GMP+ Feed Safety Assurance scheme

Method of and criteria for supervision of certification bodies

GMP+ C2

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EN

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Feed for Food

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1 Introduction

1.1 General

The GMP+ Feed Safety Assurance scheme (GMP+ FSA) has been developed since 1992. It was managed from 1992 up until 2009 by the Product Board Animal Feed, The Hague, The Netherlands. Since 2010, this scheme is managed by GMP+ International.

It is a scheme for assuring feed safety in all the links in the feed chain. It is also an international scheme, applicable worldwide.

The establishment and development of the scheme was primarily the result of demand from the subsequent links in the animal production chain for better control of feed safety. Another contributory factor was the damage caused by more and less serious contamination incidents.

In the initial phase the demand arose for better differentiation in an increasingly saturated European sales market for animal products. Since 1999, feed & food safety has been a top issue internationally both politically and commercially, because of serious incidents in the feed sector. Because of this, demonstrable assurance of feed safety has become a sales prerequisite.

The basic principle of the GMP+ FSA scheme is that the feed chain is part of the whole animal production chain. Proper assurance of feed safety worldwide is a high priority. Companies must live up to their responsibilities and respond properly and convincingly to the needs of animal production. The GMP+ Feed Safety Assurance scheme is an aid to realise this.

1.2 Sturcture of the GMP+ FSA scheme

The documents within the GMP+ FSA scheme are subdivided into a number of series. A description follows of these:

A General (framework) documents	These documents contain the requirements for participation in the certification scheme for companies and certification bodies (framework regulation, the use of logo's, etc.). This series also includes a general list of definitions and abbreviations.
B Normative documents.	These documents contain the international standards and additional country notes for use by companies with respect to the various feed products and production phases including cultivation and industrial production, treatment and processing, collection, trade, means of transport, storage and transhipment.

These documents are divided in several subgroups, with a code and a name

Document	Code	Name
⇒ Standard	GMP+ Bxx	
⇒ Appendix	GMP+ BAxx	
⇒ Country Note	GMP+ BCNxx	

C Certification requirements		These documents contain the Rules of Certification including those for the approval of certification bodies and auditors, the frequency of audits, minimum audit time, assessment criteria, checklists, etc. There is also an explanation of how the supervision by certification bodies is implemented and of how GMP+ International supervises the certification process..
Document	**Code**	**Name**
⇒ Standard	GMP+ Cxx	e.g. GMP+ C2 *Method of and criteria for supervision of certification bodies*

D Interpretations and accompanying texts	In addition to the above-mentioned normative documents, there are also supporting documents in the D series including a list of frequently-asked questions, manuals and guidances with additional information.

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

The document in the present case is referred to as standard GMP+ C2 *Method of and criteria for supervision of certification bodies* and is part of the GMP+ FSA scheme.

2 Scope and structure of the document

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.

Structure of the document
This standard has a structure of its own.

GMP+ Appendices (GMP+ BAxx), to which there are also references, are separate GMP+ documents within the B segment of the GMP+ FSA Scheme. If there is a reference in this standard to such an GMP+ BAxx-appendix, then it applies within the framework of this standard. GMP+ BAxx-appendices are indicated as such.

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.

3 Supervision

3.1 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 included in the GMP+ FSA 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+ FSA Scheme.

GMP+ International supervises compliance by the certification bodies with that which is laid down in the GMP+ FSA 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* during GMP+ certification and GMP+ C5 *Checklists*.

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+ FSA Scheme.

3.2 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+ FSA 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 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+ FSA 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* and the GMP+ C3 / GMP+ C6 *Assessment and Certification Criteria* 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.

3.3 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). • 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.