GMP+ Feed Certification scheme

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GMP+ C12

Assessment and Certification Criteria for GMP+ Certification – Feed Safety Management System Certification

12

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Feed for Food

History of the document

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INDEX

1 Introduction

1.1 General

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 (focussed on feed safety) and GMP+ Feed Responsibility Assurance (focussed on responsible feed).

GMP+ Feed Safety Assurance is a complete module with standards for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA standards, such as requirements for a feed safety management system, for application of HACCP principles, to traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

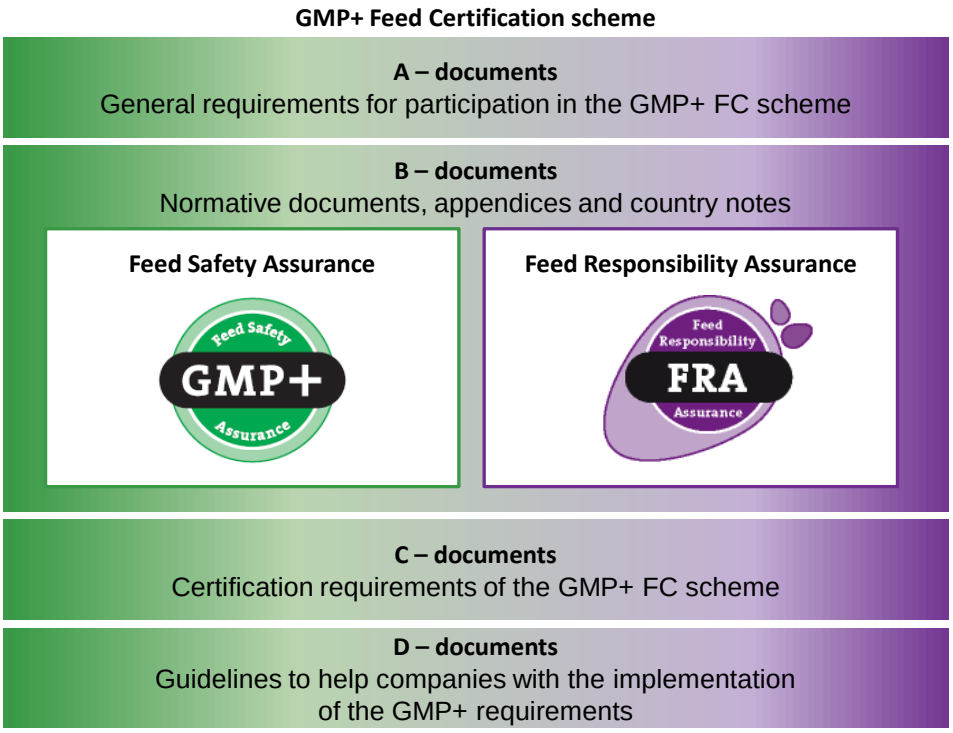
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and 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. GMP+ International facilitates via independent certification the demands from the market.

Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

1.2 Structure of the GMP+ Feed Certification scheme

The documents within the GMP+ Feed Certification scheme are subdivided into a number of series. The next page shows a schematic representation of the content of the GMP+ Feed Certification scheme:



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

This document is referred to as standard GMP+ C12 *Assessment and Certification Criteria for GMP+ Certification – Feed Safety Management System Certification* and is part of the GMP+ Feed Certification scheme.

1.3 Scope

This document contains the assessment and certification criteria relating to the carrying out of audits of companies as defined in GMP+ A1 *General Regulations* of the GMP+ FC scheme of GMP+ International.

These assessment and certification criteria must be used by certification bodies in the carrying out of audits at companies for feed safety management system certification for the GMP+ FC scheme.

1.4 Structure of the document

This standard has a structure of its own.

Next to this, also reference to a number of other annexes is made. These annexes are only part of this standard, and are attached to it. To indicate them, only the word 'Annex' is used.

2 Assessment programme

2.1 General

The GMP+ C12 *Assessment and Certification Criteria for GMP+ Certification – Feed Safety Management System Certification* is based on the ISO/IEC17021 and ISO/TS22003.

A certification body approved by GMP+ International under the GMP+ FC scheme is entitled to certify companies who have an interest for one or more GMP+ standards/scopes for the feed sector as specified in GMP+ FC scheme.

The following regular audits are provided for:
a. Initial audit
b. Surveillance audit
c. Recertification audit.

In addition, additional audits can also be carried out such as a compliance audit, a repeat audit or stricter supervision.

2.2 Initial audit

The certification body will carry out an initial audit in order to assess whether the company meets the criteria for the relevant GMP+ standard.

A GMP+ certificate may or may not be granted by the certification body on the basis of this initial audit, depending on whether the assessment criteria set out in Annex 1 are met. The period of validity of the certificate is a maximum of three years.

The certification body will carry out the full implementation of this audit, that is to say the planning, assessment of documents, the on-site audit, reporting and certification.

The initial audit is a comprehensive assessment of the feed safety management system and consists of:

a. Application review
   Before proceeding with the audit, the certification body will carry out a review of the application and supplementary information for certification to ensure that:
   - the information about the applicant organization and its management system is sufficient for the conduct of the audit;
   - the requirements for certification are clearly defined and documented, and have been provided to the applicant organization;
   - any known difference in understanding between the certification body and the applicant organization is resolved;
   - the certification body has the competence and ability to perform the certification activity;
   - the scope of certification sought, the location(s) of the applicant organization's operations, time required to complete audits and any other points influencing the certification activity are taken into account (language, safety conditions, threats to impartiality, etc.);
   - records of the justification for the decision to undertake the audit are maintained.

The certification body, following the review of the application, shall either accept or decline an application for certification (the reasons for declining an application, the review of the application, shall be documented and made clear to the client).

Based on the review, the certification body shall determine the competences it needs to include in its audit team and for the certification decision.

The audit team shall be appointed and composed of a lead auditor who has the competences identified by the certification body for the certification of the applicant organization as set out in GMP+ C10- Acceptance requirements and Procedure for Certification Bodies – Feed Safety Management System Certification.

b. Assessment of the feed safety management system documentation (Stage 1)
There will be an investigation of whether what should be written down, according to the applicable GMP+ standards/scopes, is also actually recorded in a feed safety management system manual or in a procedure or job instruction book such as organisation, scope, management statement, risk assessment, etc.

It is possible, on the basis of a positive assessment of the feed safety management system documentation (Stage 1), to issue a temporary acceptance (maximum 4 months) for an initial audit at a company which is starting its GMP+ activities in the feed sector. The purpose of this assessment of the feed safety management system documentation (Stage 1) is:

a. Audit the company's feed safety management system documentation
b. The evaluation of the place and the specific requirements of the company location(s) and/or company resources (for example means of transport)
c. To proceed with an evaluation of the company and its understanding of the requirements of the standard
d. The collection of all the required information for the additional initial audit
e. Review the allocation of resources for the on-site audit and agree with the company on the details of the on-site audit
f. Provide a focus for planning the on-site audit by gaining a sufficient understanding of the company's feed safety management system and site operations in the context of possible significant aspects.
g. To determine whether the internal audit(s) and management review have been planned and carried out and whether the level of the implementation of the feed safety management system documentation confirms that the company is ready for the additional initial audit.

