



GMP+ Feed Safety Assurance scheme

Assessment and Certification Criteria for GMP+ certification - Product Certificate

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GMP+ C3

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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 food 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 Structure of the GMP+ Feed Safety Assurance 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.
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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 transshipment.

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
⇒ Standard

Code
GMP+ Cxx

Name
e.g. *GMP+ C3 Assessment and Certification Criteria for GMP+ Certification – product certificate*

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 guidelines 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+ C3 Assessment and Certification Criteria for GMP+ Certification – product certificate* and is part of the GMP+ FSA scheme.

1.3 Scope

This document contains the assessment and certification criteria relating to the carrying out of audits of companies as defined in GMP+ A1 *General Regulations* of the GMP+ Feed Safety scheme of GMP+ International, referred to hereafter as the “GMP+ FSA scheme”.

These assessment and certification criteria must be used by certification bodies in the carrying out of audits at companies for product certification for the GMP+ FSA scheme .

1.4 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.

2 Assessment programme

2.1 General

A certification body approved by GMP+ International under the GMP+ FSA-scheme is entitled to certify companies who have an interest for one or more GMP+ standards as specified in the GMP+ FSA scheme.

The following regular audits are provided for:

- a. Initial audit
- b. supervision audit
- c. extension audit.

In addition, additional audits can also be carried out such as a compliance audit, a repeat audit or stricter supervision.

2.2 Initial audit

The certification body will carry out an initial audit in order to assess whether the company meets the criteria for the relevant GMP+ standard.

A GMP+ certificate may or may not be granted by the certification body on the basis of this initial audit, depending on whether the assessment criteria set out in appendix 1 are met. The period of validity of the certificate is a maximum of three years.

The certification body will carry out the full implementation of this audit, that is to say the planning, assessment of documents, the on-site audit, reporting and certification.

The initial audit is a comprehensive assessment of the quality system and consists of:

- a. Assessment of the quality documentation
There will be an investigation of what, according to the applicable GMP+ standards, is also actually recorded in a quality manual or in a procedure or job instruction book such as organisation, scope, management statement, risk assessment, etc.
- b. On-site audit
At the company locations there will be an investigation into whether the implementation of the requirements of the GMP+ standards is taking place in the correct manner. In addition, if applicable, there is an assessment of products (section 3.5).

It is possible, on the basis of a positive assessment of the quality documentation, to issue a temporary acceptance (maximum 3 months) for an initial audit at a company which is starting its GMP+ activities in the feed sector. The purpose of this assessment of the quality documentation is:

- a. The checking of the quality documentation
- b. The evaluation of the place and the specific requirements of the company location(s) and/or company resources (for example means of transport)
- c. To proceed with an evaluation of the company and its understanding of the requirements of the standard
- d. The collection of all the required information for the additional initial audit
- e. To determine whether the internal audit(s) have been planned and carried out and whether the level of the implementation of the quality documentation confirms that the company is ready for the additional initial audit.

When a company carries out production and/or (simple) processing and/or storage and transport activities then part of the assessment of the quality documentation must take place at the company location(s) so that the infrastructural facilities can be better inspected. If the company carries out other activities then part of the assessment of the quality documentation may take place at the company location(s) if the certification body considers this necessary.

During these three months the additional initial on-site audit should be carried out to assess whether the implementation of the GMP+ requirements has taken place correctly. In addition, if applicable, there is an assessment of products (section 3.5). The total certification process must be finished off within these three months including the updating of GMP+ International's database (including status and certificate dates) by the certification body.

If the company also complies during the additional initial audit with the GMP+ requirements then a certificate with a maximum period of validity of 3 years may be issued calculated from the date of the final assessment of the additional initial audit. However, if the company does not appear to comply during the additional initial audit with all the GMP+ requirements then no certificate may be issued. If the company still does not comply within the temporary approval period with all the GMP+ requirements then the temporary approval which was issued for a maximum of three months, will be withdrawn.

Companies which are already GMP+ certified are not eligible for a temporary approval. This also applies to companies which were previously GMP+ certified or which had a temporary approval but who because of a suspension or withdrawal at their own request had their certificate or temporary approval withdrawn.

2.3 Supervision audit

The certification body will carry out supervision audits during the period of validity of the GMP+ certificate, to assess whether the company continues to meet the requirements for certification. These supervision audits are in principle announced. The frequency of these supervision audits is specified for each GMP+ standard as in appendix 2.

The certification body will draw up an audit programme for this purpose. Account should be taken of the implementation of any improvement measures and those elements and assessment criteria which should be taken into consideration as a minimum in the GMP+ checklists.

A supervision audit aimed at all areas of the certification requirements consists of:

- a. Assessment of the quality documentation
There will be an examination of those sections which on the basis of the applicable GMP+ standards must be laid down in writing such as organisation, scope, risk assessment, etc., in a quality manual or in a book of work or procedure instructions.
- b. On-site audit
At the company branches there will be an investigation into whether the implementation of the requirements the GMP+ standards is taking place in the correct manner. In place of this the audit can in the case of the GMP+ B4.1 *Road Transport* also take place at a branch which is not the official registered address of the company. See the requirements in appendix 8. In addition, if applicable, there is an assessment of products (section 3.5).

2.4 Extension audit

The GMP+ certificate may be extended only where it is established during an extension audit that the company still complies with all the GMP+ requirements.

In good time, before the end of the period of validity of a certificate, an extension audit must be carried out to assess whether the company still complies with the requirements for GMP+ certification. In addition, before the period of validity of the certificate expires, the total certification process must be finished off including the updating of GMP+ International's database (including status and data certificate) by the certification body. The extension audit is a comprehensive assessment of the quality system.

If an extension audit is not carried out before the expiry of the period of validity of the certificate then an initial audit must be carried out. The company is in the intervening period not GMP+ certified.

