



GMP⁺-Certification Scheme Animal Feed Sector 2006

Laboratory testing

GMP⁺ Standard B10

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1. SUBJECT AND AREA OF APPLICABILITY

1.1 *Purpose*

The carrying out of analyses on samples of additives, feed materials, premixes and feed in the context of quality control under the GMP⁺ Certification Scheme for the Animal Feed Sector 2006 should take place in such a way the reliability of the results produced is controlled and assured. This standard specifies the requirements for a quality assurance system in which a laboratory can ensure that the results of the analyses under the GMP⁺ Certification Scheme are sufficiently reliable.

A laboratory may participate for its analysis activities in the GMP⁺ Certification Scheme. To do this it should establish a quality assurance system which complies with the requirements of this standard and then become certified.

Certification will take place according to the type of subject as well as the analytical method and matrix employed, which are also to be stated on the certificate. A subject is something which can be analysed by means of an analytical method.

1.2 *Application area*

This standard is intended for laboratories which carry out analyses within the framework of internal company auditing (quality control) under the GMP⁺ certification regulation at the behest of companies in the animal feed sector.

The applicant must manage and ensure compliance with critical points such as receipt, storage and treatment of samples, analysis, registration, reporting and archiving.

N.B. In this standard the words 'laboratory' and 'applicant' are used diversely. Both words refer to the organisation which has implemented the quality system.

The word 'laboratory' sometimes refers in addition to the building or area where the analysis activities take place.

2. ORGANISATION AND QUALITY POLICY

2.1 *Quality system*

The applicant must have a quality system in place which includes the organisation and documentation of responsibilities, authorisations, procedures, processes and the provisions made in relation to the management and guaranteeing of the reliability of the analytical results. Responsibility for the proper structure and operation of the quality system rests with the directors of the business.

2.2 Organisational diagram

An organisational chart should be provided to show how the laboratory fits into the organisation of the business. The applicant and its personnel should have a position independent of any activities related to the production and trading of additives, feed materials, premixes and feed carried on elsewhere in the business. The manager of the quality system must have direct access to the company directors. Internal inspections (internal audits) should be carried out by a person who is suitably independent of the activities to be audited. The auditor must also possess adequate knowledge of the activity to be audited.

2.3 Management of the quality system

There must be a procedure in place to govern authorisations in connection with amendments, modifications, additions or reviews of the quality system. A manager will be appointed within the business to be responsible for the currency, management and distribution of the manual.

3. DOCUMENTATION

3.1 Records

In recording events it is necessary, both for the proper functioning of the laboratory and for the purpose of demonstrability with respect to any assessor, that all the matters indicated by the participant in the quality system are recorded or clearly observable. Everyone in the laboratory involved with any element of the quality system must be aware of this and actively work towards its achievement.

It will be clear that mere paper recording will not suffice. It must also be demonstrable from the people doing the work, from the equipment used and the working arrangements, etc., that the relevant elements of this standard function in practice.

3.2 Manual

One of the requirements for the proper functioning of the quality system is that it should be set down in a manual. Only in this way does the cohesion among the critical points and the quality of the results of analysis become transparent by the applicant.

Putting the quality system into writing will create the manual, which provides an ongoing reference source for the implementation and maintenance of the quality system. The manual must demonstrably be kept up to date.

3.3 Date and authorisation

The documented instructions and procedures must be dated and authorised by a person nominated by the directors of the business.

4. ACCOMODATION

4.1 Environment

The environment/location where the analytical procedures are carried out must not affect the accuracy and precision of the analytical results.

4.2 Access regulation

There is to be a procedure controlling access to the laboratory, approved by the Directors, which will ensure that the integrity of the results is not affected.

The following matters must be dealt with, as a minimum:

- a. sample storage is secure against unauthorised access
- b. data is secure

The laboratory must be accessible only to laboratory personnel. Other persons may only enter the room in the presence of laboratory personnel.

4.3 Facilities

Provision should be made for:

- a. the reception of sample material
 - b. the storage of samples
 - c. the cleaning of glasswork and other equipment
 - d. the preparation and storage chemical reagents and similar
 - e. the carrying out of the tests, including the preparation of samples.
- These provisions should be appropriate given the aims of the quality system.

5. PERSONNEL

The laboratory personnel are of crucial importance in managing and guaranteeing the quality of the analytical results. The personnel must therefore have the knowledge and capabilities required for their allotted tasks in this context.

In order to achieve this it is necessary in any event that:

- a. their tasks, responsibilities and authority are made clear to them, in writing
- b. there is an established procedure in place to ensure that all personnel involved are aware of the necessary instructions and standards. They should be kept informed at least in writing, on a regular basis, and certainly in the event of essential modifications. This also applies to temporary personnel
- c. personnel received adequate initial and follow-up training. This should be apparent from the personal files and/or a training programme.