The objectives of the stage 1 audit are to provide a focus for planning the stage 2 audit by gaining an understanding of the feed safety management system in the context of the company's feed safety hazard identification, analysis, HACCP plan and pre-requisites, policy and objectives, and, in particular, the company's state of preparedness for audit by reviewing the extent to which:

a. the company has identified pre-requisite programs that are appropriate to the business,
b. the feed safety management system includes adequate processes and methods for the identification and assessment of the company's feed safety hazards, and subsequent selection and categorization of control measures,
c. feed safety legislation is in place for the relevant sector(s) of the company,
d. the feed safety management system is designed to achieve the company's feed safety policy and the implementation programme justifies proceeding to the on-site audit (stage 2),
e. the validation, verification and improvement programmes conform to the requirements of the GMP+ FC scheme,
f. the documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties, and
g. additional documentation needs to be reviewed and/or what knowledge needs to be obtained in advance.

The stage 1 audit shall be carried out in order to achieve the objectives stated above.

When a company carries out production and/or (simple) processing and/or storage and transport activities then part of the assessment of the feed safety management system documentation (Stage 1) must take place at the company location(s) so that the infrastructural facilities can be better inspected. If the company carries out other activities (trade in feed and affreightment) then part of the assessment of the feed safety management system documentation may take place at the company location(s) if the certification body considers this necessary (the stage 1 off-site must be considered in the minimum audit time for audits (Annex 2)).

The company shall be informed that the results of the stage 1 audit may lead to postponement or cancellation of the stage 2 audit. Any part of the feed safety management system that is audited during the stage 1 audit and determined to be fully implemented, effective and in conformity with requirements, may not need to be re-audited during the stage 2 audit. However, the certification body shall ensure that the already audited parts of the feed safety management system continue to conform to the certification requirements. In this case, the stage 2 audit report shall include these findings and shall clearly state that conformity has been established during the stage 1 audit.

c. <u>On-site audit (Stage 2)</u>
At the company locations there will be an investigation into whether the implementation of the requirements of the GMP+ standards/scopes is taking place in the correct manner.

The interval between the assessment of the feed safety management system documentation (Stage 1) and the on-site audit (Stage 2) is reasonably expected to be not longer than 4 months (stage 1 audit should be repeated if a longer interval is needed). During these four months the additional initial on-site audit should be carried out to assess whether the implementation of the GMP+ requirements has taken place correctly.

The total certification process must be finished off within these four months including the updating of GMP+ International's company database (including status and certificate dates) by the certification body. It means that the certification body has to execute the audit preferable within three months in order to ensure that nonconformities detected can be closed within the four months mentioned above.

If the company also complies during the additional initial audit with the GMP+ requirements then a certificate with a maximum period of validity of 3 years may be issued calculated from the date of the final assessment (certification decision) of the additional initial audit. However, if the company does not appear to comply during the additional initial audit with all the GMP+ requirements then no certificate may be issued. If the company still does not comply within the temporary acceptance period with all the GMP+ requirements then the temporary acceptance which was issued for a maximum of four months, will be withdrawn.

Companies which are already GMP+ certified are not eligible for a temporary acceptance. This also applies to companies which were previously GMP+ certified or which had a temporary acceptance but who because of a suspension or withdrawal at their own request had their certificate or temporary acceptance withdrawn.

2.3 Surveillance audit

The certification body will carry out surveillance audits during the period of validity of the GMP+ certificate, to assess whether the company continues to meet the requirements for certification. The surveillance audit must be performed within twelve months after the last date of initial audit (stage 2) was carried out. These surveillance audits are in principle announced. The frequency of these surveillance audits is specified for each GMP+ standard as in Annex 2.

The certification body will draw up an audit programme for this purpose. Account should be taken of the implementation of any corrective actions and those elements and assessment criteria which should be taken into consideration as a minimum in the GMP+ checklists.

A surveillance audit aimed at all areas of the certification requirements consists of:

a. Assessment of the feed safety management system documentation
   There will be an examination of those sections which on the basis of the applicable GMP+ standards must be laid down in writing such as organisation, scope, risk assessment, etc., in a feed safety management manual or in a book of work or procedure instructions.

b. On-site audit
   At the company branches there will be an investigation into whether the implementation of the requirements the GMP+ standards is taking place in the correct manner.

   There will also be a check if the GMP+ logo is used properly.

2.4 Recertification audit

The GMP+ certificate may be extended only where it is established during a recertification audit that the company still complies with all the GMP+ requirements.

In good time, before the end of the period of validity of a certificate, a recertification audit must be carried out to assess whether the company still complies with the requirements for GMP+ certification. In some cases the certification decision can be done at the latest three months after the end date of validity of the certificate. In addition, before the three months after the period of validity of the certificate expires, the total certification process must be finished off including the updating of GMP+ International's company database (including status and data certificate) by the certification body. The recertification audit is a comprehensive assessment of the feed safety management system.

If a recertification audit is not carried out before the expiry of the period of validity of the certificate and the certification decision is not carried out at the latest three months after the end date of validity of the certificate then an initial audit must be carried out. The company is in the intervening period not GMP+ certified.

A recertification audit shall consist of:

a. Assessment of the feed safety management system documentation
   It will be investigated whether those items required to be recorded in writing by the GMP+ standards such as organisational arrangements, scope, a management statement, risk assessment etc., have indeed been so recorded in a feed safety management manual or in a book of working or procedural instructions.

b. On-site audit
   At the company locations there will be an examination of whether the implementation of the requirements the GMP+ standards is taking place in the correct manner.

2.5 Additional audits

If the results of the audit indicate it then an additional audit should be carried out. The circumstances in which this would be appropriate are indicated in Annex 1.

Compliance audit
If one or more Major nonconformities are observed then the certification body may carry out a compliance audit. This audit is in addition to the normal audit cycle and is aimed at specific aspects related to the observed nonconformity and the corrective actions taken. A Major nonconformity can also be handled administratively on the basis of corrective actions formulated by the company.

Stricter supervision
In the event of the observation of one or more Critical nonconformities a certification body may decide to withdraw the certificate or temporary acceptance of the company, to suspend the company or to place the company under stricter supervision. This last will only be done if satisfactory corrective actions are taken. The stricter supervision will take place for the period determined in Annex 1 and will be a minimum of 3 months and a maximum of 6 months.

At least one on-site stricter supervision audit must be conducted. For the rest of the monthly stricter supervision audits, the certification body can decide to conduct an audit on site or not on-site. The stricter supervision must be focussed on the Critical nonconformity(ies) and relevant aspects related to the nonconformity(ies).

Repeat audit
In special circumstances there may be a repeat audit. This audit is aimed in principle at all the requirements of the GMP+ FC scheme. The reason for a repeat audit may be an EWS alert, complaints or incidents, or something else. Depending on the nature and content of the indications GMP+ International have the following repeat audits carried out:

a. The certification body of the company in question will be asked by GMP+ International to carry out a repeat audit in the short term (within a few days). This will consist of at least an on-site audit. In addition, physical and/or administrative checks and a sampling may be carried out. The required appointments and communication on this will be made with the company by the certification body.
b. GMP+ International may ask the certification body to carry out a repeat audit in the short term (within a few days) in the presence of a lead auditor and/or a~~n~~ technical expert from GMP+ International. This repeat check will consist of at least one on-site audit. In addition, physical and/or administrative checks and a sampling may be carried out. The required appointments and communication on this will be made with the company by the certification body in consultation with GMP+ International.

The costs of the repeat audit will be met in principle by GMP+ International. However, if it appears that one or more Major or Critical nonconformities are observed then the costs will be charged to the company.

2.6 Duration of audits and rotation of lead auditors

The minimum frequency and duration for the completion of the various audits (including the assessment of documentation) and reporting is stated in Annex 2 of this document.

