



Method of and Criteria for the Compliance Assessment of Certification Bodies

GMP+ C 11

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GMP+ Feed Certification scheme

History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
1.0 / 09-2016	Completely new document.	Entire document	01-09-2016
2.0 / 11-2017	Editorial changes and clarification regarding “through the certification body” Adding ISO/IEC17065 Adding Critical location audits and Ad-Hoc audits Certification Bodies are always responsible for solving NC Adding frequency regarding Critical location audit and Ad-Hoc audit Critical location added GMP+ International auditors are responsible for closing Major nonconformities New assessment criteria regarding the lack of a file of a GMP+ accepted auditor at the Certification Body Suspension/withdrawal of the CB will automatically result in the suspension/withdrawal of the Critical-, Non-Critical location and Outsourcing Party.	Entire document and Paragraph 1.4 Paragraph 2.1 Paragraph 2.2. Paragraph 2.3 Paragraph 2.3 Annex 1	01.07.2018
2.1 / 05 2018	Since the chain oriented audit is a result of consecutive parallel audit this type of audit has been deleted.	Paragraph 2.2	01.07.2018

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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 was published. For this purpose, two modules have been 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.

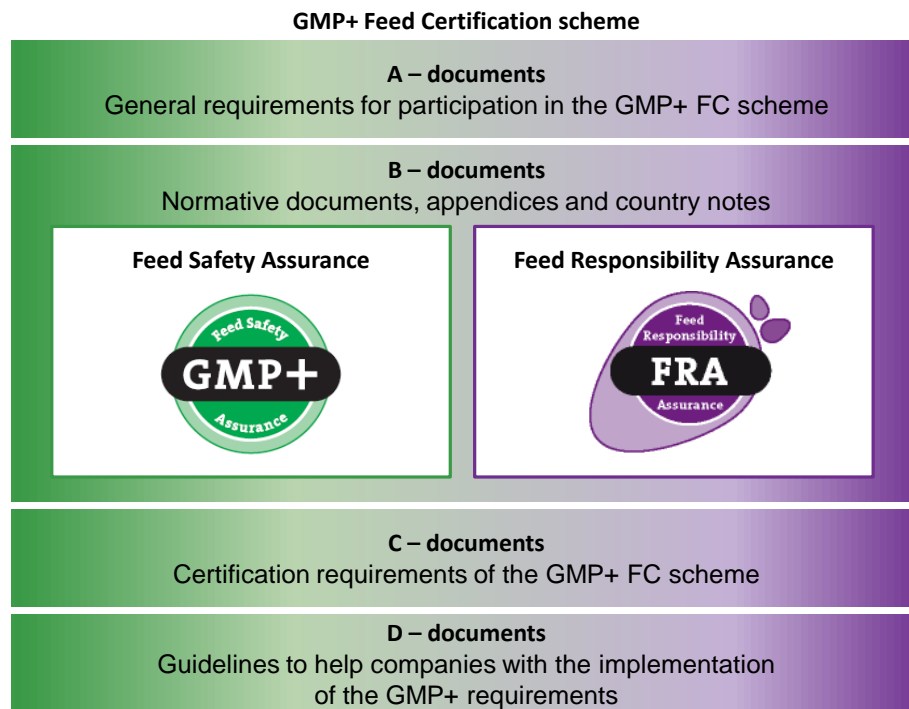
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and 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.gmp-plus.org).

This document is referred to as standard GMP+ C2 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.

In addition to this, reference to a number of other appendices is made as well. These appendices are only part of this standard, and are attached to it. To indicate them, only the word 'annex' is used.

Throughout this document the terminology "through the certification body" is used indicating that all activities performed by critical-, non-critical locations and outsourcing party are conducted under the responsibility/liability of the GMP+ accepted certification body.

2 Compliance assessment

2.1 General

Any certification body accepted by GMP+ International on the basis 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+ Feed Certification Scheme License Agreement with GMP+ International for this purpose. By entering into this 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+ C10 *Acceptation requirements and procedure for certification bodies*, 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 of the criteria as laid down in this document is made in compliance assessment audits and in determining sanctions.

