Throughout this document the terminology “through the Certification Body” is used indicating that all activities performed by critical-, non-critical locations and outsourcing party are conducted under the responsibility/liability of the GMP+ accepted Certification Body.
4. Process requirements

4.1. Pre-certification activities

4.1.1. Application

<table>
<thead>
<tr>
<th>Relevant requirements must apply</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/IEC 17025:2017</td>
<td>Article 7.1</td>
</tr>
<tr>
<td>ISO/IEC 17020:2012</td>
<td>Article 7.1.1</td>
</tr>
</tbody>
</table>

In addition relevant details of the applicant organization conform ISO/IEC 17025:2017:
- Number of analysis
  - Accredited analysis,
  - Partly accredited analysis,
  - Not accredited analysis.

For FRA relevant details of the applicant organization including its name and addresses as specified in the official legal business registration by the competent authority and information as mentioned in Annex 1 of this document. In addition the 5th bullet of article 5.1.1. of the CR 2.0 Assessment and Certification applies.

4.1.2. Application review

<table>
<thead>
<tr>
<th>Relevant requirements must apply</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/IEC 17025:2017</td>
<td>Article 7.1</td>
</tr>
<tr>
<td>ISO/IEC 17020:2012</td>
<td>Article 7.1.1</td>
</tr>
</tbody>
</table>

The certification body must not exclude activities, processes, products and services from the scope of certification when these can have an influence on the feed safety. For FRA the application review is also mandatory.

4.1.3. Certification agreement

Article 5.1.3 of the CR 2.0 Assessment and Certification is applicable. In deviation on requirement 5.1.3.b, the minimum obliged audit/inspection duration per scope(s)/standard(s) as stated in Annex 1 of this document per audit type is applicable, referring to Annex 1 is insufficient.

4.1.4. Audit/Inspection team assignment

Persons who are performing the audit/inspection must comply with the applicable requirement of Annex 2 and Annex 3 (if applicable) of the CR 1.0 Acceptation requirements.

4.1.5. Rotation of auditors/inspector

Rotation of auditors scope laboratory testing:
• Once the certification cycle of 3 years is finalized, a new auditor has to be assigned through the Certification Body for the start of the new certification cycle. Should an alternative auditor not be available, an exemption can be made by the certification body and the period can be extended for a maximum of 1 extra certification cycle. The decision must be motivated and documented.

Rotation of auditors/technical expert scope registered laboratory:
• The auditor and technical expert may only perform the desk study of the same GMP+ Certified Company six consecutive times. Then rotation of the auditor and technical/material expert must take place.

Rotation of Inspector:
• A new inspector must be assigned after 3 consecutive inspections.

Rotation of FRA auditors:
• Article 5.1.4.1 of the CR 2.0 Assessment and Certification is applicable.

4.1.6. Audit plan
For FRA an audit plan for each type of audit must be send to the GMP+ Certified Company prior to the audit.
For the scope laboratory testing, audit on site, for each type of audit an audit plan must be sent to the GMP+ Certified Company prior to the audit.

4.2. Certification process

4.2.1. Audit/Inspection

4.2.1.1. General
Article 5.2.1.1. of the CR 2.0 Assessment and Certification is applicable. The minimum obliged audit/inspection frequency and duration are determined in Annex 1 of this document. In deviation of article 5.2.1.1.:

a) The assessment for the scope registered laboratories will be performed by means of a desk study (or on site if applicable).

b) The administrative assessment of the scope laboratory testing, if all analyses are accredited in accordance with ISO17025 must be performed once per year.

c) On site assessment of the scope laboratory testing if not all analyses are accredited in accordance with ISO17025 must be performed once per year for the non-ISO 17025 accredited analyses.

d) On site assessment of the scope laboratory testing if the laboratory is not accredited in accordance with ISO17025 must be performed once per year for system assessment.
4.2.1.2. Initial certification audit/inspection

<table>
<thead>
<tr>
<th>Relevant requirements must apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/IEC 17020:2012</td>
</tr>
</tbody>
</table>

An initial certification audit/inspection will be performed through the certification body in order to assess whether the company meets the criteria set out in Annex 1 of the CR 2.0 Assessment and Certification or in the GMP+ checklist inland waterway transport and short sea shipping of feed. The initial certification audit/inspection must be conducted within 3 months after concluding an certification agreement with the applicant organization.