The duration of the audit is dependent on the size of the company and the number of activities requiring certification.

A lead auditor can:

a. carry out a maximum of six consecutive audits after which the progress of the auditing is carried out by a least three consecutive audits by another lead auditor, or
b. Only carry out the recertification audit if the lead auditor has conducted a maximum of three audits from the six previous audits at the GMP+ participant.

2.7 Assessment and reporting

The audit objective is to verify the ability of the feed safety management system to ensure that the organization meets applicable statutory and regulatory requirements and contractual arrangements and this information must be addressed in the audit report.

The certification body will assess the companies for compliance with the general assessment criteria specified in Annex 1 of this document and the additional assessment criteria in the checklists. If the certification body establishes in some other way that the participant does not comply fully or partly with what is determined in or by virtue of the GMP+ FC scheme the general assessment criteria as specified in Annex 1 are applicable. During the audit or review of the feed safety management system documentation in the event of a temporary acceptance it is mandatory to work with the GMP+ checklists. These checklists indicate the minimal frequency for assessment of each element of the GMP+ standard. In a repeat audit as specified above it may be decided to deviate from this in consultation with GMP+ International. All deviations which are observed during this audit or review of the feed safety management system documentation in the event of a temporary acceptance should be done in writing on a registration form (NCR). The lead auditor will leave a copy of this registration form at the company.

The company representative will provide the recorded corrective actions and the result of the internal verification to the certification body within the agreed and recorded period of time.

The certification body will report, with respect to the GMP+ audit or review of the feed safety management system documentation in the event of a temporary acceptance, in accordance with the sample report in Annex 3 of this document. The reporting should be worked out completely and entered into a digital file.

The technical reviewer should check all the reports drafted by the lead auditors and provide with a final assessment. Reports related to audits during which shortcomings have been established, should, next to the mentioned final assessment, also be provided with any corrective actions.

The technical reviewer or another competent person is responsible for decision with respect to GMP+ certification.
The technical reviewer or another competent person shall confirm, prior to making a decision with respect to GMP+ certification, that:

a) the information provided by the lead auditor (audit team) is sufficient with respect to the certification requirements and the scope for certification;
b) it has reviewed, accepted and verified that effectiveness of corrections and corrective actions, for all non-conformities in accordance with the Annex 1 “Assessment criteria and measures”;
c) it has reviewed and accepted the company’s planned correction and corrective action for any other non-conformities in accordance with the Annex 1 “Assessment criteria and measures”.

The certification body will, within 6 weeks after finishing the audit, send the final report together with any data from the certificate or the temporary acceptance to the company. In the event of a repeat audit the reporting period should be determined in consultation with GMP+ International.

The certification body keeps the participants details up to date using the Internet application. The certification body will fill in the scope part of the company in the Internet application. Every company location which is given certification or temporary acceptance should have its own GMP+ International registration number. The information from the audit checklists should also be included in GMP+ International’s company database by way of this web application within a maximum of 2 weeks of the end of the audit (with the exception of a recertification audit, see section 2.4).

If GMP+ International requests the audit reports then the certification body will make these available immediately.

2.8 Certification and temporary acceptance

Temporary acceptance will be given for a period of a maximum of four months. Certificates will be issued for a period of a maximum of three years. A GMP+ certificate or temporary acceptance will only be issued by a branch of the certification body approved by GMP+ International and with which GMP+ International has entered into a contract. A certificate will only be issued if there is full compliance with the requirements for certification taking into account the Annex 1: *Assessment criteria and measures*. The classification of the nonconformities should take place in both cases in accordance with the specified criteria and interpretations.

The certification body reports to GMP+ International and provides the data specified in Article 5 of GMP+ A1 *General Regulations*. GMP+ International manages and publishes a public register of GMP+ certified companies.

The certification body must put the following text on the certificate or temporary acceptance:

A text for a certificate

Name of the certification body
GMP+ International registration number of the certification body
GMP+ logo:

FEED SAFETY MANAGEMENT SYSTEM CERTIFICATE

Name, address, location of the business location
Visit address
GMP+ International registration number of the business location

=*name of CB*= declares that is has justifiable confidence that the company =*name of the company location*= " has implemented and maintains a Feed Safety Management System in accordance with the applicable requirements and conditions of the standard(s) GMP+ Bx =*Name of standard (Version)*= (Annex 5), of the GMP+ FC scheme / FSA module (based on the GMP+ C12) of GMP+ International for the scope: *XXX (see Annex 6 (GMP+ C12)).*

FREE SECTION
See Annex 6 (GMP+ C12)

Registered office of the certification body
Certificate number
Begin and end date of the certificate Accreditation mark

Notes:

a. It is not permitted to specify brand names in any way whatsoever on the certificate.
b. It is mandatory to show the GMP+ logo and the Accreditation Mark (if applicable) on the certificate.
c. The begin date of the certificate is a date which is in any event after the date of the positive final assessment.

B text for a temporary acceptance

Name of the certification body:
GMP+ International registration number of the certification body:

TEMPORARY ACCEPTANCE
Name, address, location of the business location
Visit address
GMP+ International registration number of the business location

"=*name of CB*= declares that it has justifiable confidence that the feed safety management system documentation of the process(es) (1st and 2nd column of the table in Annex 6) at the company location =*name of company* = complies with the applicable requirements and conditions of the standard(s) GMP+ Bx =*name of standard* = (Annex 5), of the GMP+ FC scheme / FSA module (based on the GMP+ C12) of GMP+ International for the scope: XXX (see Annex 6 (GMP+ C12)).

FREE SECTION
See Annex 6 (GMP+ C12)

Registered office of the certification body
Temporary acceptance number
Begin date and end date of temporary acceptance

Notes:
a. It is not permitted to depict the GMP+ logo or accreditation mark on a temporary acceptance. In addition, the document may not be called a "certificate" but should be designated as a "temporary acceptance".
b. It is not permitted to specify brand names in any way whatsoever on the temporary acceptance.

2.9 Suspension or withdrawal of a certificate or temporary acceptance

If it is established that a GMP+ certified or temporarily approved company no longer complies with the requirements then the certification body is obliged to impose measures and sanctions immediately in accordance with Annex 1.

In the event of Critical nonconformities as specified in Annex 1 the lead auditor is obliged to report his findings within 24 hours to the responsible coordinator. The certification body will immediately inform GMP+ International by using the Critical non conformity report. This also applies in the event of certification or temporary acceptance being revoked or not extended.

2.10 Contracts / agreements

In the agreements (or tenders which are part of the agreements) between the certification body and companies the GMP+ audit time should be included. This audit time should at least conform with the minimum audit time expenditure as laid down in GMP+ C12 *Assessment and Certification Criteria for GMP + Certification – Feed Safety Management System Certification*. Reference to GMP+ C12 *Assessment and Certification Criteria for GMP + Certification – Feed Safety Management System Certification* is insufficient.

It is not permitted to deviate from the minimum duration in the binding guidelines by way of invoicing on the basis of the costs.

If on the basis of the lead auditor's findings a longer audit time should be used then this can be done in consultation with the company.

The certification body will establish in a contract that the GMP+ certified company may make use of the GMP+ logo and that it undertakes strict compliance with conditions set for this by GMP+ International. Companies which have a temporary acceptance are not permitted to make any use whatsoever of the GMP+ logo.

In addition, the certification body must record the obligation on the companies to provide cooperation in the carrying out of witness audits, parallel audit and supplementary audits (compliance audits, stricter supervision and repeat audits) in the contract with the company.