6. EQUIPMENT

6.1 *Items to be recorded*

The following matters should be recorded with regard to the equipment and tools provided which might affect the outcome of the analytical work:

- a. an inventory of the equipment available, stating the method of identification employed
- b. a maintenance system, stating the frequency and nature of the maintenance work to be carried out, including adjustment, calibration and validation, and stating who is authorised to carry out such activities. The calibration should be able to be derived from primary standards
- c. the suitability of quality inspection equipment for its particular purposes: in the event of faults in equipment: the measures that are and must be taken in relation to the use of the equipment, as well as the assessment of the validity of inspection results obtained previously

6.2 *Logbook*

The maintenance activities, repaired faults, calibrations, adjustments and validations as specified under 6.1 should be recorded in a logbook.

Malfunctioning equipment must be marked as such (“quarantined”).

7. SAMPLES, STANDARD, REFERENCE AND AUXILIARY MATERIAL

7.1 *Specifications*

Specifications should be available for the required quality of standard and reference materials and auxiliary material (chemicals). These should be recorded.

7.2 *Check*

Standard, reference and auxiliary materials should be checked on delivery to establish that what was ordered was in fact received.

7.3 *List of authorised suppliers*

There should be information available on the quality and reliability of suppliers of standard, reference and auxiliary materials. A list of authorised suppliers should be drawn up on the basis of this information.

Checks should be carried out on the usability of critical standard, reference and auxiliary materials. Frequency of checks is dependent on the extent to which the standard, reference and auxiliary materials are critical for the outcome of the analyses. A procedure must be laid down for this.

7.4 Identification

Standard, reference and auxiliary materials must be uniquely identified and provided with an expiry date and storage instructions where these are important for quality.

7.5 Precautionary measures

Precautionary measures should be in place at all stages of storage, sample preparation and processing and investigation, in order to avoid any possible unfavourable effects on the results of analysis. Instructions should be available for these purposes, and these should be kept under review.

7.6 Instructions

Instructions should be available covering receipt, storage life and destruction of samples and standard, reference and auxiliary materials.

8. INSTRUCTIONS

8.1 Instructions and description

Instructions should be available to cover:

- a. the operation, maintenance, calibration and adjustment of equipment
- b. the handling of samples
- c. the realization of the testing (the analysis), including the control provisions to be carried out. A control sample should be included in each series, the frequency is matched to single or duplicate control tests), the way in which the results of the control provisions are interpreted and the records and reports of the results. The responsibility for acceptance and reporting of analytical results should be clearly set out

The test instructions set down by the Product Board Animal Feed are to serve as a reference methodology

In the event of use of other test instructions the basic requirements (for example quantities, method of extraction and extraction time) of the method prescribed by the Product Board Animal Feed should be complied with

Other requirements may be deviated from if the laboratory is able to show through proficiency testing (if available) that the results do not deviate from the reference method

In addition it must be demonstrable from the validation report that the method used is equivalent to the reference method on the basis of detection limits, precision (repeatability), correctness, specificity and selectivity

Any test instructions should include at least a description of the following:

- a. equipment
- b. reagents
- c. other auxiliary materials, and
- d. acceptance criteria for the analytical results obtained.

It should also be stated whether and when the determination should be carried out on a single or duplicated basis. In the case of single analysis there should be sufficient guarantees built in to ensure the quality of the analytical result, for example through the inclusion of additional control analyses.

8.2 Familiarity with the instructions

The current instructions must be known to the personnel involved. Work must be carried out in accordance with the (current version of the) instructions.

9. REGISTRATION, REPORTING AND ARCHIVING

9.1 Registration

The following data should be unambiguously recorded:

- a. the identity of the sample (type, source, sample number)
- b. date of receipt of sample
- c. testing methodology adopted
- d. results of analysis; in the case of microbiological analysis, stating the quantity used in the test
- e. results of confirmatory tests (if applicable)
- f. results of control analyses Determination and evaluation to be in accordance with the methodology described under 11.2 and 11.3
- g. any irregularities detected
- h. names of those carrying out the investigation and authenticating the results.

The records should be preserved so as to prevent their unintended loss, and any amendments must be verifiable.

9.2 Reporting

Results may be reported only by authorised persons on behalf of the participant. The following items must be reported in the case of each sample:

- a. identity of the sample
- b. sample number
- c. any batch or reference number (provided by the client)
- d. date of receipt of the sample
- e. final result or results
- f. any remarks
- g. report date by the person responsible for drawing up the report
- h. authorisation by the person responsible for the report
- i. person for whom the report is intended
- j. the testing method used including the version number (possibly reclaimable).

9.3 Archiving

All data which might be significant in reconstructing how a particular result was achieved must be retained. The following items should be archived (possibly in electronic form) for at least 2 years:

- a. the records mentioned in section 9.1;
- b. a copy of each of the reports mentioned under 9.2
- c. the equipment log-books mentioned under 6.2
- d. results of internal inspections and checks
- e. replaced documents (manual, procedures, instructions etc).

9.4 Protection of data

There should be adequate security to prevent unauthorised access to and amendment of information.