Scope laboratory testing:
The initial certification audit is an assessment of the quality system/documentation. The most important analyses must be assessed during the initial certification audit. At least once during the audit cycle all analyses must be assessed.

4.2.1.3. Temporary acceptance

The text of article 5.2.1.3.1 of the CR 2.0 Assessment and Certification is applicable.

4.2.1.4. Surveillance audits

The first surveillance audit must be executed each 12 months, plus and minus 2 months, after the certification decision date.
The second surveillance audit must be executed each 24 months, plus and minus 2 months, after the certification decision date.

4.2.1.5. Announced surveillance audits

An announced surveillance certification audit will be performed during the period of validity of the GMP+ certificate through the certification body in order to assess whether the company meets the criteria set out in Annex 1 of the CR 2.0 Assessment and Certification. The frequency and duration of the announced surveillance audit are determine in Annex 1 of this document.

4.2.1.6. Unannounced surveillance audits

See article 4.2.1.5 above. In addition if the FRA module is audited together with the FSA module the audit will be unannounced for all scopes.

4.2.1.7. Recertification audit

Prior to the extension of validity of a certificate/statement an recertification certification audit/inspection must be carried out through the Certification Body.
A GMP+ certificate/statement may or may not be granted by the Certification Body based on the assessment criteria as specified in Annex 1 of the CR 2.0 Assessment and Certification or in the GMP+ checklist inland waterway transport and short sea shipping of feed are met.

If a recertification audit is not carried out before the expiration date of the validity of the certificate/statement, then an initial certification audit must be carried out. The company is in the intervening period not GMP+ certified.

### 4.2.1.8. Expansion audit

Article 5.2.1.6. of the CR 2.0 Assessment and Certification is applicable.

### 4.2.2. Special audits / Inspections

The following audits/inspections can be applicable, assessment must be done in accordance with Annex 1 of the CR 2.0 Assessment and Certification or the checklist inland waterway transport and short sea shipping of feed.

#### 4.2.2.1. Stricter supervision

Article 5.2.2.1. of the CR 2.0 Assessment and Certification is applicable.

#### 4.2.2.2. Repeat audit / Inspection

Article 5.2.2.2. of the CR 2.0 Assessment and Certification is applicable.

In deviation, the reason for a repeat inspection may be an EWS alert, complaints or incidents, or other special circumstances. In principle the repeat inspection is aimed on these reason(s) but can also be aimed at all requirements of the GMP+ Feed Certification scheme.

- a) GMP+ International may ask the Certification body to carry out a repeat inspection on short term in principle in the presence of a GMP+ International auditor and/or a technical expert.
- b) The repeat inspection must be carried out by a GMP+ inspector. The involved Certification body must motivate the choice of the GMP+ inspector and document its decision.
- c) The deadline will be assessed per case but ultimately determined by GMP+ International. The inspection will be on the vessel. Physical and/or administrative checks and a sampling may be carried out.
- d) The required appointments and communication on this will be made with the GMP+ Certified Company by the Certification body in consultation with GMP+ International.
- e) In principle the costs of the repeat inspection will be at the expenses of GMP+ International. However, if it appears that 1 or more requirements with text in the guidance “Non Conform” in the checklist are observed, the costs will be charged to the GMP+ Certified Company.

### 4.2.3. Extraordinary events

Article 5.2.3. of the CR 2.0 Assessment and Certification is applicable.
4.2.4.  Identifying and recording Audit/Inspection findings

<table>
<thead>
<tr>
<th>Relevant requirements must apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/IEC 17020:2012</td>
</tr>
</tbody>
</table>

If the applicant organization/GMP+ Certified Company does not comply with the applicable requirements of the GMP+ Feed Certification scheme, the sanctions as specified in Annex 1 of the CR 2.0 Assessment and Certification.

For the scope inland waterway transport and short sea shipping of feed the following applies:
If a “Not Conform” with a description is observed, a GMP+ certificate cannot be issued. The GMP+ certificate can only be issued if the “Not Conform” with a description is resolved.