The GMP+ agreement entered into by the certification bodies and the GMP+ participants should provide the GMP+ participants with the possibility to terminate the GMP+ agreement before the end of the certification cycle.

The certification body will establish in a contract that in case of a determined non-compliance of a permitted level of a contaminant, the company is obliged to notify a EWS report within 12 hours after confirmation of the contamination, to its Certification Body, competent authority, and GMP+ International.

2.11 Exclusion of *GMP+ International* liability

GMP+ International has no liability whatsoever with respect to the assessment of companies by the certification bodies. The certification bodies in question will GMP+ International in this respect.

2.12 Tariffs

The certification body will use its own rates.

2.13 Disputes between certification bodies and companies

Disputes between certification bodies and companies with respect to the assessment will initially be handled in accordance with the disputes regulation of the certification body. If this does not lead to a solution then the dispute may be handled, in the second instance, in accordance with the GMP+ A4 *Disputes Procedure.*

Annex 1: Assessment criteria and measures

GMP+ FSA module

Nonconformities are to be classified on the basis of the general assessment criteria stated below. In addition the specific assessment criteria shown in the checklists remain in force. With reference to the section 9 of the GMP+ A1 document, the measures and sanctions specified should be imposed as a minimum. A certification body is allowed to impose stricter measures, but not to deviate from them by less strict measures.

Classification: Minor Nonconformity	
Definition:	• Any nonconformity which does not adversely affect the health or safety of a product.
Conclusion:	• Where 10 or more minor nonconformities are observed during an audit, an additional audit or the assessment of feed safety management system documentation, the certification body is not allowed to issue GMP+ certification or temporary acceptance.
Minor nonconformity	**Measures and sanctions**
• This relates to a nonconformity where the risk that there will no longer be compliance with the feed safety requirements under the GMP+ normative standards is slight. • An element previously described is not updated, while this is required as a consequence of amended requirements and regulations. • Quality records have been overlooked or are out of date (< 2 months), clearly of an incidental nature (no related to EWS or traceability). • It is reasonable to assume that the nonconformity is an incident.	• The company is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The company is obliged to send the planned correction and corrective actions to the certification body for reviewing and acceptance for the certification decision (initial certification or recertification audits) and within 6 months after the surveillance audits. • The company is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the certification body (at the latest during the next on site audit). Nonconformities can be handled administratively by the certification body unless an (extra surveillance) assessment is necessary in practice. • If the nonconformity is not or not fully resolved then it will be converted to a major nonconformity.
• 10 or more minor nonconformities	• The company is obliged to take the necessary corrective actions to take care of the nonconformities (10 or more) within the period of time set by the certification body (maximum 6 weeks).

Classification: Major nonconformity	
Definition:	• Any nonconformity other than critical, which may result in failure for health or safety and which cannot be completely eliminated by rework or reduced to a minor nonconformity. • When a requirement of the GMP+ normative document has been addressed but there is insufficient evidence to demonstrate that it has been properly controlled or implemented.
Conclusion:	• The company does not meet the requirements for GMP+ certification or temporary acceptance. • If one or more major nonconformities are observed during an initial audit, surveillance audit and recertification audit or a review of the feed safety management system documentation, then the GMP+ certificate or the temporary acceptance may not be issued or extended.
Major Nonconformity	**Measures and sanctions**
• A minor nonconformity was observed earlier and inadequate or no corrective actions has taken place. • A requirement of the normative document is absent or is incompletely described in the documentation. • Quality records are structural very out of date (> 2 months), (not related to EWS or traceability). • A requirement of the normative document is not being properly implemented, but this will have only a limited negative effect on the basic quality of the product.	• The company is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the certification body (maximum 6 weeks). • The company is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The company will be subject in *all* cases – unless stated otherwise above – to at least one compliance audit within a period of 3 months. This may be handled administratively except in those cases where an assessment on-site is necessary.
• A serious nonconformity related to GMP+ requirements excluding what is listed under Critical Nonconformity.[1] • A serious nonconformity of an incidental nature without direct consequences for the subsequent links in the chain.	• Immediate recall of all the products in question unless the company can show to the satisfaction of the certification body that the nonconformity has no harmful health effects for animals and/or humans and the existing legal standards for animal products are not breached. • The company is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the certification body (maximum 6 weeks). • The company is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The company will be given at least one compliance audit within 3 months. This may be handled administratively except in those cases where assessment on-site is necessary.
• During the compliance audit a previously observed major nonconformity is not put right in time or not completely. • Any recall is not carried out properly or (due to own negligence) is not carried out in time.	• This nonconformity will be converted into a critical nonconformity.

[1] *This includes in any event about a) inadequate entry checks of delivered feed materials, b) purchase of feed materials which are not included in Feed Support Products, c) non-compliance with the feed legislation.*

Classification: Critical nonconformity	
Definition:	• Any nonconformity which may result in hazardous or unsafe for individuals and animals. • A regulatory violation or a complete feed safety failure to implement a requirement of the GMP+ normative document.
Conclusion:	• The company does not meet the requirements for GMP+ certification or temporary acceptance. • If one or more critical nonconformities are observed during an initial audit, surveillance audit and recertification audit or a review of the feed safety management system documentation, then the GMP+ certificate or the temporary acceptance may not be issued or extended.
Critical Nonconformity	**Measures and sanctions**
• There has been a previous major nonconformity but only inadequate or late corrective actions have been implemented.	• The company is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the certification body (maximum 2 weeks). • The company is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The company will be given at least one compliance audit. • The company will be placed under stricter supervision for a period of at least 3 and maximum 6 months. • If the company does not take corrective actions within the period of time established and food safety is at risk then the certification body will suspend the certificate or temporary acceptance for a maximum of 3 months. • Lifting of suspension is only possible if the certification body has established during a compliance audit that proper corrective actions have been taken. The company will be placed under stricter supervision for at least 3 to a maximum of 6 months. • If the company does not take corrective actions within the period of time established then the certification body will withdraw the certificate or temporary acceptance for a period of at least 1 year from participation in the GMP+ FC scheme.