An extension audit shall consist of:

- a. Assessment of the quality documentation
It will be investigated whether those items required to be recorded in writing by the GMP+ standards such as organisational arrangements, scope, a statement by the Director, risk assessment etc., have indeed been so recorded in a quality manual or in a book of working or procedural instructions.
- b. On-site audit
At the company locations there will be an examination of whether the implementation of the requirements the GMP+ standards is taking place in the correct manner. In addition, if applicable, there is an assessment of products (section 3.5).

2.5 Assessment of products

A sample will be taken by the certification body at the company site from each product group of premixes, feed additives, feed materials or compound feeds. This will be in accordance with the method defined in appendix 9 to this document unless determined otherwise in GMP+ BA4 *Minimum Requirements for Sampling and Analysis*. The certification body will have the samples analysed in accordance with the product standards defined in GMP+ BA1 *Product Standards* which are applicable to those products on the basis of the company's own risk analysis. The methods to be used are specified on this website: www.pdv.nl

These analyses should be carried out by a laboratory which is ISO 17025 accredited for the analysis in question (if this is possible). A laboratory may deviate from the methods laid down by GMP+ International if it can be shown that the non-standard method has at least the same performance characteristics (determination limit, repeatability, reproducibility, etc.). The costs of these analyses will be charged to the company. The results of the analyses will be used for the certification process of the company and will also be made available to GMP+ International's Database of Undesirable Substances.

2.6 Additional audits

If the results of the audit indicate it then an additional audit should be carried out. The circumstances in which this would be appropriate are indicated in appendix 1.

Compliance audit

If one or more Category 2 shortcomings are observed then the certification body may carry out a compliance audit. This audit is in addition to the normal audit cycle and is aimed at specific aspects related to the observed nonconformity and the improvement measures taken. A Category 2 nonconformity can also be handled administratively on the basis of compliance measures formulated by the company.

Stricter supervision

In the event of the observation of one or more Category 1 nonconformities a certification body may decide to withdraw the certificate or temporary approval of the company, to suspend the company or to place the company under stricter supervision. This last will only be done if unsatisfactory improvement measures are taken. The stricter supervision will take place for the period determined in appendix 1 and will be a minimum of 3 months and a maximum of 6 months. An on-site audit will take place each month aimed at all the GMP+ requirements.

Repeat audit

In special circumstances there may be a repeat audit. This audit is aimed in principle at all the requirements of the GMP+ FSA scheme. The reason for a repeat audit may be an EWS alert, complaints or incidents, or something else. Depending on the nature and content of the indications GMP+ International have the following repeat audits carried out:

- a. The certification body of the company in question will be asked by GMP+ International to carry out a repeat audit in the short term (within a few days). This will consist of at least an on-site audit. In addition, physical and/or administrative checks and a sampling may be carried out.
The required appointments and communication on this will be made with the

- company by the certification body.
- b. GMP+ International may ask the certification body to carry out a repeat audit in the short term (within a few days) in the presence of an auditor and/or an expert from GMP+ International. This repeat check will consist of at least one audit. In addition, physical and/or administrative checks and a sampling may be carried out. The required appointments and communication on this will be made with the company by the certification body in consultation with GMP+ International.

The costs of the repeat audit will be met in principle by GMP+ International. However, if it appears that one or more Category 1 or 2 nonconformities are observed then the costs will be charged to the company.

2.7 Duration of audits and rotation of auditors

The minimum frequency and *duration* for the completion of the various audits (including the assessment of documentation) and reporting is stated in appendix 2 of this document.

The duration of the audit is dependent on the size of the company and the number of activities requiring certification.

An auditor can:

- a. carry out a maximum of six consecutive audits after which the progress of the auditing is carried out by a least 4 consecutive audits by another auditor, or
- b. only carry out the extension audit on the basis of which the certification body takes the decision to extend the certificate or not if he or she has carried out less than four previous audits of this GMP+ participant.

2.8 Assessment and reporting

The certification body will assess the companies for compliance with the general assessment criteria specified in appendix 1 of this document and the additional assessment criteria in the checklists (GMP+ C5 *Checklists*). During the audit or review of the quality documentation in the event of a temporary approval it is mandatory to work with the GMP+ checklists. These checklists indicate the minimal frequency for assessment of each element of the GMP+ standard. In a repeat audit as specified above it may be decided to deviate from this in consultation with GMP+ International. All deviations which are observed during this audit or review of the quality documentation in the event of a temporary approval, should be done in writing on a registration form (NCR). The auditor will leave a copy of this registration form at the company.

The company representative will provide the recorded compliance measures and the result of the internal verification to the certification body within the agreed and recorded period of time.

The certification body will report, with respect to the GMP+ audit or review of the quality documentation in the event of a temporary approval, in accordance with the sample report in appendix 3 of this document. The reporting should be worked out completely and entered into a digital file. Only an audit checklist has to be completed for the standards GMP+ B3.2 *Trade to Livestock Farms* and GMP+ B4.3 *Inland Waterways Transport*. Further reporting is not necessary. In the event of combinations with the GMP+ B3.2 *Trade to Livestock Farms*, audit reporting is mandatory.

The technical reviewer checks the report drawn up by the auditor for deviations which are observed during the audit and gives a final assessment including any sanctions. The agreed measures are then assessed and also the method for assessing the resolution of deviations.

Raw data is to be stored in conformity with the accreditation requirements in EN 45011 (where applicable). The technical reviewer or another competent person is responsible for decision with respect to GMP+ certification.

The certification body will, within 6 weeks after conducting the audit, send the final report (for the standards GMP+ B3.2 *Trade to Livestock Farms* and GMP+ B4.3 *Inland Waterways Transport* only a final audit checklist) together with any data from the certificate or the temporary approval to the company. In the event of a repeat audit the reporting period should be determined in consultation with GMP+ International.