4.2.5.  Audit report

<table>
<thead>
<tr>
<th>Relevant requirements must apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/IEC 17020:2012</td>
</tr>
</tbody>
</table>

The text of article 5.2.6. of the CR 2.0 Assessment and Certification is applicable.
In deviation, a checklist has to be completed for the scope inland waterway transport and short sea shipping of feed and uploaded in the GMP+ database within 8 weeks after the execution of the inspection on site. Within 8 weeks following the execution of the inspection on site, the final checklist must be sent to the GMP+ Certified Company together with any data from the certificate or the temporary acceptance. In the event of a repeat inspection, GMP+ International must have received the final checklist within 5 working days.

4.2.6.  Review

Article 5.2.7. of the CR 2.0 Assessment and Certification is applicable. In addition, review of the checklist inland waterway transport and short sea shipping of feed is mandatory.

4.2.7.  Certification decision

The certification decision must be based on:

a) For any type of nonconformities/non conforms, the certification body has reviewed, accepted and verified the correction and corrective actions;

b) Assessment or the applicant organization/GMP+ Certified Company took place in accordance with Annex 1 of the CR 2.0 Assessment and Certification and the checklist inland waterway transport and short sea shipping of feed. If in the description of nonconformities is referred to feed safety, for the FRA scopes, feed safety is not applicable.

c) The assessment and decision of a certification body must be demonstrably based on objective evidence of conformity and non-conformity obtained.

4.2.8.  Certificate/temporary Acceptance/Statement

4.2.8.1.  Certificates

A certificate has the following maximum validity:
• FRA certificates (all scopes) 3 years,
• Scope laboratory testing 3 years,
• Scope inland waterway transport and short sea shipping of feed 2 years,
calculated from the date of a positive certification decision. Within 8 weeks following the execution of the audit/inspection on site, the certification body will send the certificate to the applicant organization/GMP+ Certified Company. The duration of the GMP+ certificate must not exceed the validity of the certification agreement.

For multi-site see article 5.2.9.1 of the CR 2.0 Assessment and Certification.

4.2.8.2. Temporary acceptance

A temporary acceptance with a maximum period of validity of 4 months may be issued by the certification body. However, if during the initial certification audit on site (if applicable), the applicant organization does not appear to comply the GMP+ requirements conform Annex 1 of CR 2.0 Assessment and Certification then the temporary acceptance must be withdrawn. The duration of the temporary acceptance must not exceed the validity of the certification agreement.

For multi site see article 5.2.9.2 of CR 2.0 Assessment and Certification.
4.2.8.3. **Certificate/temporary Acceptance Templates:**

A) **Text for a certificate:**

Name of the Certification Body:

GMP+ International registration number of the Certification Body:

Certificate / Temporary Acceptance

GMP+ FRA/FSA logo

Name, address, location of the GMP+ Certified Company
(Address where GMP+ activities take place)
Name and EU number of vessel (if applicable)
GMP+ International registration number of the GMP+ Certified Company

Fixed section:
=name CB= declares that there is justifiable confidence that the GMP+ scopes (1st column of the table in Annex 3) at the GMP+ Certified Company =name of GMP+ Certified Company = comply with the applicable requirements and conditions of the GMP+ standard(s) (2nd column of the table in Annex 3), of the GMP+ Feed Safety Assurance/Feed Responsibility Assurance Module (Choose the applicable module) 2020.

Free section:
See F 0.3 Scope of certification

Registered office of the Certification Body

Certificate number / temporary acceptance number

Begin and end date of certificate / temporary acceptance

In addition:

a. The data of the GMP+ Certified Company must exactly be the same as registered in the legal business registration of the GMP+ Certified Company (for example Chamber of Commerce/registration at competent authority, tax/vat number).

b. It is mandatory to show the GMP+ FSA/FRA logo.
c. It is **not** permitted to use the GMP+ FSA/FRA logo on a temporary acceptance. In addition, the document may **not** be called a “certificate” but must be designated as a “temporary acceptance”.

d. It is **not** permitted to use the logos of Critical Location, non-Critical Location and outsourced party on the GMP+ certificate and temporary acceptance other than the GMP+ accepted Certification Body.

e. The begin date of the certificate/temporary acceptance is a date which is in any event equal or after the date of the positive certification/temporary acceptance decision.

f. In case of expansion of scopes the end date of the valid GMP+ certificate may not be extended. The Certification Body can also grant the GMP+ Certified Company a new GMP+ certificate for the additional scope.

g. It is **not** permitted to specify brand names in any way whatsoever on the certificate or temporary acceptance.