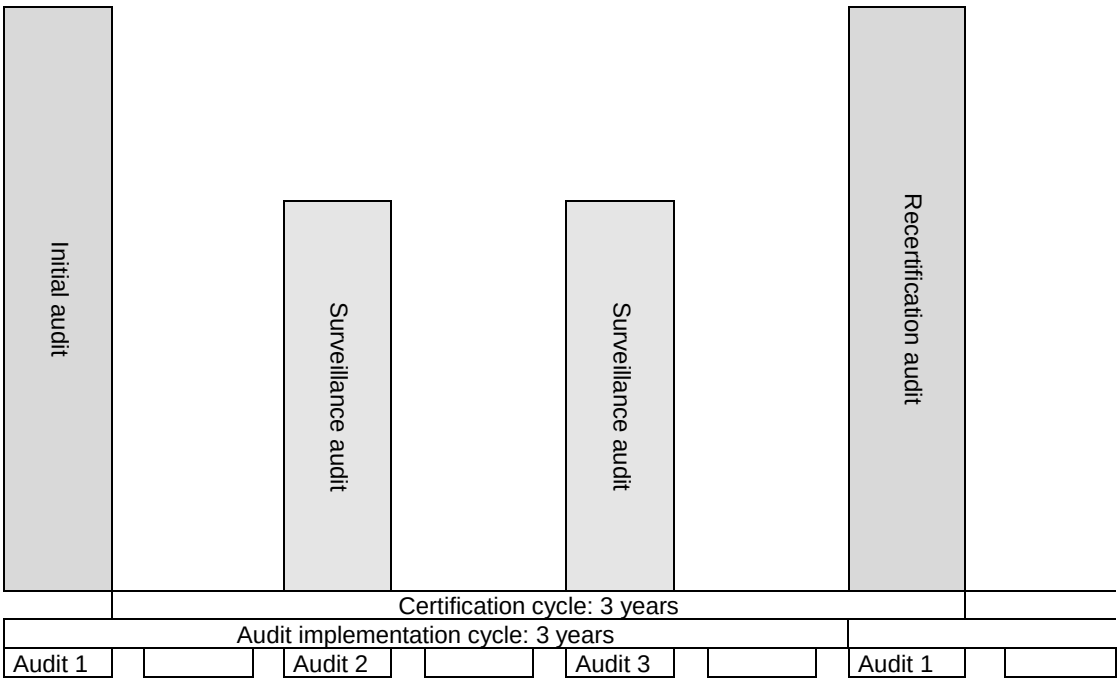
Critical Nonconformity	Measures and sanctions
• A serious nonconformity, incidental, with a direct or possible hazard to the safety of humans, animals or the environment and possible direct consequences for the subsequent links in the chain.	• The company is obliged to undertake an immediate recall of all the products in question unless the company can show to the satisfaction of the certification body that the nonconformity has no harmful health effects for animals or humans and the existing standards are not breached. • The company is obliged to take corrective actions immediately (within 24 hours). The company will be placed under stricter supervision for a period of at least 3 and maximum 6 months. • If the company does not take corrective actions immediately then the certification body will suspend the certificate or the temporary acceptance for a maximum of 3 months. • Lifting of suspension is only possible if the certification body has established during a compliance audit that proper corrective actions have been taken. The company will be placed under stricter supervision for at least 3 to a maximum of 6 months. • If the company does not take corrective actions within the period of time established then the certification body will withdraw the certificate or temporary acceptance for a period of at least 1 year from participation in the GMP+ FC scheme.
• The participant refuses and/or does not cooperate in (planning/conducting) audits for (stricter) supervision by the certification body. • For the period of time when a company is under impending prosecution related to feed safety. • It is reasonable to assume that there is case of gross negligence, fraudulent actions or economic malpractice related to feed safety.	• The certification body suspends the certificate or temporary acceptance for a maximum period of three months. • Lifting of suspension is only possible if the certification body has established during a compliance audit that proper corrections and corrective actions have been taken. The company will be placed under stricter supervision for at least 3 to a maximum of 6 months. • The company is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • If the company does not take corrective actions within the period of time established then the certification body will withdraw the certificate or temporary acceptance for a period of at least 1 year from participation in the GMP+ FC scheme.

Critical Nonconformity	Measures and sanctions
• A structural nonconformity related to critical GMP+ requirements. This relates in any event to: a) incorrect cleaning and disinfections, loading sequence, with a forbidden pre-load, for GMP+ transport, b) no risk assessment for a feed material, c) purchasing feed products and services not in accordance with the purchase requirements, d) intended, on purpose or regularly practice non-compliance with the specific feed safety limits. • The company did not send an EWS to the certification body and competent authority and GMP+ International within the time frame as determine in the GMP+ BA5. • Customers involved are not informed on the time within the time frames established in the specific B standards. • A requirement of the normative document is not being implemented and is critical for the feed safety of the product. • Quality records related to EWS, traceability and tracking and trace are not implemented. • Previously observed critical nonconformities are not properly fixed after a 3 months suspension of the GMP+ certificate or the temporary acceptance has not been properly released or other such nonconformities are established. • Delivery of products from non- GMP+ (or equivalent) certified source(s), under the implicit or explicit suggestion that has been produced in compliance with the GMP+ requirements.	• The certification body will immediately withdraw the certificate or temporary acceptance. • The company or natural persons involved are excluded for a period of at least 1 year from participation in the GMP+ FSA module.

Annex 2: Frequency and time expenditure from GMP+ audits

Frequency

Audits should be carried out in accordance with the following cycle.



This is a qualitative representation of the audit cycle for the implementation of GMP+ audits.

Minimum time expenditure for audits

The following tables provide binding guidelines for the minimal allocation of time in days for GMP+ audits at feed companies. The reporting time it is not considered in the table, it is responsibility of the certification body to establish the time.

In the event of compliance audits, repeat audits and stricter supervision as specified in section 2.5, the period of time will apply which is considered necessary by the certification body or GMP+ International.

A working day is 8 hours.

To determine the main activity of the company the following ranking should be applied:

a. Production and Processing
b. Trade

Within these main activities the following ranking should be applied based on the ISO/TS 22003:2007 requirements. The GMP+ audit scope, is outlined as follow:

		ISO 22003 (2007-02-15)	ISO 22003 (2013-12-15)
a.	Compound feeds	(Category F)	(Category D)
b.	Premixtures	(Category L)	(Category K)
c.	Feed additives	(Category L)	(Category K)
d.	Feed materials	(Category F)	(Category D)
e.	Pet foods	(Category F)	(Category D)
f.	Trade in feed	(Category H)	(Category F)
g.	Storage and transhipment	(Category J)	(Category G)
h.	Transport	(Category J)	(Category G)
i.	Rail transport	(Category J)	(Category G)
j.	Affreightment	(Category J)	(Category G)

For the calculation of the obliged minimum initial audit time (ICA) for a single site the following formula will be used:

Ts=TD+TH+FTE+CA

Where:

Ts: minimum initial audit time
TD: is the basic on-site audit time, in days;
TH: is the number of audit days for additional HACCP studies and/or an additional scope;
TFTE: Is the number of audit days per number of employees;
CA: Is production of compound feeds with the use of critical feed additives and critical veterinary medical products.

Note for audit time reduction:
Deviation from these binding guidelines is only possible where this can be justified by the nature of the company. The reduction of audit times shall not exceed 30% of the minimum obligated time. If there is a deviation from the minimum audit times then the certification body should request this in advance from GMP+ International. GMP+ International will check the reasoning and assess this and adjust if necessary. The certification body should make clear to GMP+ International what the audit duration was. This temporary deviation agreed in writing by GMP+ International from the audit times is valid as long as:

a. no changes take place in the activities and organisation of the company
b. no changes are made to Annex 2, GMP+ C12 *Assessment and Certification Criteria for GMP+ Certification*, frequency and time expenditure for GMP+ audits.

In the event of unchanged business operations and unchanged GMP+ requirements, then during the period of validity of the certificate (the certification cycle) a single audit time reduction can be applied for and given.

