GMP+ Feed Certification scheme

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GMP+ C2
Method of and Criteria for
Supervision Certification Bodies

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Version: 1 March 2013

EN

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Feed for Food

History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0 / 09-2010	Transfer of the document from PDV to GMP+ International	Entire document	01-01-2011
0.1 / 09-2011	Introduction has been updated Textual adjustments Addition on the category 3 non conformities Transfer of the document from standard to scope	1.1; 1.2 Entire document Appendix 1 Entire document	01-01-2012
0.2 / 11-2012	Editorial change Editorial change New introduction and modified text regarding the Feed Certification Scheme	2.1 2.2e Entire document	01-03-2013

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

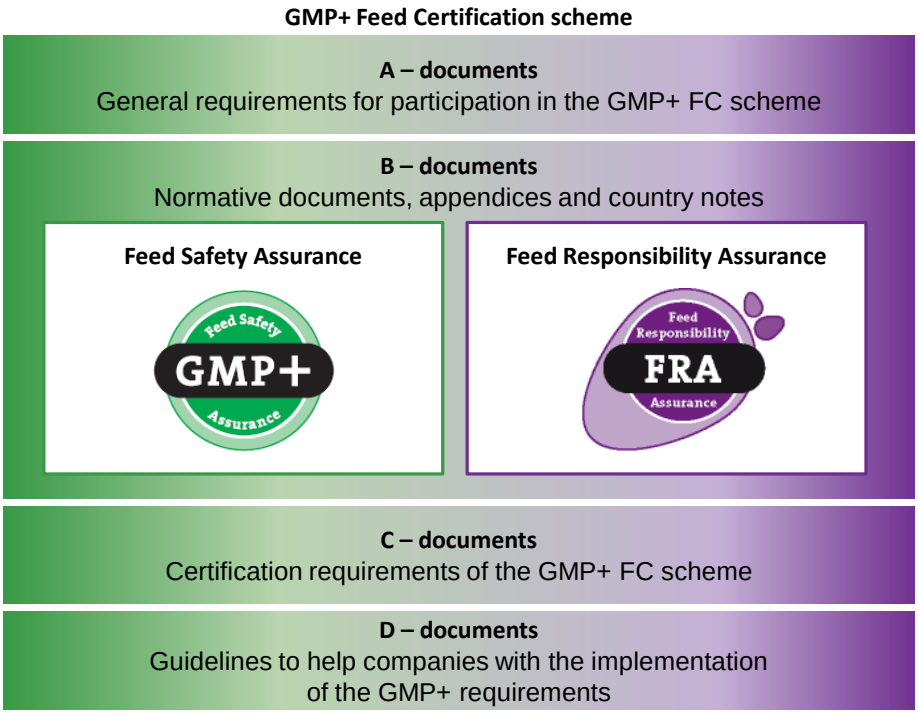
GMP+ Feed Safety Assurance is a complete module for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA module, such as requirements for the quality management system (ISO 9001), HACCP, product standards, 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 by GMP+ participants. The animal feed sector is confronted with requests on working responsibly. This includes, for example, the use of soy (including soy derivatives and soy products) and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance.
Together with the GMP+ partners, GMP+ International transparently sets clear requirements to guarantee feed safety & responsibility. 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+ C2 *Method of and criteria for supervision of certification bodies* and is part of the GMP+ FC scheme.

1.3 Scope

This document contains the procedure , assessment criteria and sanctions for supervision of those certification bodies which carry out GMP+ audits at companies as specified in the Regulation (A1) of the GMP+ FSA Scheme of GMP+ International.
These assessment criteria and sanctions must be used in the supervision 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 ‘appendix’ is used.

2 Supervision

2.1 General

Any certification body approved by GMP+ International on the basis of Article 8 of the Regulation (A1) 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 contract with GMP+ International for this purpose. By entering into this contract the certification body states that it will accept and comply with, where applicable, that which is stated in or by virtue of 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+ C1 *Approval requirements and procedure for certification bodies,* GMP+ C3 / GMP+ C6 *Assessment and Certification Criteria for GMP+ Certification and GMP+ C7 Assessment and Certification/Inspection Criteria for GMP+ Certification/Inspection - additional scopes* during GMP+ certification.

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

The accreditation bodies ensure (in as far as applicable) that the certification bodies approved by GMP+ International comply with the requirements of NEN-EN 45011 with respect to the implementation of the GMP+ FC scheme.

2.2 Supervision of certification bodies and auditors / inspectors / technical reviewers

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

a. Supervision of technical meetings, coordination and harmonisation meetings
   GMP+ International checks whether updating of professional expertise by the certification body has at least taken place in accordance with appendix 2 of the GMP+ C1 *Approval requirements and procedure for certification bodies* standard.