If a company for the scope registered laboratory complies with assessment criteria mentioned in the CR 2.0 **Assessment and Certification** a statement will be issued. The validity of the statement is maximum 14 months. The duration of the statement must no exceed the validity of the certification agreement.
The text is as follows:

<table>
<thead>
<tr>
<th>No</th>
<th>Operation</th>
<th>Material/matrix</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Feed material</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feed additives and premixtures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feed (compound feed and complementary feed)</td>
</tr>
</tbody>
</table>

### 1. Aflatoxin B1
1.01 Aflatoxin B1

### 2. Dioxins and dioxin-like PCBs
2.01 Sum of dioxins and dioxin-like PCBs
2.02 Dioxins
2.03 Dioxin-like PCBs
2.04 Non-dioxin-like PCBs

### 3. Heavy metals and fluorine
3.01 Arsenic
3.02 Lead
3.03 Cadmium
3.4 Mercury
3.5 Fluorine

Date of audit

Certification Body Details
Statement start date and end date
4.3. **Suspension or withdrawal of a certificate/Temporary acceptance**

The text of article 5.3 of the CR 2.0 *Assessment and Certification* is applicable. In deviation, for the scope inland waterway transport and short sea shipping of feed the following applies: If a “Not Conform” with a description is observed, the GMP+ certificate must be withdrawn. A GMP+ certificate can only be issued if the “Not Conform” with a description is resolved.

4.4. **Transfer to another Certification Body**

Article 5.4. of the CR 2.0 *Assessment and Certification* is applicable.

4.4.1. **Pre-transfer review**

Article 5.4.1. of the CR 2.0 *Assessment and Certification* is applicable. In deviation on article 5.4.1.c., for the scope inland waterway transport and short sea shipping of feed the following applies:

An evaluation of the last checklist to established if a “Non Conform” with description were observed. This evaluation can include other relevant documentation, regarding the (re)-certification process i.e. notes, etc.

4.4.2. **Certification process during transfer**

Article 5.4.2. of the CR 2.0 *Assessment and Certification* is applicable. In deviation on article 5.4.2.b., for the scope inland waterway transport and short sea shipping of feed the following applies:

Open “Non Conform” with description established during the last inspection must be closed by the accepting Certification Body/Critical location during the initial inspection.

5. **Exclusion of GMP+ International Liability**

Chapter 6 of the CR 2.0 *Assessment and Certification* is applicable.

6. **Tariff**

Chapter 7 of the CR 2.0 *Assessment and Certification* is applicable.
7. Disputes between Certification Bodies and GMP+ certified companies

Chapter 8 of the CR 2.0 Assessment and Certification is applicable.
Annex 1: Frequency and Audits/ Inspection Duration:

See Annex 2 of the CR 2.0 Assessment and Certification.
In addition audit duration reduction is not applicable.