Initial Audit (IA): Ts=TD+TH+TFTE+CA					
		Basic on-site audit time in days	**N° audit days for each additional HACCP[1)] study/scope per site**	**Nr of employees (FTE relevant for personnel related to GMP+ activities, expressed in audit days)**	**Production of compound feeds with the use of critical feed additives and critical veterinary medical products**
Scope	**GMP+ scopes**	**TD**	**TH**	**TFTE**	**CA**
F (D)	Production of compound feed	1.75	0.5	1 to 19 = 0 20 to 49 = 0,5 50 to 79 = 1,0 80 to 199 = 1,5 200 to 499 = 2,0 500 to 899 2,5 900 to 1 299 = 3,0 1 300 to 1 699 = 3,5 1 700 to 2 999 = 4,0 3 000 to 5 000 = 4,5 >5 000 = 5,0	0.25 days per site
F (D)	Production of premixtures	1.75	0.5		Not applicable
L (K)	Production of feed additives	1.75	0.5		
F (D)	Production of feed materials	1,5	0.5		
H (F)	Forage trade	1,0	0,25		
H (F)	Trade in feed	1.25	0.25		
J (G)	Storage and transshipment	1.25	0.25		
J (G)	Transport	1,0	0.25		
J (G)	Affreightment.	1,0	0.25		

[1)] *The minimum audit time is established for the audit which includes only one HACCP study. A HACCP study corresponds to a hazard analysis for a family of products/services/processes with similar hazards and similar production technology and, where relevant, similar storage technology (i.e. similar family of products/services/processes: compound feed for pig, cattle, etc., in this case ONE HACCP study could be applicable), (i.e. for a company with both production and trade in its scope, TWO HACCP studies could be applicable).*

Additional requirements on audit time calculation (increase and reduction)	Initial audit (IA) and/or surveillance and/or recertification audits
Combined audit GMP+ with valid versions of: ISO 9001 and/or ISO 22000+PAS 222 and/or HACCP and/or IFS Food and/or BRC Production and/or GMP-Ovocom and/or FAMI-QS) and/or FSSC 22000	**REDUCTION** with a maximum of 30% of the total (cannot be combined with other reduction time ((i.e. each additional site visited))
Presence of certified relevant management system (ISO 9001, ISO 22000 + PAS 222)	**REDUCTION** of 0.25 in days
Each additional production site[1)] visited	**REDUCTION** of 50% of minimum on-site audit time for the relevant scope at the additional site with a minimum of 1.0 TD.
Each additional site[1)] visited	**REDUCTION** of 50% of minimum on-site audit time for the relevant scope at additional site (applicable for Trade in feed, storage and transshipment, transport, affreightment)
Trade (H), Road transport (J), Storage and transshipment (J), and Affreightment (J): • **Companies equal or less than 5 employees/products** • **Transport more than 2 employees up to equal or less then 5 employees.**	**REDUCTION** of 50% of the total IA (cannot be combined with other reduction time ((i.e. each additional site visited)). (Minimum surveillance audit time: same as IA Minimum recertification audit time: same as IA)
Forage trade equal or less than 5 employees/products	**REDUCTION** of 50% of the total IA (cannot be combined with other reduction time ((i.e. each additional site visited)). (Minimum surveillance audit time: two-thirds of the IA time Minimum recertification audit time: same as IA)
Road transport companies equal or less then 2 employees	**REDUCTION IA** 0,5 days (as a minimum) surveillance- recertification audit time 0,25 days (as a minimum).
Road transport > 15 - ≤ 19 employees	**INCREASE** IA, surveillance and re-certification audit 0,25 days (as a minimum).
Tractionairs own manual	**REDUCTION IA** 0,5 days (as a minimum) surveillance- recertification audit time 0,25 days (as a minimum).

Tractionairs in customers manual	**REDUCTION** IA, surveillance and re-certification audit 0,25 days (as a minimum).
Short Sea shipping and inland waterways transport	**REDUCTION:** inspection once per two year 0,25 days (as a minimum).
Gatekeeper dossiers/files	**INCREASE** of 0.25 days (as a minimum) per file and with a maximum of 1.25 day (**IA, surveillance and recertification audit**).

*[1] **Additional Site**: A site who has a legal or contractual link with the main office of the organization and be subject to a common management system, which is laid down, established and subject to continuous surveillance and internal audits by the central office. This means that the central office has rights to require that the sites implement corrective actions when needed in any site. Where applicable this should be set out in a formal agreement between the central office and the sites.*

Calculation of the surveillance and recertification audit time:

* For production of compound feed, premixtures and feed additives (scopes F and L), the minimum surveillance audit time must be two-thirds of the IA time with a minimum of 1,5 days and the minimum recertification audit time must be the same time established for the IA.
* For production of feed materials (scope F), trade in feed (scope H) and storage and transshipment, transport and affreightment (scope J), the minimum surveillance and recertification audit time must be two-thirds of the IA time.

	GMP+ FSA	Number of Analyses	Audit frequency	Minimum time expenditure in hours [1]			Comment	
				Initial or extension audit	Supervision audit			
GMP+ B10 Laboratory Testing								
	ISO 17025 accredited		1x / year	2.0				
		5-15	1x / year	3.0				
		>15	1x / year	4.0				
	Partially ISO17025 accredited	≤ 5	1x / year	5.5	5.5			
		5-15	1x / year	8.0	7.5		1)	
		>15	1x / year	9.5	9.5		2)	
	Not ISO17025 accredited						3)	
	Main location (incl. system)	≤ 5	1x / year	8.0 + 8.0	6.5 + 6.5			
		5-20	1x / year	9.5 + 9.5	9.5 + 9.5			
		>20	1x / year	12.0 + 12.0	9.5 + 9.5			
	Secondary location (analyses)	≤ 5	1x / year	5.0	5.5			4)
		5-20	1x / year	6.5	7.5			
		>20	1x / year	8.0	9.5			

1) The most important analyses must be assessed during the initial audit. At least once during the audit cycle all analyses should be assessed.

2) Types of laboratories:
- The laboratory has all analyses under ISO 17025; administrative assessment once per year. If the laboratory is accredited for more than 50 analyses according to ISO 17025 the minimal time expenditure may be raised to 0.75.
- If the laboratory does not have all analyses under ISO 17025 then just the material specialist visits for the non-ISO 17025 analyses.
- Where the laboratory is not accredited according to ISO 17025; both the material specialist and the auditor visit for system assessment.

3) If a laboratory is certified for both GMP+ B10 *Laboratory Testing* and ISO 9001; 2000 or ISO22000 then a 35% audit time reduction may be applied on the condition that the laboratory is included in the scope of the ISO certificate.

4) These reduced audit times may only be used if all locations of the laboratory work under the same feed safety management system. The system requirements and analyses will be assessed at the main location. At the sub-locations only the analyses are assessed. The audit at the sub-location will be carried out by the GMP+ B10 auditor, scope materials.

Annex 3: Reporting model

1 General details

Details of main location
Name of the company :
Address :
Postal code and location :
Telephone :
Fax :
E-mail :
Registration number :
Contact person :

Overview of all business locations (incl. head office) and GMP+ standards

Registration number	***Name location***	***Address Postal code, Location***	***GMP+ standard(s) (incl. scope for GMP+ B1 and GMP+ B3) Incl. version date and additional product criteria***	***Expiry date of current certificate or temporary acceptance:***

List of locations in the event of multi-site certification (if applicable)

Registration number location	***Name of location***	***Address Postal code, Location***	***Visit date***

Audit details:

- *Initial audit*
- *Surveillance audit*
- *Recertification audit*
- *Compliance audit*
- *Repeat audit*
- *Stricter supervision*
- *Documents review (in the event of a temporary acceptance)*
- *Other;*

Date of document assessment :

Date of audit inspection :

Report date :

Staff involved in inspection:
Name Position

Documents consulted :
Certification body :
Lead auditor(s) :
Materials expert(s) :

Name Signature

2 Scope company/locations

Specify the type of company and its activities. Describe the products and quantities. Specify the nature and the numbers of personnel (permanent, temporary) per location.
Describe the organisational structure. Also take note of other companies on the same site or under the same holding (with similar names or incompatible activities).
Provide a brief summary of purchasing, production process and sales of main and subsidiary product streams (focusing on the relationship with the activities covered by the application). Also indicate whether the company applies the Gatekeeper principle and describe the activities.

