GMP+ International

# Method of and Criteria for the Compliance Assessment of Certification Bodies

## GMP+ C 11

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**GMP+ Feed Certification scheme**

Feed Safety Worldwide

gmpplus.org

## History of the document

| Revision no. / Date of approval | Amendment | Concerns | Final imple-mentation date |
|---|---|---|---|
| 0.0 / 07-2015 | This is a new document. | Entire document | 01-08-2015 |
| 0.1 / 09-2016 | Completely rewritten document. | Entire document | 15-09-2016 |

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# 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 (focused on feed safety) and GMP+ Feed Responsibility Assurance (focused 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, for traceability, monitoring, prerequisites programs, chain approach and the Early Warning System.

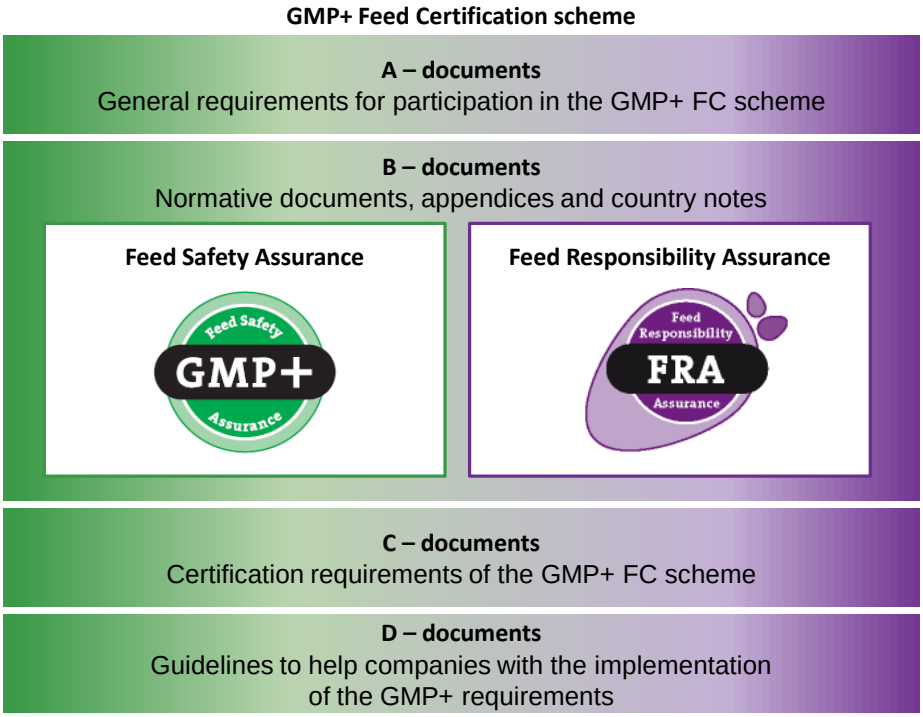
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a participant 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+ C11 *Method of and Criteria for the Compliance Assessment of Certification Bodies* and is part of the GMP+ FC scheme.

## 1.3 Scope

This document contains the procedure, assessment criteria and sanctions for the compliance assessment of those certification bodies which carry out GMP+ audits at companies as specified in the GMP+ A1 General Regulations of the GMP+ FC scheme of GMP+ International.

These assessment criteria and sanctions must be used in the compliance assessment of certification bodies by GMP+ International.

## 1.4 Structure of the document

This standard has a structure of its own.

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

# 2 Compliance assessment

## 2.1 General

Any certification body accepted by GMP+ International on the basis of Article 7 of the GMP+ A1 *General Regulations* is entitled to certify interested companies in respect of one or more of the GMP+ standards/ scopes included in the GMP+ FC scheme. This certification body has entered into a GMP+ License Agreement with GMP+ International for this purpose. By entering into this GMP+ License Agreement the certification body states that it will accept and comply with the requirements and obligation as stated in the GMP+ FC scheme.

