



GMP⁺ Certification Scheme Animal Feed Sector 2006

Method of and criteria for supervision of certification bodies

C.2

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1 AIM OF THE DOCUMENT

This document contains the 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⁺ Certification Scheme for the Animal Feed Sector 2006 (abbreviated to GMP⁺:2006) from the Product Board Animal Feed (PDV).

2 SCOPE

These assessment criteria and sanctions must be used in the supervision of certification bodies by the Co-ordinating Office for Animal Feed Certification and Monitoring (BCD) of the Product Board Animal Feed.

3 ASSESSMENT PROGRAMME

3.1 General

Any certification body approved, on behalf of the Central College of Experts for the Animal Feed Sector (CCvDD), by the Product Board 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⁺ Certification Scheme for the Animal Feed Sector 2006. This certification body has entered into a contract with the CCvDD via the Product Board Animal Feed for this purpose. By entering into this contract the certifying body states that it will accept and comply with, where applicable, that which is stated in or by virtue of the GMP⁺ Certification Scheme for the Animal Feed Sector 2006.

The Co-ordinating Office for Animal Feed Certification and Monitoring (BCD) supervises, on behalf of the CCvDD, compliance by the certification bodies with that which is laid down in the GMP⁺ : 2006, especially in the following standards: C1 Approval Requirements and Procedure for Certification Bodies GMP⁺ Animal Feed 2006, C3 Assessment and Certification Criteria GMP⁺ Animal Feed Sector 2006 and C4 Checklists.

Supervision then takes place in a way and at a frequency specified in appendix 2.

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

3.2 Supervision of certification bodies and auditors

Appendix 2 includes the method of supervision by the Co-ordinating Office for Animal Feed Certification and Monitoring (BCD) of the certification bodies. This supervision is carried out in various different ways:

- a. Technical meetings, coordination and harmonisation meetings

The BCD will check, on behalf of the CCvDD, whether updating of professional expertise by the certification body has at least taken place in accordance with appendix 2 of the GMP C1 standard.

The BCD audits on behalf of the CCvDD that all auditors and the coordinators or decision makers are obliged to take part in a periodic examination given on behalf of the CCvDD by the BCD with respect to their expertise in the field of animal feed. Only with a valid reason (illness, pregnancy or insurmountable traffic) can there be any deviation from this in written consultation with the BCD. In the event of suspension the BCD will ensure on behalf of the CCvDD that the auditor carries out no GMP audits during suspension.

In addition to the information meeting a policy harmonisation meeting will be organised 4 times per year. There must be at least one person per certification body (preferably the coordinator) present. The participation of the auditors or coordinators will be recorded.

b. Parallel audits

In order to verify the way in which the audit which is planned, executed and reported by the certification body together with the company, the BCD, on behalf of the CCvDD, carries out at least one annual, independent, parallel audit at a GMP⁺-certified company for each certifying body (for GMP-B2 1 x /2 years). This parallel audit will take place as quickly as possible after the audit by the certification body was carried out and reported. The reporting for this audit as well as the assessment will be sent to the certification body.

c. Witness audits

The BCD, on behalf of the CCvDD, supervises the GMP⁺ auditor by assessing his or her method of working and classification of findings during the carrying out of the audit. The individual auditor or the audit team is assessed during a witness audit. Per certification body there will be a minimum of 1 or 2 auditors assessed each year (see schedule appendix 2). The reporting of the findings will be sent to the certification body.

d. Reporting assessment

The BCD, on behalf of the CCvDD, will assess on a random sample basis the reports on audits carried out by certification bodies under GMP⁺ Certification Scheme for the Animal Feed Sector 2006. The findings will be reported to the certification body.

e. Certification body audit

The BCD, on behalf of the CCvDD, will carry out at least once or twice a year (depending on the findings; see schedule appendix 2) an audit at the certification body to assess whether the implementation of the requirements of C1 Approval Requirements and Procedure for Certification Bodies GMP⁺ Animal Feed Sector 2006 and C3 Assessment and Certification Criteria in GMP⁺ 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 auditors and certification bodies are recorded by the BCD in a report. The BCD will send this report to the Secretary of the Product Board Animal Feed and to the certification body within 6 weeks.

Each year a summary report per certification body is drawn up by the BCD on behalf of the CCvDD which is used to determine whether the certification body has complied with the approval conditions.

Appendix 1 contains the general criteria for the classification of observed findings during assessment by the Co-ordinating Office for Animal Feed Certification and Monitoring (BCD). The follow-up actions are described in the following table.