<table>
<thead>
<tr>
<th>Scope: Laboratory testing</th>
<th>Number of analyses</th>
<th>Audit/Inspection frequency</th>
<th>Minimum audit/inspection duration in days</th>
<th>Initial or re-certification audit/inspection</th>
<th>Announced surveillance audit</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 17025 accredited</td>
<td>&lt; 5</td>
<td>1x / year</td>
<td>0.25</td>
<td>0.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5-15</td>
<td>1x / year</td>
<td>0.38</td>
<td>0.38</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;15</td>
<td>1x / year</td>
<td>0.50</td>
<td>0.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partially ISO17025 accredited</td>
<td>&lt; 5</td>
<td>1x / year</td>
<td>0.69</td>
<td>0.69</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5-15</td>
<td>1x / year</td>
<td>1.00</td>
<td>0.88</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;15</td>
<td>1x / year</td>
<td>1.19</td>
<td>1.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not ISO17025 accredited</td>
<td>&lt; 5</td>
<td>1x / year</td>
<td>1.00 + 1.00</td>
<td>0.81 + 0.81</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main location (incl. system)</td>
<td>5-20</td>
<td>1x / year</td>
<td>1.19 + 1.19</td>
<td>1.19 + 1.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;20</td>
<td>1x / year</td>
<td>1.50 + 1.50</td>
<td>1.19 + 1.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary location (analyses)</td>
<td>&lt; 5</td>
<td>1x / year</td>
<td>0.63</td>
<td>0.69</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6-20</td>
<td>1x / year</td>
<td>0.81</td>
<td>0.94</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;20</td>
<td>1x / year</td>
<td>1.00</td>
<td>1.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GMP+ FSA module</td>
<td>Number of analyses</td>
<td>Audit/Inspection frequency</td>
<td>Minimum audit/inspection duration in days</td>
<td>Initial or re-certification audit/inspection</td>
<td>Announced surveillance audit</td>
<td>Comment</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>--------------------</td>
<td>----------------------------</td>
<td>-------------------------------------------</td>
<td>---------------------------------------------</td>
<td>-----------------------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Scope: inland waterway and short sea shipping transport of feed</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1x / 2 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Scope: registered laboratories</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>outsourcing all analysis</td>
<td>1x / year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>partly outsourcing analysis</td>
<td>1x / year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>without outsourcing of any analysis</td>
<td>1x / year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Types of laboratories:

- If the laboratory is accredited for more than 50 analyses according to ISO17025 the minimum audit duration may be raised with 0.75 hours.

2. If a laboratory is certified for both GMP+ B10 Laboratory Testing and ISO 9001, 2000 or ISO22000 then a audit duration reduction of 35% may be applied under the condition that the laboratory has the applicable ISO certificate(s). The reduced audit duration may only be used if all secondary locations are working under the quality system of the main location. The system requirements and analyses will be assessed at the main location. At the secondary locations only the analyses are assessed.

3. The requirements of the scope Laboratory Testing and the other GMP+ scopes are so different that a combined audit for the scope Laboratory Testing and one or more of the other GMP+ scopes will not give any audit duration reduction.

4. The audit times are for the assessment of one analysis. For the assessment of each outsourced additional analysis 0.5 hours must be added.

5. The audit times are for the assessment of one analysis. For the assessment of each performing additional analysis 2.0 hours must be added.

6. The audit times auditing B11 may be reduced up to 50% if the assessment will be performed in combination with de scope Laboratory testing. The audit times auditing B11 may be reduced up to 50% if the company has an accreditation in accordance with ISO17025.
### GMP+ B100 Feed Responsible Management System

<table>
<thead>
<tr>
<th>Minimum audit duration in days</th>
<th>Audit frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial certification or recertification audit</td>
</tr>
</tbody>
</table>

### GMP+ MI101 Production and trade of RTRS soy

### GMP+ MI102 Responsible pig and poultry feed

### GMP+ MI103 Responsible dairy feed

### GMP+ MI105 GMO Controlled

In addition to a GMP+ FSA standard (or equivalent as mentioned in chapter 3 of GMP+ BA10):