3 Audit objectives

The audit objectives shall describe what it is to be accomplished by the audit and must include the following topics:

a) *Determination of the conformity of the Feed Safety Management System.*
b) *Evaluation of the ability of the Feed Safety Management System to ensure the participant's organisation meets applicable statutory, regulatory and contractual requirements.*
c) *Evaluation of the effectiveness of the Feed Safety Management System to ensure the participant's organisation is continually meeting its specified objectives.*

4 Summary of the assessment and conclusion

Start with a standard phrase such as "The company was visited for a surveillance audit of the GMP+ requirements. The company was checked for the requirements of the applicable GMP+ standards".
Indicate whether the audit findings, observed in the previous audit, have been resolved.
Make a summary per company location and in total, including verification of the (non)conformity(ies).
The evaluation of the use of the GMP+ logo must also be described.
Give a brief summary of the general impression of the Feed Safety Management System of the company.
Possible postscript after a final assessment by the technical reviewer: review of additional documents and follow-up inspection.

Summary of the assessment and the number of audit nonconformities observed									
Location	**During previous audit**			**During audit visit**			**At final assessment**		
	Number of audit non-conformities			**Number of audit non-conformities**			**Number of audit non-conformities**		
	Critical	*Major*	*Minor*	*Critical*	*Major*	*Minor*	*Critical*	*Major*	*Minor*

Audit conclusion: the company meets/fails the requirements of the GMP+ standard and applicable statutory, regulatory and contractual requirements and participant's organisation is continually meeting its specified objectives.

Measures and sanctions: compliance audit, repeat audit, stricter supervision (including period of time), suspension, withdrawal.

4. Appendices

Checklists used, report forms for audit nonconformities.

Annex 4: Multi site certification

Option 1:
Multi site certification is possible:
a. At a company with a main office with 100% subsidiaries, or
b. At a group of companies which have joined together as a quality community.

Note: *'A multi site organization need not to be a unique legal entity, but all sites must have a legal or contractual link with the main office of the organization and be subject to a common feed safety management system, which is laid down, established and subject to continuous surveillance and internal audits by the central office. This means that the central office has rights to require that the sites implement corrective actions when needed in any site. Where applicable this should be set out in a formal agreement between the central office and the sites'.*[2]

Guidance
Multi site certification is reserved for companies which are part of the feed sector. Companies, participating in a multi site organisation, should demonstrate this.

Multi site certification is not to be used if various independent companies have joined together in a branch organisation, union, federation, association, via an independent consultancy office or similar.

This applies for the activities:
a. Transport
b. Trade
c. Storage
d. Transhipment
e. Collection
f. Affreightment

Note: In a group of companies in which the above activities take place, in addition to the general requirements (see under A) which apply to a multi-site certification, there must also be compliance with the requirements under B.

For **unprocessed goods** (i.e. grain, seeds and pulses) which are collected, handled, stored or transported with own transport, the minimum requirements for multi-site certification, as laid down in a separate section under Certification, can be used.

Guidance
a. For a definition of collection see GMP+ A2 *Definitions and Abbreviations*.
b. If, for example, a group contains multiple production locations and storage locations, the production locations in this group cannot be certified under multi-site but perhaps the storage locations can.
c. If both collection and transport (incl. affreightment) takes place at locations, the certification of this may also be combined under the multi-site requirements.

[2] IAF MD1:2007 - Document for the Certification of Multiple Sites Based on Sampling

A) General requirements:

1) General

a. All locations fall under the same feed safety management system which is managed centrally (referred to hereafter as the main office). This feed safety management system complies with the relevant GMP+ standards and there must be compliance at all locations with the relevant GMP+ requirements (see also the guidance under C) Certification).
b. The same methods and procedures are used at all the locations.
c. Corrective actions may be imposed from the main office on all branches.
d. There must be a written agreement between the participating subsidiaries and the main office. This agreement should be signed by all the participating parties and the signed agreement should be present at the main office and available to the auditor. The statement will include at least:
    1. a commitment by the company to the main office that it will comply with the requirements set in the feed safety management system.
    2. that corrective actions imposed by the main office are binding
    3. that the above applies to all feed activities (and therefore those which are carried out more or less independently).
e. All the locations are included in the programme of internal audits.
f. The main office must show that it is able to collect data from every location, to analyse the data and, where necessary, to implement changes with respect to:
    1. System documents and changes
    2. Management review
    3. Complaints handling
    4. Corrective actions
    5. Planning of internal audits and corrective actions.

Guidance

Central management of the training plan is one of the possibilities.

2) Requirements for the internal auditor:

The internal auditor must:

a. Be independent and may not check his own daily activities
b. Have demonstrable knowledge of feed safety management systems through training or work experience
c. Have demonstrable knowledge through training and/or work experience of the field of work which will be audited

3) Requirements for the internal audit:

a. An internal audit will be carried out at least yearly (1 x per 12 months) at all locations.
b. The internal auditor will have to carry out an internal audit in which all the aspects of the feed safety management system are addressed. Use will preferably be made of the checklist used by the certification bodies (see GMP+ *Checklists*).
c. The internal audit reporting must be drawn up in such a way that the certification body can make use of this information.

B) Additional requirements:

The following additional requirements apply to a group of companies:

4) Trade
If not all feeds are traded via the main office but via a secondary location, this trade in feeds must be completely guaranteed by the main office. During the internal audit, (the trading of) these feeds will also be included.

5) Transport
A carrier (sub-contractor) can only be certified under multi-site requirements if the carrier (sub-contractor) carries out all the feed activities for the main office exclusively. If this is not the case, the carrier must be independently certified.

Guidance
A production company and a number of carriers (sub-contractors) may unite in a quality community, for example. The certification can take place under multi-site requirements.

C) Certification
If a main office has a different GMP+ scope to one of the locations or companies, the main office must also additionally be certified for this scope.

Guidance
If the main office is a production company (GMP+ B1 Production, Trade and Services) and the other companies have a transport scope (GMP+ B4 Road Transport) and/or trading scope (GMP+ B3) Trade, Collection and Storage & Transhipment) etc., the production company must also be certified for this scope (transport and/or trade) because the management and control of the feed safety management system lies centrally with the production company.

In the event of multi-site certification the audit frequency for the locations (with the exception of the main office) is lowered where each location must be visited at least once per three years.

Guidance
In determining the locations which must be visited the certification body will use a random selection system. Account will be taken of:
- the results of the internal audit as carried out by the main office
- the activities which take place at the various locations.

Before an initial audit can take place, the contracts between the main office and the participating companies and also the internal audit report must be able to be handed over to the certification body for review.

In an initial audit the main office and ⅓ of the locations should always be visited before a certificate can be issued.

If a new location joins a company or a group of companies, a verification of the relevant subjects must take place at the main office and the new location should be audited.

Minimum time to be spent per visit in hours:

Location	*Number of employees**	*Minimum time expenditure per visit*
Main office	Time expenditure as recorded in the table of the GMP+ 12 increased with extra time per included multi-site location of 2 hours up to a maximum of 10 extra hours.	
Location / companies with only transport	≤ 5 employees 6-15 employees >15 employees	2.0 3.0 4.0
Location / companies with only storage		2.0
Location / companies with both storage and transport	≤ 5 employees 6-15 employees >15 employees	2.0 3.0 4.0
Location / companies with storage and/or transport and limited trading		4.0
Location / companies with only trade	≤ 5 employees 6-15 employees >15 employees	2.0 3.0 4.0
Location / companies with only affreightment		2.0

*By the number of employees is meant the sum of the number of employees per audited branch per year.