The certification body keeps the participants details up to date using the Internet application. Every company location which is given certification or temporary approval should have its own GMP+ International registration number. The information from the audit checklists should also be included in GMP+ International's database by way of this web application within a maximum of 2 weeks of the end of the audit (with the exception of an extension audit, see section 3.4) .

If GMP+ International requests the audit reports then the certification body will make these available immediately.

2.9 Certification and temporary approval

Temporary approval will be given for a period of a maximum of three months. Certificates will be issued for a period of a maximum of three years (GMP+ B4.3 *Inland Waterways Transport*: two years). A GMP+ certificate or temporary approval will only be issued by a branch of the certification body approved by GMP+ International and with which GMP+ International has entered into a contract. A certificate will only be issued if there is full compliance with the requirements for certification taking into account the appendix 1: Assessment criteria and measures. The classification of the nonconformities should take place in both cases in accordance with the specified criteria and interpretations.

The certification body reports to GMP+ International and provides the data specified in Article 5 of GMP+ A1 *General Regulations*. GMP+ International manages and publishes a public register of GMP+ certified companies.

The certification body must put the following text on the certificate or temporary approval:

A text for feed products (feed materials, feed additives, premixes and compound feeds); producers and traders.

FIXED SECTION

"=*name CB*= declares that there is a justifiable confidence the feed products = 2nd column of the table in appendix 6= from the business location =*name of company*= complies on delivery with the applicable product requirements in appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA scheme of GMP+ International.

This has been shown by periodic verification of the feed safety system and the process control requirements in standard GMP+ Bx =*name of standard* = (appendix 5) and the assessment of the product(s) in accordance with the applicable norms in appendices GMP+ BA1 and GMP+ BA3 (if done by CB), as determined in the GMP+ C3 *Assessment and Certification Criteria for GMP+ Certification of the GMP+ FSA scheme of GMP+ International.*"

The scope of this certificate relates to: table appendix 6.

FREE SECTION

See appendix 6.

B text for service product road transport; transport companies.

FIXED SECTION

"=*name CB*= declares that there is justifiable confidence that the road transport of feeds delivered by the business location =*name of company*= complies on delivery with the applicable requirements and conditions for road transport of the GMP+ FSA scheme of GMP+ International.

This has been shown by periodic verification of the feed safety system and process control requirements in standard GMP+ B4.1 *Road Transport* and the verification of the conditions for road transport in GMP+ BA14, as determined in the GMP+ C3 *Assessment and Certification Criteria for GMP+ Certification of the GMP+ FSA of GMP+ International.*"

The scope of this certificate relates to: table appendix 6.

FREE SECTION

See appendix 6.

C text for services road transport, inland waterway affreightment, sea-going transport affreightment, rail transport affreightment and storage & transshipment.

FIXED SECTION

"=*name CB*= declares that there is justifiable confidence that the service (appendix 6) delivered by the business location =*name of company*= complies on delivery with the applicable process requirements in Chapter 7 of standard GMP+ Bx of the GMP+ FSA scheme of GMP+ International.

This has been shown by periodic verification of the feed safety system and process control requirements in standard GMP+ Bx = *name of standard* = (appendix 5) as determined in the GMP+ C3 *Assessment and Certification Criteria for GMP+ Certification* of the GMP+ FSA scheme of GMP+ International."

The scope of this certificate relates to: table appendix 6.

FREE SECTION

See appendix 6.

D text for combination A and B.

FIXED SECTION

"=*name CB*= declares that there is a justifiable confidence that the feed products = 2nd column of the table in appendix 6= and the road transport from the business location =*name of company*= complies on delivery with the applicable requirements and conditions of appendices GMP+ BA1 and GMP+ BA3 and the applicable requirements for road transport of the GMP+ FSA scheme of GMP+ International.

This has been shown by periodic verification of the feed safety system and the process control requirements in standard GMP+ Bx =*name of standard* = (appendix 5) and the GMP+ B4.1 *Road Transport* as well as the assessment of the feed product(s) in accordance with the applicable standards in appendices GMP+ BA1 and GMP+ BA3 (if done by CB) and the conditions for road transport in GMP+ BA14, as determined in the GMP+ C3 *Assessment and Certification Criteria for GMP+ Certification* of the GMP+ FSA scheme of GMP+ International."

The scope of this certificate relates to: table appendix 6.

FREE SECTION

See appendix 6.

E text for combination A and C.

FIXED SECTION

=*name CB*= declares that there is a justifiable confidence that the feed products = 2nd column of the table in appendix 6= and the service (appendix 6 first column) from the business location = *name of company* = complies on delivery with the applicable product requirements of appendices GMP+ BA1 and GMP+ BA3 and the process requirements of Chapter 7 of the standard GMP+ By of the GMP+ FSA scheme of GMP+ International.

This has been shown by periodic verification of the feed safety system and the process control requirements in standard GMP+ Bx =*name of standard* = and GMP+ By = *name of standard* = (appendix 5) as well as the assessment of the feed product(s) in accordance with the applicable standards in appendices GMP+ BA1 and GMP+ BA3 (if done by CB) and the process requirements in Chapter 7, as determined in the GMP+ C3 *Assessment and Certification Criteria for GMP+ Certification* of the GMP+ FSA scheme of GMP+ International.“

The scope of this certificate relates to: table appendix 6.

FREE SECTION

See appendix 6.

F text for GMP+ certificates which do not fall under accreditation such as GMP+ B2: scope trade and storage of feed additives, GMP+ B3.2 (distributive trades), GMP+ B4.3 (inland waterways), GMP+ B6 (cultivation) and GMP+ B10 (laboratory)

FIXED SECTION

“=*name CB*= declares that there is justifiable confidence that the service (*appendix 6*) delivered by the business location =*name of company*= complies on delivery with the applicable requirements of the GMP+ FSA scheme of GMP+ International.

This has been shown by periodic verification of the feed safety system or quality system (whichever is applicable) and process control requirements in standard GMP+ Bx = *name of standard* = as determined in the GMP+ C3 *Assessment and Certification Criteria for GMP+ Certification* of the GMP+ FSA scheme of GMP+ International.“

The scope of this certificate relates to: table appendix 6.