<table>
<thead>
<tr>
<th></th>
<th>1x / year</th>
<th>0.25 + 0.25X²</th>
<th>0.25 + 0.25X²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Segregation</td>
<td>1x / year</td>
<td>0.25 + 0.25X²</td>
<td>0.25 + 0.25X²</td>
</tr>
<tr>
<td>Additional audit duration per production location</td>
<td>1x / year</td>
<td>0.25 + 0.25X²</td>
<td>0.25 + 0.25X²</td>
</tr>
<tr>
<td>Mass Balance</td>
<td>1x / year</td>
<td>0.25 + 0.25X²</td>
<td>0.25 + 0.25X²</td>
</tr>
<tr>
<td>Responsible pig and poultry feed</td>
<td>1x / year</td>
<td>0.25 + 0.25X²</td>
<td>0.25 + 0.25X²</td>
</tr>
<tr>
<td>Responsible dairy feed</td>
<td>1x / year</td>
<td>0.25 + 0.25X²</td>
<td>0.25 + 0.25X²</td>
</tr>
<tr>
<td>Production of compound feed - GMO Controlled</td>
<td>1x / year</td>
<td>0.25 + 0.125X²</td>
<td>0.25 + 0.125X²</td>
</tr>
<tr>
<td>Production of premixtures - GMO Controlled</td>
<td>1x / year</td>
<td>0.25 + 0.125X²</td>
<td>0.25 + 0.125X²</td>
</tr>
<tr>
<td>Production of feed additives - GMO Controlled</td>
<td>1x / year</td>
<td>0.25 + 0.125X²</td>
<td>0.25 + 0.125X²</td>
</tr>
<tr>
<td>Production of feed material - GMO Controlled</td>
<td>1x / year</td>
<td>0.25 + 0.125X²</td>
<td>0.25 + 0.125X²</td>
</tr>
<tr>
<td>Trade in feed - GMO Controlled</td>
<td>1x / year</td>
<td>0.25 + 0.125X²</td>
<td>0.25 + 0.125X²</td>
</tr>
<tr>
<td>Storage &amp; Transshipment of feed - GMO Controlled</td>
<td>1x / year</td>
<td>0.25 + 0.125X²</td>
<td>0.25 + 0.125X²</td>
</tr>
<tr>
<td>Road transport of feed - GMO Controlled</td>
<td>1x / year</td>
<td>0.25 + 0.125X²</td>
<td>0.25 + 0.125X²</td>
</tr>
</tbody>
</table>

As a stand-alone standard:

<table>
<thead>
<tr>
<th></th>
<th>1x / year</th>
<th>0.75 + 0.25X²</th>
<th>0.75 + 0.25X²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Segregation</td>
<td>1x / year</td>
<td>0.75 + 0.25X²</td>
<td>0.75 + 0.25X²</td>
</tr>
<tr>
<td>Additional audit duration per production location</td>
<td>1x / year</td>
<td>0.75 + 0.25X²</td>
<td>0.75 + 0.25X²</td>
</tr>
<tr>
<td>Mass Balance</td>
<td>1x / year</td>
<td>0.75 + 0.25X²</td>
<td>0.75 + 0.25X²</td>
</tr>
<tr>
<td>Responsible pig and poultry feed</td>
<td>1x / year</td>
<td>0.75 + 0.25X²</td>
<td>0.75 + 0.25X²</td>
</tr>
<tr>
<td>Responsible dairy feed</td>
<td>1x / year</td>
<td>0.75 + 0.25X²</td>
<td>0.75 + 0.25X²</td>
</tr>
<tr>
<td>Production of compound feed - GMO Controlled</td>
<td>1x / year</td>
<td>0.50 + 0.125X²</td>
<td>0.50 + 0.125X²</td>
</tr>
<tr>
<td>Production of premixtures - GMO Controlled</td>
<td>1x / year</td>
<td>0.50 + 0.125X²</td>
<td>0.50 + 0.125X²</td>
</tr>
<tr>
<td>Production of feed additives - GMO Controlled</td>
<td>1x / year</td>
<td>0.50 + 0.125X²</td>
<td>0.50 + 0.125X²</td>
</tr>
<tr>
<td>Production of feed material - GMO Controlled</td>
<td>1x / year</td>
<td>0.50 + 0.125X²</td>
<td>0.50 + 0.125X²</td>
</tr>
<tr>
<td>Trade in feed - GMO Controlled</td>
<td>1x / year</td>
<td>0.50 + 0.125X²</td>
<td>0.50 + 0.125X²</td>
</tr>
<tr>
<td>Storage &amp; Transshipment of feed - GMO Controlled</td>
<td>1x / year</td>
<td>0.50 + 0.125X²</td>
<td>0.50 + 0.125X²</td>
</tr>
<tr>
<td>Road transport of feed - GMO Controlled</td>
<td>1x / year</td>
<td>0.50 + 0.125X²</td>
<td>0.50 + 0.125X²</td>
</tr>
</tbody>
</table>

1) Audit duration for the first FRA scope in combination with FSA at the same location.