Assessment	Approval	Follow-up actions
Audit finding In accordance with requirements	The certification body complies with the conditions for approval.	Not applicable
Less than 5 audit findings in Category 3.	The certification body complies with the conditions for approval.	The certification body should take the necessary measures within a period of time to be determined by the Co-ordinating Office for Animal Feed Certification and Monitoring (BCD) to improve the audit findings properly
In the event of 5 or more audit findings in Category 3.	The certification body <i>does not</i> comply with the conditions for approval.	The certification body should take the necessary measures within a period of time to be determined by the Co-ordinating Office for Animal Feed Certification and Monitoring (BCD) to improve the audit findings properly This period of time may be a maximum of 6 weeks.
One or more audit findings in Category 2	The certification body <i>does not</i> comply with the conditions for approval.	The certification body should take the necessary measures within a period of time to be determined by the Co-ordinating Office for Animal Feed Certification and Monitoring (BCD) to improve the audit findings properly This period of time may be a maximum of 6 weeks.
One or more audit findings in Category 1	The certification body <i>does not</i> comply with the conditions for approval.	Approval by the Product Board Animal Feed will be suspended immediately. If the audit findings have not been improved adequately within three months then the approval will be revoked. The accreditation body will be informed of this.

APPENDIX 1: ASSESSMENT CRITERIA

Audit findings during assessments by the Co-ordinating Office for Animal Feed Certification and Monitoring (BCD) are to be classified on the basis of the general criteria stated below.

Audit finding	Classification	Conclusion
<ul style="list-style-type: none"> - 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 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. - It is adjudged that the audit finding is an isolated occurrence. 	<p>Category 3</p>	<ul style="list-style-type: none"> - 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. - 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 the Co-ordinating Office for Animal Feed Certification and Monitoring (BCD). - If the audit findings are not or not fully resolved then they will be converted to a Category 2 audit finding.

Audit finding	Classification	Conclusion
<ul style="list-style-type: none"> - 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 shortcoming is of a structural nature. - BCD not immediately informed of Cat. 1 shortcoming, suspension, withdrawal or non-extension of certificate. 	<p>Category 2</p>	<ul style="list-style-type: none"> - The certification body <i>does not</i> comply with the conditions for approval. - The certification body should take proper improvement measures to resolve the audit finding within the period of time determined by the auditor. 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.

Audit finding	Classification	Conclusion
<ul style="list-style-type: none"> - 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 the Product Board. 	<p>Category 1</p>	<ul style="list-style-type: none"> - The certification body <i>does not</i> comply with the conditions for approval. - 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 the Product Board then withdrawal of approval will be initiated immediately.

APPENDIX 2: METHOD OF SUPERVISION BY BCD OF CERTIFICATION BODIES

	Supervision of certification body				Supervision of auditors		
	Audit at office of certification body	Policy harmonisation Meeting	Parallel audit	Report assessment	Information meeting for auditors	Periodic examination for auditors	Witness audit
GMPB1	Minimum 1x/year. If shortcomings are observed 2x per year	Minimum 4x/year.	Minimum 1x/year.	Random sample ¹	1x per year	1x per year or 1x/ per 2 year	Minimum 2x per year
GMPB2			Minimum 1x/2 year				Minimum 1x/year
GMPB3			Minimum 2x/year				Minimum 1x/year.
GMPB4.1							
GMPB4.2							
GMPB4.3							
GMPB4.4							
GMPB4.5			Minimum 1x/year.				
GMPB5			Minimum 2x per year				
GMPB6							
GMPB7	n/a						
GMPB8	Minimum 1x/year. If shortcomings are observed 2x per year	Minimum 4x/year.	Minimum 1x/year.	Random sample	1x per year	1x per year 1x/ per 2 year	Minimum 2x per year
GMPB9							
GMPB10							

¹ Except for B04.3 because only a checklist for verification is used

APPENDIX 3: REPORTING PROCEDURE AND MODELS

2.1: Reporting model parallel audits

Date of parallel audit:

Co-ordinating Office for Animal Feed Certification and Monitoring (BCD) Auditor:
.....