   GMP+ International checks whether all auditors / inspectors, technical reviewers participate in a periodic examination by GMP+ International with respect to their expertise in the field of the GMP+ FC scheme. Only with a valid reason (illness, pregnancy or insurmountable traffic problems) can there be any deviation from this in written consultation with GMP+ International. In the event of suspension, GMP+ International ensures that the auditor / inspector does not carry out GMP+ audits / inspections during the suspension.

   A meeting on policy coordination and harmonisation will be held ~~3~~ 2 times per year.

At least one auditor per certification body (preferably the coordinator) should participate. The participation of the auditors or coordinators will be registered.

b. Parallel audits
GMP+ International carries out parallel audits at GMP+ certified companies to verify the method by which an audit is planned, executed and reported by the certification body. This parallel audit will take place as quickly as possible after the audit by the certification body has been carried out and reported to GMP+ International.

c. Witness audits
GMP+ International supervises the GMP+ auditors / inspectors by assessing their working method and the way in which they categorise their findings during the execution of their audit. The individual auditor / inspector or the audit team will be assessed during a witness audit.

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

e. Audits at certification bodies
GMP+ International will carry out at least once or twice a year (depending on the findings) an audit at the certification bodies to assess whether the implementation of the requirements of the Regulation (A1), the GMP+ C1 *Approval Requirements and Procedure for Certification Bodies,* the GMP+ C3 / GMP+ C6 *Assessment and Certification Criteria and GMP+ C7 Assessment and Certification/Inspection Criteria for GMP+ Certification/Inspection - additional scopes* in the GMP+ FSA scheme audits 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.

2.3 Reporting

The assessments of the auditors / inspectors / technical reviewers and certification bodies are recorded in reports by GMP+ International. GMP+ International sends these reports within 6 weeks to the Secretary of GMP+ International and to the certification bodies.

Each year a summary report is drawn up by GMP+ International for the International Expert Committee (IEC) per certification body.

The appendix 1 contains the general criteria for the classification of observed findings during assessment by GMP+ International. The follow-up actions are described in the following table.

Appendix 1: Assessment criteria

Audit findings during assessments by GMP+ International are to be classified on the basis of the general criteria stated below.

Classification: Category 3

Conclusion	• Where less than 5 audit findings fall into Category 3 the certification body will be deemed to meet the conditions for approval. • If 5 or more audit findings fall into Category 3 the certification body will be deemed *not* to meet the conditions for approval.

Finding	**Measures**
• With respect to a finding where there is doubt of the guaranteeing of the quality of the audits by the certification body. • A part of GMP+ C1 or GMP+ C3 / GMP+ C6 is not fully described in the documentation although this is required. • An element previously described is not updated, while this is required as a consequence of amended legislation. • An element is not being properly implemented, but the assessment is that this will have only a limited negative effect on the quality of the audits. • The data for the participants in GMP+ International database is not up-to-date. • The observed non-conformity is of a structural nature. • The certification body is not represented at the harmonisation meeting (without dispensation from GMP+ International). The certification body has not sent in a study case (once a year) for the harmonization meeting. • On an incidental basis, the certification body has not recorded or maintained the certification status of the GMP+ participants in the database of GMP+ International.	• The certification body must always take the necessary improvement measures in order to improve the audit findings within the specified period. This period of time will be determined by GMP+ International. • If the audit findings are not or not fully resolved then they will be converted to a Category 2 audit finding.

Classification: Category 2

Conclusion	• The certification body does *not* comply with the requirements for approval.

Finding	**Measures**
• With respect to a finding where there is doubt of the guaranteeing of the quality of the audits by the certification body. • A Category 3 audit finding has been observed and inadequate improvement has taken place. • An element is absent or is very incompletely described in the documentation, such that the functioning of the quality system is put in question. • An element is not being correctly implemented and an assessment on the basis of objective observation shows that this is critical for the quality of the audits. • The observed nonconformity is of a structural nature. • GMP+ International is not immediately informed of Cat. 1 non-conformity, suspension or withdrawal. • 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.	• The certification body should take proper improvement measures to resolve the audit finding within the period of time determined by the auditor from GMP+ International. This period of time may be a maximum of 6 weeks. • If the audit findings are not or not fully resolved then they will be converted to a Category 1 audit finding.

Classification: Category 1

Conclusion	• The certification body does *not* comply with the requirements for approval.

Finding	**Measures**
• There has been a previous Category 2 audit finding but only inadequate or late improvement measures have been implemented. • A Category 2 audit finding has previously been determined and resolved but reoccurs within a year of being observed. • The certification body no longer has the applicable accreditation • The certification body does not meet its financial obligations to GMP+ International. • Structural or systematic non-compliance with the requirements stated in the GMP+ FSA scheme.	• GMP+ International submits a proposal for the suspension of the certification body to the IEC. • If necessary and with the approval of the IEC, the approval of the certification body will be suspended for a maximum of 3 months. • If the certification body has not demonstrably resolved the audit finding within 3 months of the suspension to the satisfaction of GMP+ International then withdrawal of approval will be initiated immediately. The accreditation body involved will be informed of the suspension or withdrawal.