FREE SECTION

See appendix 6.

G text for a temporary approval

FIXED SECTION

"=*name CB*= declares that there is justifiable confidence that the service (*appendix 6*) delivered by the business location =*name of company*= complies on delivery with the applicable requirements of the GMP+ FSA scheme of GMP+ International.

This has been shown during a review of the quality documentation for the standard GMP+ Bx =*name of standard*=, as determined in the GMP+ C3 *Assessment and Certification Criteria for GMP+ Certification* of the GMP+ FSA scheme of GMP+ International."

The scope of this temporary approval relates to: table appendix 6.

FREE SECTION

See appendix 6.

Note:

- It is not permitted to depict the GMP+ logo or accreditation mark on a temporary approval. In addition, the document may not be called a "certificate" but should be designated as a "temporary approval".

H text layout for every certificate or temporary approval

Name of the certification body:

GMP+ International registration number of the certification body:

Name, address, location of the business location
(Name of vessel + EU number of vessel)

Visit address

GMP+ International registration number of the business location

FIXED SECTION

FREE SECTION

Registered office of the certification body

Certificate number / temporary approval number
mark

Accredita-

Begin date and end date of certificate / temporary approval
applicable)

(if

Notes:

- It is not permitted to depict the GMP+ logo or accreditation mark on a temporary approval. In addition, the document may not be called a "certificate" but should be designated as a "temporary approval".
- It is not permitted to specify brand names in any way whatsoever on the certificate or temporary approval.
- It is mandatory to show the GMP+ logo and the Accreditation Mark (if applicable) on the certificate.
- The begin date of the certificate is a date which is in any event after the date of the positive final assessment.

2.10 Suspension or withdrawal of a certificate or temporary approval

If it is established that a GMP+ certified or temporarily approved company no longer complies with the requirements then the certification body is obliged to impose measures and sanctions immediately in accordance with appendix 1.

In the event of Category 1 nonconformities as specified in appendix 1 the auditor is obliged immediately to report his findings to the responsible coordinator. The certification body will immediately inform GMP+ International. This also applies in the event of certification or temporary approval being revoked or not extended.

2.11 Contracts / agreement

In the agreements (or tenders which are part of the agreements) between the certification body and companies the GMP+ audit time should be included. This audit time should at least conform with the minimum audit time expenditure as laid down in *GMP+ C3 Assessment and Certification Criteria for GMP+ Certification*. Reference to *GMP+ C3 Assessment and Certification Criteria for GMP+ Certification* is insufficient. It is not permitted to deviate from the minimum duration in the binding guidelines by way of invoicing on the basis of the costings. If on the basis of the auditor's findings a longer audit time should be used then this can be done in consultation with the company.

The certification body will establish in a contract that the GMP+ certified company may make use of the GMP+ logo and that it undertakes strict compliance with conditions set for this by GMP+ International.. Companies which have a temporary approval are not permitted to make any use whatsoever of the GMP+ logo.

In addition, the certification body must record the obligation on the companies to provide cooperation in the carrying out of witness audits , parallel audit and supplementary audits (compliance audits, increased supervision and repeat audits) in the contract with the company.

2.12 Exclusion of GMP+ International liability

GMP+ International has no liability whatsoever with respect to the assessment of companies by the certification bodies. The certification bodies in question will GMP+ International in this respect.

2.13 Tariffs

The certification body will use its own rates.

2.14 Disputes between certification bodies and companies

Disputes between certification bodies and companies with respect to the assessment will initially be handled in accordance with the disputes regulation of the certification body. If this does not lead to a solution then the dispute may be handled, in the second instance, in accordance with the *GMP+ A4 Disputes Procedure*.

Appendix 1: Assessment criteria and measures

Audit nonconformities are to be classified on the basis of the general assessment criteria stated below. In addition the specific assessment criteria shown in the checklists remain in force. The measures specified should be imposed as a minimum. A certification body is able to impose stricter measures.

Classification: Category 3

<p>Conclusion</p>	<ul style="list-style-type: none"> Where 10 or more Category 3 audit nonconformities are observed during an audit, an additional audit or the assessment of quality documentation, the company does not meet the requirements for GMP+ certification or temporary approval.
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Nonconformity	Measures
<ul style="list-style-type: none"> This relates to a nonconformity where the risk that there will no longer be compliance with the feed safety requirements under the GMP+ norms is slight. Some required element is not completely described in the documentation. An element previously described is not updated, while this is required as a consequence of amended requirements and regulations. Quality records have been overlooked or are out of date (< 2 months), clearly of an incidental nature. An element is not being properly implemented, but this will have only a limited negative effect on the basic quality of the product. The standard for an undesirable substance is breached, without direct hazard for humans, animals and/or the environment, without there being adequate improvement measures taken. It is reasonable to assume that the nonconformity is an incident. The above only applies if (it is reasonable to assume that) there is <i>not</i> a case of gross negligence, fraudulent actions or economic malpractice. 	<ul style="list-style-type: none"> The company is obliged to take the necessary improvement measures to take care of the nonconformity within the period of time set by the certification body (maximum 6 months). Nonconformities can be handled administratively by the certification body unless an (extra interim) assessment is necessary in practice. If the nonconformity is not or not fully resolved then it will be converted to a Category 2 nonconformity.