10. QUALITY CONTROL PLAN AND INTERNAL AUDITS

10.1 Quality control plan

The applicant is to draw up a quality control plan to include all relevant checking recorded in the quality system. The results are to be compared to the company's internal standards.

The quality control plan is to include at least the following elements:

- a. identification of critical points, in a logical and systematic sequence
- b. the required checks, and their frequency
- c. persons responsible for carrying out checks.

10.2 Records

The results of the quality control plan are to be recorded on inspection forms developed for the purpose, stating the following as a minimum:

- a. items to be inspected, and the results
- b. the section of the laboratory involved
- c. inspection date
- d. name of inspector
- e. actions taken.

The applicant should instigate an investigation into the cause of any irregularities, and to rectify these. The action taken, the rationale and the results should be recorded.

10.3 Frequency

Internal audits should be carried out at least once per year.

10.4 Reporting

The results, their evaluation and the actions taken should be reported to the directors of the laboratory. The (final) responsibility for taking action in the case of irregularities rests with the directors of the business.

11. PEER GROUP TESTING

11.1 Participation

The applicant should take part in inter-laboratory tests (peer group tests) dealing with the analytical methods used by the participant and based where possible on proficiency testing.

11.2 Administration

For each operation, the laboratory's results, as compared with the mean calculated from the relevant peer group test are to be retained and archived for a minimum of 3 years. The results should show the deviation from the mean, expressed as multiples of the spread ("s") calculated for the peer group test in question, and presented as a summary or graph.

11.3 Instigation of testing

The laboratory must instigate an investigation into the cause of deviations and rectify them, where the following occurs:

- a. one deviation of more than $3 \times s$
- b. two consecutive times with a deviation of more than $2 \times s$ on the same side of the average
- c. or eleven consecutive results on the same side of the average.

This action taken, the rationale and the results should be recorded.

12. CONTRACTING OUT TO OTHER LABORATORIES

Analytical work may only be contracted out to laboratories which are certified for the work in question under this or some other equivalent standard.

Operations which are contracted out are not eligible for certification.

Where analytical work is contracted out to third parties, the report to the client must make it clear that the analysis was not carried out in-house, but rather contracted out.

13. COMPLAINTS PROCEDURE

The participant should have a system in place for the recording and handling of complaints.

14. QUALITY CONTROL OF THE TESTING AND CALIBRATION RESULTS

The laboratory must have procedures in place for quality control to monitor the validity of the analyses and calibrations carried out.

The details must be recorded in such a way that trends are noticed and, where practically possible, statistical methods can be used to assess the results. This monitoring should be evaluated periodically and modified where applicable.

During this periodic evaluation the analysis methods used should also be evaluated. A check should be carried out on whether use is made of the most current version of a method and whether there is a need to (re)validate the method.

15. SEROLOGICAL CLASSIFICATION FOR SALMONELLA

If a laboratory carries out serological classification for Salmonella within the framework of its GMP+ B10 certification then it should comply with the following additional requirements:

1. The laboratory must be able to classify feed materials for at least the following serological types:
 - o Enteritidis
 - o Typhimurium
 - o Infantis
 - o Virchow
 - o Hadar
 - o Java
 - o Agona.
2. The laboratory is prepared and able to receive and further analyse the isolates from laboratories which do not carry out serological classifications.
3. Analyses will be carried out in accordance with the Kauffmann White antigene scheme .

Group	serological classification	Somatic antigens (O)	Flagellin antigens	
			Phase 1	Phase 2
D	Enteritidis	1,9,12	g,m	
B	Typhimurium	1,4,5,12	l	1,2
B	Java	1,4,5,12	b	1,2
C1	Infantis	6,7	r	1,5
C1	Virchow	6,7	r	1,2
B	Agona	1,4,12	f,g,s	-
C2	Hadar	6,8	z10	e,n,x

Table 1: Antigens scheme for Salmonella according to the Kauffman White scheme (Source: Bergey's manual of Determinative Bacteriology)

4. If it is a type which can not be classified by the laboratory then the sample must still be fully classified by the RIVM.
5. The laboratory is obliged to participate in the training courses organised by the RIVM for the serological classification of Salmonella.
6. The laboratory is obliged (where possible) to participate in ring tests for serological classification.
7. The laboratory is obliged to send each year a **minimum** of 30 isolates to the RIVM for serological classification (duplicate testing). The results of the analyses will then be checked or confirmed.

16. COMMENTARY

A company's own internal monitoring (under a quality control plan) has an important place in the various GMP⁺ standards. Such monitoring will in part be carried out by means of laboratory testing. The quality of such laboratory testing is therefore an essential element of quality control in the animal feed sector.

This standard for laboratories has been drawn up in the interests of ensuring the quality level of these laboratory tests.

The standard consists in broad terms of the following three elements:

- minimum requirements on the laboratory's quality system, derived from EN 17025;
- application of officially recognised methods (or methods providing equivalent performance) thereby ensuring uniformity;
- participation in inter-laboratory peer-group testing, on the basis of proficiency.

Certification under this GMP⁺ standard may be combined with certification under ISO 17025.