Unprocessed goods (i.e. grain, seeds and pulses)
This multisite construction is applicable for transport and storage for unprocessed goods. Trade is excluded, also as transport and storage of processed goods.
If a multisite company consists of more than 20 sub locations and there are only unprocessed goods involved, another method to calculate the minimum frequency and audit times can be used:

- The requirements as laid down for the internal audit will be the same as in a regular multisite certification; the internal audit program must cover all sites every year, including sites that are not used the whole year round.
- All sites with unprocessed goods must be located in the same country or in the bordering regions of neighbouring countries.
- The sampling programme for the external audit can be risk based. All sites, including sites that are not used the whole year round, must be part of the sampling programme of the external audit. For the external audit the main office will be audit every year. The sub locations will be audited during the certification period (3 years) as follows:
  a. up to 20 sites; all sites;
  b. from the 21st site; every fifth site.

The sub locations will be chosen randomly. The certification body may divide the sub locations into groups or districts.

Extra points of interests
As all locations / companies must work in accordance with the same methods and procedures and under the same feed safety management system, the review of the documentation can remain limited to verification of the presence of up to date documentation and the completeness of the HACCP documentation with respect to the audited location.

During audits of locations where storage is done the following GMP+ requirements must assessed:
a. verification and administration of received products
b. process control: Good Housekeeping, control measures with respect to critical points
c. tracking & tracing
d. delivery, verification of loading compartments
e. inspections and records
f. delivery of feeds
g. if transport activities also take place, the operational aspects should also be assessed
h. complaints and nonconformities

During audits of locations where transport is done the following GMP+ requirements must assessed:
a. reception of transport orders incl. product category classification
b. journey sheets; identification of loading compartments, products, cleaning, loading and unloading addresses, etc.
c. inspection of the trucks present
d. administration, use of third parties, instructions with respect to GMP+ product categories
e. if storage activities also take place, the operational aspects should also be assessed
f. complaints and nonconformities

During audits of locations where trading is done the following GMP+ requirements must be assessed:
a. trading methods with respect to purchasing and delivery of feeds (possibly including the review of contracts)
b. method of verification and administration
c. tracking & tracing
d. inspections and records
e. complaints and nonconformities

An overview should be included in the GMP+ report showing when all the locations / companies were visited.

If serious nonconformities are observed at the main office, the whole company or quality community does not meet the requirements for GMP+ certification. If nonconformity is observed at the level of a location, this can influence the location and/or the main office. This is to be assessed by the certification body.

A checklist should be completed only at the level of the main office. Audit findings which are observed at one of the storage locations / companies should be reported in the checklist and the GMP+ report.

Only one certificate (or temporary acceptance where appropriate) will be issued for multi-site. This certificate will have an annex with the companies which belong to the multi-site. An individual location or company can also receive a certificate.

Annex 5: Accredited normative documents

GMP+ activity	Normative document	Related Appendices
Production of Compound Feed	GMP+ B1 *Production, Trade and Services*	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA module
Production of Premixtures	GMP+ B1 *Production, Trade and Services*	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA module
Production of Feed Material	GMP+ B1 *Production, Trade and Services* GMP+ B2 *Production of feed ingredients*	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA module
Production of Feed Additives	GMP+ B1 *Production, Trade and Services* - assessment product(s) GMP+ B2 *Production of feed ingredients*	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA module

Annex 6: non accredited normative documents.

GMP+ activity	Normative document	Related appendices
Pet foods	GMP+ B8 *Production of and Trade in Pet Foods foods* - assessment product(s)	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA module
Trade in animal feed	GMP+ B3 *Trade, Collection and Storage & Transhipment* (GMP+ B1 *Production, Trade and Services)*	Appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA module
Storage & Transhipment of animal feed	GMP+ B3 *Trade, Collection and Storage & Transhipment* (GMP+ B1 *Production, Trade and Services)*	Appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA module
Road transport of animal feeds (including affreightment of road transport)	GMP+ B4 *Transport* Assessment IDTF	IDTF of the GMP+ FSA module
Rail transport of animal feeds	GMP+ B4 *Transport*	IDTF of the GMP+ FSA module
Short sea shipping and inland waterways transport affreightment	GMP+ B4 *Transport*	Process require-ments as specified in Chapter 7 of GMP+ B4.2 of the GMP+ FSA module.
Affreightment of sea transport	GMP+ B4 *Transport*	Process require-ments as specified in Chapter 7 of GMP+ B4.4 of the GMP+ FSA module
Affreightment of rail transport	GMP+ B4 *Transport*	Process require-ments as specified in Chapter 7 of GMP+ B4.5 of the GMP+ FSA module
Short sea shipping and inland water-ways transport	GMP+ B4.3 *Short sea shipping and inland waterways transport*	
Laboratory testing	GMP+ B10 *Laboratory testing*	

standard GMP+ FSA ⟶ ↓ scope of process	B1	B2	B3	B4
Production of compound feed	x			
Production of premixtures	x			
Production of feed additives	x	x		
Production of feed materials	x	x		
Trade of feed.	x		x	
Storage and transhipment of feed	x		x	
Road transport				x
Affreightment				x
Railtransport				x
Production of pet food	x			
Trade in pet food	x			

Annex 7: Products and process stages/services

On the certificate or temporary acceptance a distinction can be made for the description of feeds which must be quality assured between a so-called fixed part and a free part.

Fixed part:
Completion of the fixed section is mandatory. The description of the assured animal feeds on the GMP+ certificate or temporary acceptance should be formulated in combination with the activities as combinations of activities and feeds as summarised in the following table which is derived from the titles of the GMP+ standards (see Annex 5 for the complete titles). The scope of the products is specified next to the activity as specified in accordance with the standard name to which the certificate or temporary acceptance refers.

GMP+ Feed Safety Assurance	
Activities	*Animal feedstuffs*
Production of ……	the animal feeds to be distinguished:
Trade in……	….. feed additives
Storage and transhipment of ...	….. feed materials
Collection of…..	….. premixtures
Road transport of ….	….. compound feeds
Rail transport of	….. feeds
Short Sea Shipping and Inland Waterways of …	
Affreightment of inland waterways transport for ….	
Affreightment of sea transport for ….	There can also be a separate mention of:
Affreightment of rail transport for ….	….. pet foods
Affreightment of short sea shipping for …	
Affreightment of road transport for….	

The standards applied by the participant are specified. (See Annex 5) followed by the product group.

Free part:
The completion of this part is mandatory. In consultation with the certification body, the participant may show a further description of the activities and the animal feeds. This description may not conflict with the fixed part.
There can, for example, be sub-processes of production which can be distinguished (bagging, packaging, extrusion, etc.). Processing may include activities such as collection, cleaning, drying, etc.
The animal feeds may also be further specified. For example, in the category compound feeds there may be mineral mixes, milk replacer feed or poultry feeds. Feed materials can also be detailed such as grains, grain by-products, etc. Or be more specific such as wheat, wheat grits.

Examples:

a. A milk replacer feed producer may specify his production of compound feeds as: production of milk replacer feed.
b. a collector of grains may specify his treatment of feed materials as collection, cleaning and drying of grains
c. a trader in grains may specify his trade in feed materials as trade in grains, etc.

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

The validity of a certificate or temporary acceptance relates to the specified scope. Unspecified products or activities do not fall within the scope of the certificate or temporary acceptance.