<ul style="list-style-type: none"> 10 or more Category 3 nonconformities 	<ul style="list-style-type: none"> The company is obliged to take proper improvement measures to take care of the nonconformities within the period of time set by the certification body (maximum 6 weeks).
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Classification: Category 2

Conclusion	<ul style="list-style-type: none"> • The company does not meet the requirements for GMP+ certification or temporary approval. • If one or more Category 2 nonconformities are observed during an initial audit, an extension audit or a review of the quality documentation, then the GMP+ certificate or the temporary approval may not be issued or extended.
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Nonconformity	Measures
<ul style="list-style-type: none"> • A Category 3 nonconformity was observed earlier and inadequate or no 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. • Quality records are very out of date (> 2 months). • An element is not being properly implemented and is possibly critical for the feed safety of the product. • The company does not carry out proper sampling or analysis or does not carry it out properly in accordance with the requirements or does not provide the results to GMP+ International in accordance with the requirements. • Internal audits not carried out or are late or incomplete • In addition it is reasonable to assume that there is <i>no</i> case of gross negligence, fraudulent actions or economic malpractice. 	<ul style="list-style-type: none"> • The company is obliged to take proper improvement measures to take care of the nonconformity within the period of time set by the certification body (maximum 6 weeks). • The company will be subject in <i>all</i> cases – unless stated otherwise above – to at least one compliance audit within a period of 3 months. This may be handled administratively except in those cases where an assessment is necessary in practice.

Nonconformity	Measures
<ul style="list-style-type: none"> • A serious nonconformity relating to critical GMP+ requirements.¹ • A serious nonconformity of an incidental nature without direct consequences for the subsequent links in the chain. • Feed additives or feed medicines are not processed in accordance with the requirements. • It is reasonable to assume that there is <i>no</i> case of gross negligence, fraudulent actions or economic malpractice. 	<ul style="list-style-type: none"> • Immediate recall of all the products in question unless the company can show to the satisfaction of the certification body that the nonconformity has no harmful health effects for animals and/or humans and the existing legal standards for animal products are not breached. • The company is obliged to take proper improvement measures to take care of the nonconformity within the period of time set by the certification body (maximum 6 weeks). • The company will be given at least one compliance audit within 3 months. This may be handled administratively except

¹ This covers in any event a) inadequate entry checks of delivered feed materials, b) unsatisfactory registration for tracking & tracing, c) purchase of feed materials which are not included in the Feed Materials Risk Assessment Database, d) non-compliance with the feed legislation. This will be detailed in the checklists.

<p>Nonconformity</p> <ul style="list-style-type: none"> • A Category 3 nonconformity was observed earlier and inadequate or no 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. • Quality records are very out of date (> 2 months). • An element is not being properly implemented and is possibly critical for the feed safety of the product. • The company does not carry out proper sampling or analysis or does not carry it out properly in accordance with the requirements or does not provide the results to GMP+ International in accordance with the requirements. • Internal audits not carried out or are late or incomplete • In addition it is reasonable to assume that there is <i>no</i> case of gross negligence, fraudulent actions or economic malpractice. 	<p>Measures</p> <ul style="list-style-type: none"> • The company is obliged to take proper improvement measures to take care of the nonconformity within the period of time set by the certification body (maximum 6 weeks). • The company will be subject in <i>all</i> cases – unless stated otherwise above – to at least one compliance audit within a period of 3 months. This may be handled administratively except in those cases where an assessment is necessary in practice.
<p>Nonconformity</p>	<p>Measures</p> <p>in those cases where assessment in practice is necessary.</p>
<ul style="list-style-type: none"> • During the compliance audit a previously observed Category 2 nonconformity is not put right in time or not completely. • Any recall is not carried out properly or (due to own negligence) is not carried out in time. 	<ul style="list-style-type: none"> • This nonconformity will be converted into a Category 1 nonconformity.

Classification: Category 1

Conclusion	<ul style="list-style-type: none"> • The company does not meet the requirements for GMP+ certification or temporary approval. • If one or more Category 1 nonconformities are observed during an initial audit, an extension audit or a review of the quality documentation, then the GMP+ certificate or the temporary approval may not be issued or extended.
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Nonconformity	Measures
<ul style="list-style-type: none"> • There has been a previous Category 2 nonconformity but only inadequate or late improvement measures have been implemented. 	<ul style="list-style-type: none"> • The company is obliged to take proper improvement measures to take care of the nonconformity within the period of time set by the certification body (maximum 2 weeks). • The company will be given at least one compliance audit. • The company will be placed under stricter supervision for a period of at least 3 and maximum 6 months. • If the company does not take improvement measures within the period of time established and food safety is at risk then the certification body will suspend the certificate or temporary approval for a maximum of 3 months. • Lifting of suspension is only possible if the certification body has established during a compliance audit that proper improvement measures have been taken. The company will be placed under stricter supervision for at least 3 to a maximum of 6 months.