GMP+ International supervises compliance by the certification bodies with that which is laid down in the GMP+ FC scheme, especially in the following standards: GMP+ A1 *General Regulations,* GMP+ A3 *GMP+ Logo's/Trademarks,* GMP+ A5 *GMP+ Feed Certification Scheme License Agreement,* GMP+ C1/C10 *Acceptation requirements and procedure for certification bodies (FSMS),* GMP+ C3 / GMP+ C6 *Assessment and Certification Criteria for GMP+ Certification (product- and process certification), GMP+ C7 Assessment and Certification/Inspection Criteria for GMP+ Certification/Inspection - additional scopes* and *GMP+ C12 Assessment and Certification Criteria for GMP+ Certification FSMS,* during GMP+ certification

Use is made in compliance assessment audits and in determining sanctions of the criteria as laid down in this document.

The accreditation bodies ensure (as far as applicable) that the certification bodies accepted by GMP+ International comply with the requirements of ISO/IEC17021 (latest version) and ISO/TS22003 (latest version) with respect to the implementation of the GMP+ FC scheme.

## 2.2 Compliance assessment of certification bodies and GMP+ auditors / inspectors.

The compliance assessment of the certification bodies that GMP+ International carries out consists of:

a. Compliance Desk Assessment to determine whether the certification body complies with the requirements laid down in the GMP+ FC scheme.

b. GMP+ International will apply the following Compliance Assessment Methods in a systematic way:

   i. Compliance Audits:
      a. Witness Audits (WA report)
         GMP+ International supervises the GMP+ auditors / inspectors by assessing their working method and the way in which they categorize their findings during the execution of their audit. The individual GMP+ auditor / inspector or the audit team will be assessed during a witness audit. If the GMP+ International auditor observes that there is a risk for the feed safety which is not identified during the audit, the GMP+ auditor will be informed by the GMP+ International auditor before the closing meeting in order to confirm whether there is a feed safety risk.

b. Parallel Audits (PA report)
GMP+ International carries out parallel audits at GMP+ participants to verify the method by which an audit is planned, carried out and reported by the certification body. The parallel audit will take place after the audit by the certification body has been carried out and reported to GMP+ International.

c. CB office audits (CB report)
GMP+ International will carry out an audit at the certification bodies at least once a year to assess whether the implementation of the requirements laid down in the GMP+ FC scheme is carried out properly. This audit is a full assessment of all conditions. The minimum time to be spent on this audit is 1 day.

d. Chain-oriented Audits (COA report)
It is a Compliance Audit at a certain participant and its certified supplier(s) and / or certified client(s) with a focus on specific requirements and consistency regarding labelling, information in purchase and sales contracts or delivery orders, information on transport documents, etc.

The compliance report will be provided to the certification body in the English, German or Dutch language.

ii. Retrospective analysis of the participant / GMP+ Auditor : It is based on special events and not on a regular basis.
   a. certification process of a specific participant (RAC report)
   It is an analysis of the reports of all Certification Audits and if available also of Compliance Audits, conducted at a specific company during the last 36 months.

   b. performance of an individual GMP+ Auditor (RAA report)
   It is an analysis of the reports of all Certification Audits conducted by a certain GMP+ auditor for a number of reports to be determined by GMP+ International and related to the relevant scope(s).

iii. Overall analysis of the performance of Certification (OACB report) it is an annual analysis of the performance of a Certification Body during the last three calendar years, based on at least:

   a. Identified nonconformities per GMP+ auditor
   b. Findings of GMP+ Compliance audits;
   c. Participation and input in harmonization meetings;
   d. Exam results of the GMP+ auditors;

   The final result of the overall analysis can result in additional compliance assessment for the Certification Body. The costs for the additional compliance assessment can be charged to the Certification Body.

iv. Examination of GMP+ auditors:
Examination of a GMP+ auditor is a tool for assessing GMP+ auditors compliance with the condition of having enough knowledge of the normative standards and rules of certification, including the classification of nonconformities as well as the characteristics of the production processes in the feed chain.

v. Report assessment
GMP+ International will - on a random sample basis - assess the reports on audits carried out by certification bodies under the GMP+ FC scheme.

### 2.3 Reporting

Zero nonconformities or only Minor nonconformities, less than five:
After the compliance audit is carried out by GMP+ International and if applicable, the Non Conformity Report (hereafter NCR) is prepared by the GMP+ International auditor and handover to the coordinator (to take actions to solve the nonconformities before the determined deadline).