Assessed company

Name of company:

Place of business:

Contact:

Certification body

Name of certification body:

Last visit date by certification body:

Type of audit:

- Initial audit
- Supervision audit (announced / unannounced)
- Extension audit
- Compliance audit
- Repeat audit
- Stricter supervision

Assessed GMP standards:

- | | | |
|--------------------------------|--------------------------------|--------------------------------|
| <input type="radio"/> GMP B1 | <input type="radio"/> GMP B4.4 | <input type="radio"/> GMP B9.2 |
| <input type="radio"/> GMP B2 | <input type="radio"/> GMP B4.5 | <input type="radio"/> GMP B10 |
| <input type="radio"/> GMP B3 | <input type="radio"/> GMP B5 | |
| <input type="radio"/> GMP B4.1 | <input type="radio"/> GMP B6 | |
| <input type="radio"/> GMP B4.2 | <input type="radio"/> GMP B8 | |
| <input type="radio"/> GMP B4.3 | <input type="radio"/> GMP B9.1 | |

BCD audit findings

Assessed elements (GMP⁺ articles)

Observed shortcomings and classification
(*Shortcoming, GMP⁺ article, department, classification*)

General impression

Comparison of audit findings

Certification body report received on:

Certification body auditor:

Certification body audit conclusion:

Correspondences and differences compared to the findings of the BCD:

Final conclusion:

Date:

Signature:

2.3: Reporting model **witness audit**

Certification body

Name of certification body:

Name of auditor:

Date of audit:

Type of audit:

- Initial audit
- Supervision audit (announced / unannounced)
- Extension audit
- Compliance audit
- Repeat audit
- Stricter supervision

Assessed GMP standards:

- | | | |
|--------------------------------|--------------------------------|--------------------------------|
| <input type="radio"/> GMP B1 | <input type="radio"/> GMP B4.4 | <input type="radio"/> GMP B9.2 |
| <input type="radio"/> GMP B2 | <input type="radio"/> GMP B4.5 | <input type="radio"/> GMP B10 |
| <input type="radio"/> GMP B3 | <input type="radio"/> GMP B5 | |
| <input type="radio"/> GMP B4.1 | <input type="radio"/> GMP B6 | |
| <input type="radio"/> GMP B4.2 | <input type="radio"/> GMP B8 | |
| <input type="radio"/> GMP B4.3 | <input type="radio"/> GMP B9.1 | |

Assessed company

Name of company:

Place of business:

Contact:

Production location(s):

.....

Certifying body report to the BCD: (date)

- g) GMP B4.4
- Knowledge:* Satisfactory
 Not satisfactory. EF no.:
- Application:* Satisfactory
 Not satisfactory. EF no.:
 not applicable
- h) GMP B4.5
- Knowledge:* Satisfactory
 Not satisfactory EF no.:
- Application:* Satisfactory
 Not satisfactory EF no.:
 not applicable
- i) GMP B5
- Knowledge:* Satisfactory
 Not satisfactory EF no.:
- Application:* Satisfactory
 Not satisfactory EF no.:
 not applicable
- j) GMP B6
- Knowledge:* Satisfactory
 Not satisfactory EF no.:
- Application:* Satisfactory
 Not satisfactory EF no.:
 not applicable
- k) GMP B8
- Knowledge:* Satisfactory
 Not satisfactory EF no.:
- Application:* Satisfactory
 Not satisfactory EF no.:
 not applicable
- l) GMP B9.1
- Knowledge:* Satisfactory
 Not satisfactory EF no.:
- Application:* Satisfactory
 Not satisfactory EF no.:
 not applicable
- m) GMP B9.2
- Knowledge:* Satisfactory
 Not satisfactory EF no.:
- Application:* Satisfactory
 Not satisfactory EF no.:
 not applicable
- n) GMP B10
- Knowledge:* Satisfactory
 Not satisfactory EF no.:
- Application:* Satisfactory
 Not satisfactory EF no.:
 not applicable
- o) Animal feed legislation
- Knowledge:* Satisfactory
 Not satisfactory EF no.:
- Application:* Satisfactory
 Not satisfactory EF no.:
 not applicable

Remarks:

.....
.....

Assessment GMP+ audit

a. Preparation: details of company, list of certificates, determination of scope, subject list, see GMP C5 Satisfactory Not satisfactory EF no.:

b. Previous audit, reports from previous audit and improvement measures associated with shortcomings of previous audit are correct Satisfactory Not satisfactory EF no.:

c. Essential elements, cf. Check list GMP C5 Satisfactory Not satisfactory EF no.:

d. Shortcomings completely recorded and correctly classified (see Assessment Criteria, appendix 1 GMP C3) Satisfactory Not satisfactory EF no.:

e. Interviews and assessment, in process environment, on the basis of records Satisfactory Not satisfactory EF no.:

f. Time expenditure Satisfactory Not satisfactory EF no.:

Report to BCD; cf. appendix 3 of GMP C3 (general details, scope, assessment summary) Satisfactory Not satisfactory EF no.:

Remarks:

.....
.....

h) Final conclusion

Reporting auditor BCD (date)

Reported to the BCD (date)

Checked by:

Remarks:

Report to the certification body: (date)