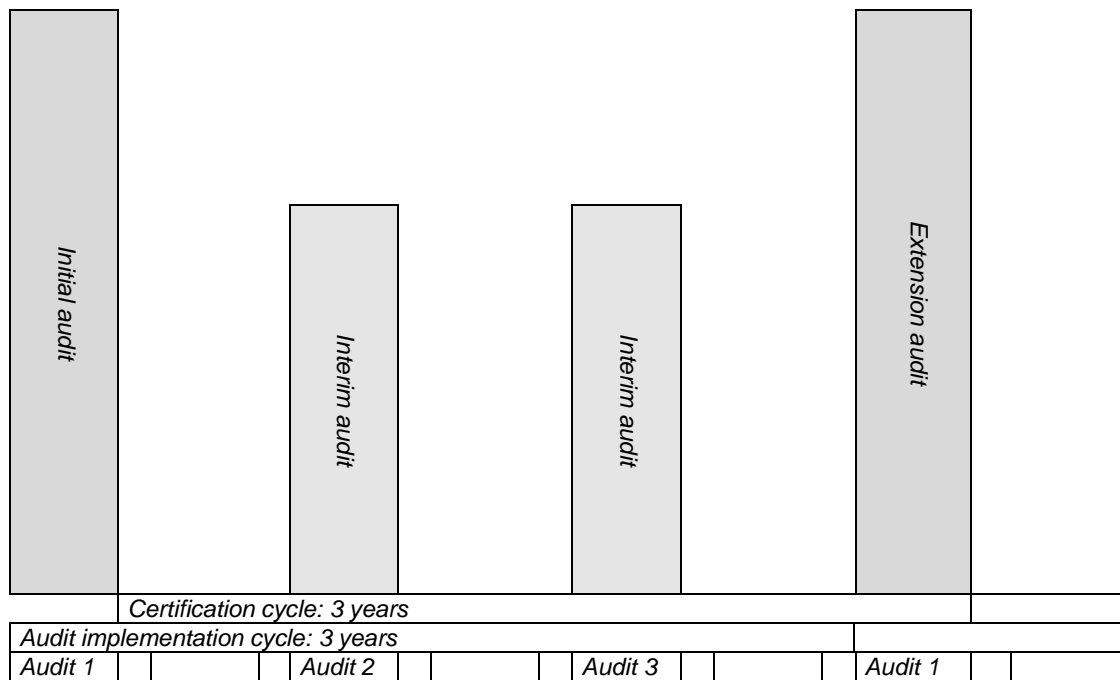
Nonconformity	Measures
<ul style="list-style-type: none"> • A serious nonconformity relating to critical GMP+ requirements.² • A serious nonconformity, incidental or structural, with a direct or possible hazard to the safety of humans, animals or the environment and possible direct consequences for the subsequent links in the chain. 	<ul style="list-style-type: none"> • The company is obliged to undertake an immediate recall of all the products in question unless the company can show to the satisfaction of the certification body that the nonconformity has no harmful health effects for animals or humans and the existing standards are not breached. • The company is obliged to take improvement measures immediately (within 24 hours). The company will be placed under stricter supervision for a period of at least 3 and maximum 6 months. • If the company does not take improvement measures immediately then the certification body will suspend the certificate or the temporary approval for a maximum of 3 months. • Lifting of suspension is only possible if the certification body has established during a compliance audit that proper improvement measures have been taken. The company will be placed under stricter supervision for at least 3 to a maximum of 6 months.
<ul style="list-style-type: none"> • Any recall is not carried out properly or (due to own negligence) is not carried out in time. 	<ul style="list-style-type: none"> • The certification body will immediately withdraw the certificate or temporary approval. • The company or natural persons involved are excluded for a period of at least 1 year from participation in the GMP+ FSA scheme.
<ul style="list-style-type: none"> • The participant does not cooperate in audits or in the supervision by the certification body. 	<ul style="list-style-type: none"> • The certification body suspends the certificate or temporary approval for a maximum period of three months. • The suspension can only be released if suitable measures for improvement have been taken. • If the company does not take improvement measures within the period of time established then the certification body will withdraw the certificate or temporary approval.
<ul style="list-style-type: none"> • Previously observed Category 1 nonconformities are not properly fixed after a 3 month suspension of the GMP+ certificate or the temporary approval has not been properly released or other such nonconformities are established. 	<ul style="list-style-type: none"> • The certification body will immediately withdraw the GMP+ certificate or temporary approval. • The company or natural persons involved are excluded for a period of 1 year from participation in the GMP+ FSA scheme.

² This relates in any event to a) incorrect cleaning and disinfections, loading sequence for GMP+ transport, b) no risk assessment for a feed material, c) purchasing from a non-GMP+ supplier, d) non-compliance with the product norms where a breach forms a hazard for animals and/or humans.

Appendix 2: Frequency and time expenditure for GMP+ audits

Frequency

Audits should be carried out in accordance with the following cycle.



This is a qualitative representation of the audit cycle for the implementation of GMP+ audits.

Minimum time expenditure for audits

The following tables provide binding guidelines for the minimal allocation of time in hours for GMP+ audits at feed companies. Deviation from these binding guidelines is possible where this can be justified by the nature of the company.

If there is a deviation from the minimum audit times then the certification body should request this in advance from GMP+ International. GMP+ International will check the reasoning and assess this and adjust if necessary. The certification body should make clear to GMP+ International what the audit duration was. This temporary deviation agreed in writing by GMP+ International from the audit times is valid as long as:

- no changes take place in the activities and organisation of the company
- no changes are made to appendix 2, GMP+ C3 *Assessment and Certification Criteria for GMP+ Certification*, frequency and time expenditure for GMP+ audits.

In the event of unchanged business operations and unchanged GMP+ requirements, then during the period of validity of the certificate a single audit time reduction can be applied for and given.

Documents review and reporting is included in the period of time for the duration of the audit.

In the event of certification in accordance with GMP+ B6 *Feed Materials Cultivation*, then an audit will be carried out once per three years and, in addition, 10% of companies will be visited each year for a supervision audit.

For GMP+ B4.3 *Inland Waterways Transport* the assessment for certification will be carried out once per 2 years.

Where samples are taken for verification during the audit, 1 hour may be added to the total audit time.

In the event of compliance audits, repeat audits and stricter supervision as specified in section 3.6, the period of time will apply which is considered necessary by the certification body or GMP+ International.

A working day is 8 hours.

To determine the main activity of the company the following ranking should be applied:

- a. Production and Processing
- b. Trade

Within these main categories the following ranking should be applied:

- a. Compound feeds
- b. Premixtures
- c. Feed additives
- d. Feed materials
- e. Pet foods
- f. Storage and transshipment
- g. Transport and affreightment