The accreditation bodies ensure (insofar as applicable) that the certification bodies accepted by GMP+ International comply with the requirements of ISO/IEC17065 and/or 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, critical location(s) and GMP+ auditors / inspectors.

The compliance assessment of the certification bodies and critical location(s) that GMP+ International carries out consists of:

- a. Compliance Desk Assessment to determine whether the certification body and critical location(s) comply 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 work method and the way 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 a feed safety risk 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, executed and reported through the certification body. The parallel audit will take place after the audit has been carried out through the certification body.
- 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 requirements. The minimum time to be spent on this audit is 1 day.
- d. Critical location(s) Audit (CL report)
GMP+ International will carry out an audit at the critical location(s) at least once every two years to assess whether the implementation of the requirements laid down in the GMP+ FC scheme is carried out properly. The minimum time to be spent on this audit is 1 day.
- e. Ad-hoc Audit (AH report)
GMP+ International can carry out ad hoc audits as a result of an EWS warning, complaints or incidents. This audit focuses on the specific topics related to the EWS warning, complaints or incidents. But all requirements of the GMP+ FC scheme can be assessed.

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, which 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 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;
 - e. Compliance assessment of the critical location(s), if applicable.

The final result of the overall analysis can result in additional compliance assessment for the Certification Body and/or critical location(s). The cost for the additional compliance assessment can be charged to the Certification Body.

- iv. Examination of GMP+ auditors:
Examination of 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
Based on random samples, GMP+ International will assess the reports on audits carried out through certification bodies under the GMP+ FC scheme.

2.3 Reporting

Zero nonconformities or Minor and/or Major nonconformities:

After the compliance assessment has been carried out by GMP+ International and where applicable, the Non Conformity Report (hereafter NCR) is prepared by the GMP+ International auditor and handed over to the coordinator and/or authorized person of the certification body. Nonconformities determined during the critical location audit will always be issued to the liable certification body.

NCR(s) can only be closed if the certification body involved conducts a root cause analysis, implements corrective and/or preventive actions and, if applicable, the certification body involved 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 for finalizing the compliance report and for assessing the CAR(s) and closing the NCR(s). Report can be sampled for assessment by GMP+ International.

Critical nonconformities:

After the compliance audit has been carried out by GMP+ International the NCR(s) is prepared by the GMP+ International auditor and handed over to the coordinator and/or authorized person of the certification body. GMP+ International is responsible if the observed NCR(s) are justified and well classified. Nonconformities determined during the critical location audit will always be issued to the liable certification body.

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.

The 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 for the Certification Body office audit, critical location(s) audit and the ad hoc audit;
- b. The minimum time to be spent on the Certification Body office audit is at least 1 day annually.
- c. The minimum time to be spent on the critical location(s) audit is at least 1 day per two years.
- d. Overall analysis of the performance of a certification body is carried out annually and/or risk based;
- e. The ad hoc audits and the retrospective analysis are carried out when applicable.

Annex 1: Assessment criteria

Nonconformities determined during compliance assessments by GMP+ International are to be classified based on the general criteria stated below.

Classification: Minor Nonconformity	
Definition:	<ul style="list-style-type: none"> Any nonconformity which does not adversely affect the performance, reliability of the certification process.
Conclusion	<ul style="list-style-type: none"> Where less than 5 audit findings fall into Minor Nonconformity the certification body complies with the requirements of acceptance. If 5 or more audit findings fall into Minor Nonconformity the certification body does <i>not</i> comply with the requirements of acceptance.

Finding	Measures
<ul style="list-style-type: none"> A part of the GMP+ FC scheme applicable is not fully described in the feed safety management system although this is required. An element of the GMP+ FC scheme applicable is not updated, while this is required as a consequence of amended legislation. An element of the GMP+ FC scheme applicable is incompletely implemented and/or described in the documentation/files, but the assessment is that this will not have negative effect on the quality of the audits. On an incidental basis the data for the participants in GMP+ International database is not up-to-date. 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. 	<ul style="list-style-type: none"> 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. In order to close the minor nonconformity the certification body must send the CAR at the latest two weeks before the deadline. In the case of 5 or more 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. In order to close the minor nonconformity the certification body must send the CAR at the latest two weeks before the deadline. If the minor nonconformity(ies) are not or not fully resolved within the determined timeframe then they will be converted to Major nonconformity(ies). The GMP+ International auditor/technical reviewer is responsible for making the decision to close the minor nonconformities.