2) Audit duration for additional FRA scopes to be certified at the same location. For each additional GMO controlled scope 0.125 can be added.
Annex 2: Feed Responsibility Assurance (FRA) Multi-site certification

Annex 4 of the CR 2.0 Assessment and Certification is applicable. In addition:

Multi-site certification is not permitted for the FRA scopes:
- (D*) Production of compound feed,
- (D*) Production of premixtures,
- (D*) Production of feed materials,
- (K*) Production of feed additives.

Multi-site certification is permitted for the FRA scopes:
- (F*) Trade in feed - GMO controlled,
- (G*) Storage and Transshipment of feed - GMO controlled,
- (G*) Road transport of feed - GMO controlled.

**Minimum obliged audit duration in day’s per multi-site location**

<table>
<thead>
<tr>
<th>Location</th>
<th>Minimum audit duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main office*</td>
<td>Audit duration mentioned in Annex 1 increase with extra audit duration per multi-site location of 0,25 day up to a maximum of 1,25 day.</td>
</tr>
<tr>
<td>Trade in feed - GMO Controlled</td>
<td>0,25</td>
</tr>
<tr>
<td>Multi-site location storage</td>
<td>0,25</td>
</tr>
<tr>
<td>Multi-site location transport</td>
<td>0,25</td>
</tr>
<tr>
<td>Multi-site location with both storage and transport</td>
<td>0,25</td>
</tr>
<tr>
<td>Multi-site location with storage and/or transport and/or limited trading</td>
<td>0,50</td>
</tr>
</tbody>
</table>
## Annex 3: Related documents

<table>
<thead>
<tr>
<th>GMP+ scopes</th>
<th>GMP+ standard</th>
<th>Related document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inland waterway transport and Short sea shipping of feed</td>
<td>TS 3.3 Short sea shipping &amp; Inland waterways transport</td>
<td>R 1.0 Feed Safety Management Systems Requirements  TS 1.8 Labelling</td>
</tr>
<tr>
<td>Laboratory testing</td>
<td>TS 4.1 Laboratory testing</td>
<td>TS 1.8 Labelling</td>
</tr>
<tr>
<td>Registered laboratory</td>
<td>TS 4.2 Registered laboratories</td>
<td>TS 1.8 Labelling</td>
</tr>
<tr>
<td>RTRS Mass Balance</td>
<td>MI 5.1 Production &amp; Trade in RTRS soy</td>
<td>R 5.0 Feed Responsibility Management Systems Requirements</td>
</tr>
<tr>
<td>RTRS Segregation</td>
<td>MI 5.1 Production &amp; Trade in RTRS soy</td>
<td>R 5.0 Feed Responsibility Management Systems Requirements</td>
</tr>
<tr>
<td>Responsible Pig &amp; Poultry feed</td>
<td>MI 5.2 Responsible Pig and Poultry feed</td>
<td>R 5.0 Feed Responsibility Management Systems Requirements</td>
</tr>
<tr>
<td>Responsible diary feed</td>
<td>MI 5.3 Responsible dairy feed</td>
<td>R 5.0 Feed Responsibility Management Systems Requirements</td>
</tr>
<tr>
<td>Production of compound feed - GMO Controlled</td>
<td>MI 5.4 GMO Controlled</td>
<td>R 5.0 Feed Responsibility Management Systems Requirements</td>
</tr>
<tr>
<td>Production of feed material - GMO Controlled</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Production of premixtures - GMO Controlled</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Production of feed additives - GMO Controlled</td>
<td>MI 5.4 GMO Controlled</td>
<td></td>
</tr>
<tr>
<td>Trade in feed - GMO Controlled</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage &amp; Transshipment of feed - GMO Controlled</td>
<td>MI 5.4 GMO Controlled</td>
<td></td>
</tr>
<tr>
<td>Road transport of feed - GMO Controlled</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Disclaimer:
This publication was established for the purpose of providing information to interested parties with respect to GMP+-standards. The publication will be updated regularly. GMP+ International B.V. is not liable for any inaccuracies in this publication.

© GMP+ International B.V.
All rights reserved. The information in this publication may be consulted on the screen, downloaded and printed as long as this is done for your own, non-commercial use. For other desired uses, prior written permission should be obtained from the GMP+ International B.V.