	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours ¹			Comment
			Initial or extension audit	Supervision audit		
GMP+ B1 Production and processing of compound feeds / semi-manufactured products						
Main office (incl. production)	≤ 50,000	1x / year	14.0 + 1.5X	13.5 + 1.5X		
	> 50,000	1x / year	15.5 + 1.5X	15.5 + 1.5X		
Production location	≤ 50,000	1x / year	10.0 + 1.5X	8.5 + 1.5X		
	> 50,000	1x / year	11.5 + 1.5X	11.0 + 1.5X		
Feed additives gatekeeper	1.5 hours per dossier					2
GMP+ B1 Production and processing of compound feeds / semi-manufactured products without the use of critical feed additives and critical veterinary medical products.						
Main office (incl. production)	≤ 50,000	1x / year	12.0 + 1.5X	11.5 + 1.5X		
	> 50,000	1x / year	13.5 + 1.5X	13.5 + 1.5X		
Production location	≤ 50,000	1x / year	8.0 + 1.5X	6.5 + 1.5X		
	> 50,000	1x / year	9.5 + 1.5X	9.0 + 1.5X		
Feed additives gatekeeper	1.5 hours per dossier					2
GMP+ B1 Production and processing of pre-mixes						
Main office (incl. production)	≤20,000	1x / year	14.0 + 1.5X	13.5 + 1.5X		
	> 20,000	1x / year	15.5 + 1.5X	15.5 + 1.5X		
Production location	≤20,000	1x / year	10.0 + 1.5X	8.5 + 1.5X		
	> 20,000	1x / year	11.5 + 1.5X	11.5 + 1.5X		
Feed additives gatekeeper	1.5 hours per dossier					2

	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours ¹			Comment
			Initial or extension audit	Supervision audit		
GMP+ B1 Production and processing of feed additives						
	Number of products					
Main office (incl. production)	≤ 5	1x / year	14.0 + 1.5X	13.5 + 1.5X		
	> 5	1x / year	15.5 + 1.5X	15.5 + 1.5X		
Production location	≤ 5	1x / year	10.0 + 1.5X	8.5 + 1.5X		
	> 5	1x / year	11.5 + 1.5X	11.0 + 1.5X		
GMP+ B1 Production and processing of feed materials						
	Number of products					
Main office (incl. production)	≤ 5	1x / year	9.0 + 1.5X	8.0 + 1.5X		
	> 5	1x / year	10.0 + 1.5X	9.0 + 1.5X		
Production location	≤ 5	1x / year	7.0 + 1.5X	6.0 + 1.5X		
	> 5	1x / year	8.0 + 1.5X	7.0 + 1.5X		
GMP+ B2 Quality control foreign suppliers						
	Number of products					
	≤ 5	1x / year	6.5 + 1.5X	5.0 + 1.5X		
	6-15	1x / year	8.0 + 1.5X	5.5 + 1.5X		
	>15	1x / year	9.5 + 1.5X	6.5 + 1.5X		
Feed additives gatekeeper	1.5 hours per dossier					2
GMP+ B3 (2006) Trade in Feeds (except forage trade) or GMP+ B1 only scope: Trade						
	Number of products					
	≤ 5	1x / year	6.5 + 1.5X	6.5 + 1.5X		
	6-15	1x / year	8.0 + 1.5X	8.0 + 1.5X		
	>15	1x / year	9.5 + 1.5X	9.5 + 1.5X		
Feed additives gatekeeper	1.5 hours per dossier					2

	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours ¹			Comment
			Initial or extension audit	Supervision audit		
GMP+ B3 (2006) Trade in Feeds (forage trade) or GMP+ B1 only scope: Trade (forage trade)	Number of products					3
	≤ 5	1 x / year	6.5 + 1.5X	2.5 + 1.5X		
	6-15	1 x / year	8.0 + 1.5X	4.0 + 1.5X		
	>15	1 x / year	9.5 + 1.5X	6.5 + 1.5X		
GMP+ B3(2007) Trade, Collection and Storage & Transhipment of Feeds	Number of products					4
This is the audit time for one scope of GMP+ B3(2007). For each additional scope of GMP+ B3(2007) the audit time is extended by 1.5 hours.	≤ 5	1x / year	6.5 + 1.5X	6.5 + 1.5X		
	6-15	1x / year	8.0 + 1.5X	8.0 + 1.5X		
	>15	1x / year	9.5 + 1.5X	9.5 + 1.5X		
Feed additives gatekeeper	1.5 hours per dossier					2
GMP+ B3.2 Feed brokerage						5, 6, 7
Administrative trade		1x / year	2.5	2.0		
(Administrative) trade + storage of packaged products and/or transport of packaged prod- ucts.		1x / year	3.0	2.5		
Extra storage for packaged products		1x / year	See appendix 4: Multisite certifica- tion for GMP+ B3.2 (option 2)			
Extra point of sale		1x / year	See appendix 4: Multisite certifica- tion for GMP+ B3.2 (option 2)			

	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours ¹			Comment
			Initial or extension audit	Supervision audit		
GMP+ B4.1 Road transport of feeds	Number of employees					
	≤ 2	1x / year	4.0 + 1.5X	2.5 + 1.5X		
	3-5	1x / year	6.5 + 1.5X	4.0 + 1.5X		
	6-15	1x / year	8.0 + 1.5X	7.0 + 1.5X		
	>15	1x / year	9.5 + 1.5X	9.0 + 1.5X		
GMP+ B4.1 Tractionair						
With own manual		1x / year	4.0	2.0		8
Included in customer's manual		1x / year	2.5	2.0		
GMP+ B4.2 Affreightment Inland Waterways		1x / year	5.5	5.5		
GMP+ B4.3 Inland Waterways Hygiene Code		1x / 2 year	2.0			
GMP+ B4.4 Affreightment sea transport		1x / year	5.5	5.5		
GMP+ B4.5 Affreightment rail		1x / year	5.5	5.5		
GMP+ B5 Storage and transhipment of feeds or GMP+ B1 only scope: Storage and tranship- ment	Number of employees					
	≤ 5	1x / year	6.5 + 1.5X	5.0 + 1.5X		
	6-15	1x / year	8.0 + 1.5X	7.0 + 1.5X		
	>15	1x / year	9.5 + 1.5X	9.0 + 1.5X		