NCR(s) can only be closed if the involved certification body conducts a root cause analysis, implement corrective and/or preventive actions and if applicable the involved certification body must submit objective evidence to GMP+ International. GMP+ International refers to this actions as Corrective Action Report (hereunder: CAR). The GMP+ International auditor and GMP+ International (technical) reviewer are responsible to make the compliance report final and to assess the CAR(s) and to close the NCR(s). Report can be sampled for assessment by GMP+ International.

Equal or more than 5 Minor nonconformities and/or one or more Major nonconformities and/or Critical nonconformities:
After the compliance audit is carried out by GMP+ International the NCR(s) is prepared by the GMP+ International auditor and handover to the coordinator (to take actions to solve the nonconformities before the determined deadline). GMP+ International is responsible if the observed NCR(s) are justified and well classified.

NCR(s) can only be closed if the involved certification body submits the CAR(s) to GMP+ International and if the CAR(s) is approved by GMP+ International. GMP+ International is responsible to make the decision to close and/or upgrade/downgrade the NCR(s) and to make the compliance assessment report final.

Annex 1 contains the general criteria for the classification of the determined NCR(s) during the compliance assessment by GMP+ International and the follow-up actions CAR(s).

### 2.4 Frequency

a. The Compliance Audits at certified companies are risk based selected, except Certification Body office audit and chain-oriented audits;
b. The minimum time to be spent by the Certification Body office audit is at least 1 day annually.
c. Overall analysis of the performance of a certification body is carried out annually and/or risk based;
d. The Chain-oriented Audits and the retrospective analysis are carried out systematically.

## Annex 1: Assessment criteria

Findings observed during compliance assessments by GMP+ International are to be classified on the basis of the general criteria stated below.

| **Classification: Minor Nonconformity** | |
|---|---|
| **Definition:** | • Any nonconformity which does not adversely affect the performance, reliability of the certification process. |
| **Conclusion** | • Where less than 5 audit findings fall into Minor Nonconformity the certification body complies with the requirements of acceptance.<br>• If 5 or more audit findings fall into Minor Nonconformity the certification body does *not* comply with the requirements of acceptance. |

| **Finding** | **Measures** |
|---|---|
| • A part of the GMP+ FC scheme applicable is not fully described in the feed safety management system although this is required.<br>• An applicable element of the GMP+ FC scheme is not updated, whereas this is required as a consequence of amended legislation.<br>• An applicable element of the GMP+ FC scheme is incompletely implemented and/or described in the documentation, but the assessment is that this will not have negative effect on the quality of the audits.<br>• On an incidental basis the data for the participants in GMP+ International database is not up-to-date.<br>• The certification body is not represented at the harmonization meeting (without dispensation from GMP+ International). The certification body has not sent in a study case (once a year) for the harmonization meeting. | • The certification body must always submit the CAR(s) to GMP+ International to eliminate the determined nonconformity. This period of time will be determined by GMP+ International but with a maximum of 6 months. GMP+ International will assess the CAR(s) in order to close the nonconformity.<br>In order to close the minor nonconformity the certification body must send the CAR at the latest two weeks before the deadline.<br>• In the case of 5 or more audit Minor Nonconformity, the certification body is obliged to send the CARs of all minor nonconformities to GMP+ International within 10 weeks after the nonconformities are determined by GMP+ International.<br>In order to close the minor nonconformity the certification body must send the CAR at the latest two weeks before the deadline.<br>• The GMP+ International auditor/technical reviewer is responsible to make the decision to close the minor nonconformities (when there are less than 5 nonconformities).<br>If there are 5 or more minor nonconformities GMP+ International is responsible to make the decision to close and/or to upgrade the minor nonconformities.<br>• If the minor nonconformity(ies) are not or not fully resolved within the determined timeframe then they will be converted to Major nonconformity(ies). |