Classification: Major Nonconformity	
Definition:	<ul style="list-style-type: none"> • 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. • 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	<ul style="list-style-type: none"> • The certification body does <i>not</i> comply with the requirements for acceptance.

Finding	Measures
<ul style="list-style-type: none"> • With respect to nonconformities where the guaranteeing of the quality of the audits by the certification body and/critical location is not in compliance. • If the minor nonconformity(ies) are not or not fully resolved within the determined timeframe then they will be converted to Major nonconformity(ies). • An element/article of the GMP+ FC scheme is absent in the documentation, such that the functioning of the feed safety management system is put in question. • An element of the GMP+ FC scheme is not implemented and/or described in the documentation/files, and the assessment is that this will have negative effect on the certification process. • The nonconformity observed is of a structural nature. • GMP+ International is not immediately informed of a Critical Nonconformity, suspension or withdrawal. • On a structural basis, the certification body and/or critical location has not recorded or maintained the certification status of the GMP+ participants in the database of GMP+ International. • The certification body does not send the requested action plan as a result of an overall- and/or retrospective analysis within the determined timeframe. 	<ul style="list-style-type: none"> • 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. • If the major nonconformity(ies) are not or not fully resolved within the determined timeframe then they will be converted to Critical nonconformity(ies). • The GMP+ International auditor/technical reviewer is responsible for making the decision to close the major nonconformities

Classification: Critical nonconformity

Definition:	<ul style="list-style-type: none"> • A regulatory violation or a complete failure to implement a requirement of the GMP+ FC scheme. • Any nonconformity which may result in hazardous or unsafe conditions for individuals using, maintaining or depending upon the product
Conclusion	<ul style="list-style-type: none"> • The certification body does <i>not</i> comply with the requirements for acceptance.

Finding	Measures
<ul style="list-style-type: none"> • If the major nonconformity(ies) are not or not fully resolved within the determined timeframe then they will be converted to Critical nonconformity(ies). • A Major Nonconformity has previously been determined and resolved but reoccurs within two years of being determined. • The certification body and/or critical location no longer has the applicable accreditation. • They no longer have an accredited QM system. • The certification body does not meet its financial obligations to GMP+ International. • Structural or systematic non-compliance with the requirements stated in the GMP+ FC scheme. • 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. • The GMP+ International auditor observes a critical NCR during a compliance audit which have impact for the feed safety. • No documentation/files that the GMP+ accepted auditor is complying with the requirements as stated in Annex 2 of the GMP+ C10. 	<ul style="list-style-type: none"> • The certification body must always submit a CAR to GMP+ International to eliminate the determined critical nonconformity. This timeframe will be determined by GMP+ International with a maximum of one week. • GMP+ International is responsible for making the decision to close the Critical nonconformities. • 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 which automatically results that the critical location, non-critical location and outsourcing party are not allowed to conduct any GMP+ activities for the same period. • 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 which automatically results in the critical location, non-critical location and outsourcing party not being permitted to conduct any GMP+ activities. The involved accreditation body will be informed of the suspension or withdrawal.
<ul style="list-style-type: none"> • It is reasonable to assume that there is case of gross negligence, fraudulent actions or economic malpractice. • The independence/impartiality requirements are breached by the certification body and/or critical location. • The certification body and/or critical location refuses and/or does not cooperate in planning/conducting compliance assessment by GMP+ International. 	<ul style="list-style-type: none"> • GMP+ International will immediately suspend the GMP+ acceptance of the certification body for a maximum of 3 months which automatically results that the critical location, non-critical location and outsourcing party are not allowed to conduct any GMP+ activities for the same period.

Finding	Measures
	<ul style="list-style-type: none"><li data-bbox="895 327 1406 698">• 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 which automatically results in the critical location, non-critical location and outsourcing party not being permitted to conduct any GMP+ activities. The involved accreditation body will be informed of the suspension or withdrawal.

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