| Classification: Major Nonconformity | |
|---|---|
| **Definition:** | • When a requirement of the GMP+ FC scheme has been addressed but there is insufficient evidence to demonstrate that it has been properly controlled or implemented.<br>• Any nonconformity other than critical, which may result in failure and which cannot be completely eliminated or reduced to a Minor Nonconformity by an approved repair |
| **Conclusion** | • The certification body does *not* comply with the requirements for acceptance. |

| Finding | Measures |
|---|---|
| • With respect to a finding where the guaranteeing of the quality of the audits by the certification body is not in compliance.<br>• If the Minor Nonconformity(ies) are not or not fully resolved within the determined timeframe then they will be converted to Major Nonconformity(ies).<br>• An element/article of the GMP+ FC scheme is absent in the documentation, in a way that the functioning of the feed safety management system is put in question.<br>• An element of the GMP+ FC scheme is not implemented and/or described in the documentation, and the outcome of the assessment has a negative effect on the certification process.<br>• The observed nonconformity is of a structural nature.<br>• GMP+ International is not immediately informed of a Critical Nonconformity, suspension or withdrawal.<br>• On a structural basis, the certification body has not recorded or maintained the certification status of the GMP+ participants in the database of GMP+ International.<br>• The certification body does not send within the determined timeframe the requested action plan as a result of an overall- and/or retrospective analysis. | • The certification body must always submit a CAR to GMP+ International to close the detected Major Nonconformity. This period of time will be determined by GMP+ International with a maximum of 6 weeks. In order to close the Major Nonconformity the certification body must send the CAR at the latest two weeks before the deadline.<br>• GMP+ International is responsible to make the decision to close and/or to upgrade/downgrade the Major Nonconformities.<br>• If the Major Nonconformity(ies) are not or not fully resolved within the determined timeframe then they will be converted to Critical Nonconformity(ies). |

**Classification: Critical nonconformity**

| | |
|---|---|
| **Definition:** | • A regulatory violation or a complete failure to implement a requirement of the GMP+ FC scheme.<br>• Any nonconformity which may result in hazardous or unsafe conditions for individuals using, maintaining or depending upon the product |
| **Conclusion** | • The certification body does *not* comply with the requirements for acceptance. |

| **Finding** | **Measures** |
|---|---|
| • If the major nonconformity(ies) are not or not fully resolved within the determined timeframe then they will be converted to Critical nonconformity(ies).<br>• A Major Nonconformity has previously been determined and resolved but reoccurs within two years of being determined.<br>• The certification body no longer has the applicable accreditation.<br>• The no longer has an accredited QM system.<br>• The certification body does not meet its financial obligations to GMP+ International.<br>• Structural or systematic non-compliance with the requirements stated in the GMP+ FC scheme.<br>• An element of the GMP+ FC scheme is not implemented and/or described in the documentation and the assessment on the basis of objective observation shows that this is critical for the quality of the audits.<br>• The GMP+ International auditor observes a critical NCR during a compliance audit which have impact for the feed safety. | • The certification body must always submit a CAR to GMP+ International to eliminate the determined critical nonconformity. This period of time will be determined by GMP+ International with a maximum of one week.<br>• GMP+ International is responsible to make the decision to close the Critical nonconformities.<br>• If GMP+ International cannot close the Critical nonconformity then GMP+ International will immediately suspend the GMP+ acceptance of the certification body for a maximum of 3 months.<br>• If the certification body has not demonstrably resolved the Critical nonconformity within 3 months of the suspension to the satisfaction of GMP+ International then the termination of GMP+ acceptance will be initiated immediately.<br>The involved accreditation body will be informed of the suspension or withdrawal. |
| • It is reasonable to assume that there is a case of gross negligence, fraudulent actions or economic malpractice.<br>• The independence/impartiality requirements are breached by the certification body.<br>• The certification body refuses and/or does not cooperate in planning/conducting compliance assessment by GMP+ International. | • GMP+ International will immediately suspend the GMP+ acceptation of the certification body for a maximum of 3 months.<br>• If the certification body has not demonstrably resolved the Critical nonconformity within 3 months of the suspension to the satisfaction of GMP+ International then the termination of GMP+ acceptance will be initiated immediately.<br>The involved accreditation body will be informed of the suspension or withdrawal. |

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