	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours ¹			Comment
			Initial or extension audit	Supervision audit		
GMP+ B6 Cultivation of feed materials						
	Number of products					9
	≤ 5	1x / 3 years	6.5			
	6-15	1x / 3 years	8.0			
	>15	1x / 3 years	9.5			
GMP+ B8 Production of pet food						
	Main office (incl. production)	≤ 10,000	1x / year	14.0 + 1.5X	12.0 + 1.5X	10, 11
		> 10,000	1x / year	15.5 + 1.5X	14.0 + 1.5X	
	Production location	≤ 10,000	1x / year	10.0 + 1.5X	7.5 + 1.5X	
		> 10,000	1x / year	11.5 + 1.5X	9.5 + 1.5X	
GMP+ B8 Trade in pet foods						
	Number of products					
	≤ 5	1x / year	6.5 + 1.5X	5.0 + 1.5X		
	5-15	1x / year	8.0 + 1.5X	8.0 + 1.5X		
	>15	1x / year	9.5 + 1.5X	9.5 + 1.5X		
GMP+ B9 Special regulations						
	Additional time expenditure per audit			1.0		
GMP+ B10 Laboratory examination						
	Number of analyses					12, 13, 14
	ISO 17025 accredited	≤ 5	1x / year	2.0		
		5-15	1x / year	3.0		
		>15	1x / year	4.0		

	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours ¹			Comment
			Initial or extension audit	Supervision audit		
Partially ISO17025 accredited	< 5	1x / year	5.5	5.5		15
	5-15	1x / year	8.0	7.5		
	>15	1x / year	9.5	9.5		
Not ISO17025 accredited						
Main location (incl. system)	< 5	1x / year	8.0 + 8.0	6.5 + 6.5		
	5-20	1x / year	9.5 + 9.5	9.5 + 9.5		
	>20	1x / year	12.0 + 12.0	9.5 + 9.5		
Secondary location (analyses)	≤ 5	1x / year	5.0	5.5		
	6-20	1x / year	6.5	7.5		
	>20	1x / year	8.0	9.5		
Combined audit GMP+ FSA-scheme with valid versions of: ISO 9001 and/or ISO 22000 and/or HACCP and/or IFS Food and/or BRC Production and/or GMP-Ovocom and/or FAMI-QS)		1x / year	Time expenditure ISO 9001, ISO 22000 and/or HACCP food audit and/or IFS Food and/or BRC Production and/or GMP-Ovocom and/or FAMI-QS) + half of the time expenditure for GMP+ FSA scheme audit		16, 17	

¹ The basis is the main activity of the company. "X" is the number of activities and/or standards to be certified at the same location.

² All dossiers should be initially assessed and then on a random sample basis during the period of validity of the certificate.

³ A forage company is a trading company which as a direct supplier to the livestock farmer takes care of the delivery of simple arable and horticultural crops (or parts thereof) harvested exclusively in Europe, which after any simple processing such as pressing or packaging but in an unchanged state are intended as feed for productive livestock. The trade in feeds from the foodstuffs industry is limited to a maximum of five products.

⁴ The scopes within GMP+ B3(2007) *Trade, Collection and Storage & Transhipment* are: a) trade and collection, b) storage and c) transport of own products. Simple actions are covered under collection.

⁵ In combination with other GMP+ standards, the audit times for these standards are counted with the times for the GMP+ B3.2 *Trade to Livestock Farms*.

⁶ For the GMP+ B3.2 *Trade to Livestock Farms* no report needs to be drawn up, just an audit checklist.

⁷ Two types are distinguished for Distribution Centre (DC):

- DC acts as the only supplier of the brokers. In this case DC can be seen as a part of the sales points and therefore falls under certification for GMP+ 3.2.
- DC is one of the suppliers of the brokers. DC acts much more independently with respect to the brokers (and vice versa) than in option 1. In this case DC is seen as an "ordinary" trader and should attain at least GMP+ B3(2007) *Trade, Collection and Storage & Transhipment*.

⁸ Time expenditure is charged to the tractionair. For reasons of efficiency the audit of the tractionair may take place at the same time as the audit of the client. A separate GMP+ report should be drawn up for both the client and the tractionair and a checklist should be completed and sent to GMP+ International.

⁹ Each year 10% of the companies are visited for a supervision audit. If nonconformities are observed then improvement measures must be implemented within the period of time set by the auditor. This period of time must lie within the current growing season. If an extra audit must be carried out to verify whether proper improvement measures have been carried out then this audit must also lie within the same growing season.

¹⁰ Where the company produces wet pet foods the scope of the production should be converted using the dry matter content.

¹¹ Based on the ranking it should be assumed in the case of a company which produces both compound feeds and pet foods that the minimum audit duration for compound feed production should be supplemented by 1.5 hours (1-3 recipes) or 3.5 hours (>3 recipes).

¹² The most important analyses must be assessed during the initial audit. At least once during the audit cycle all analyses should be assessed.

¹³ Types of laboratories:

- The laboratory has all analyses under ISO 17025; administrative assessment once per year. If the laboratory is accredited for more than 50 analyses according to ISO 17025 the minimal time expenditure may be raised to 0.75.
- If the laboratory does not have all analyses under ISO 17025 then just the material specialist visits for the non-ISO 17025 analyses.
- Where the laboratory is not accredited according to ISO 17025; both the material specialist and the auditor visit for system assessment.

¹⁴ If a laboratory is certified for both GMP+ B10 *Laboratory testing* and ISO 9001; 2000 then a 35% audit time reduction may be applied on the condition that the laboratory is included in the scope of the ISO certificate.

¹⁵ These reduced audit times may only be used if all locations of the laboratory work under the same quality system. The system requirements and analyses will be assessed at the main location. At the sub-locations only the analyses are assessed. The audit at the sub-location will be carried out by the GMP+ B10 auditor, scope materials.

¹⁶ The correspondences between the GMP+ B10 *Laboratory Testing* and the other GMP+ standards are so few that a combined audit for GMP+ B10 *Laboratory Testing* and one or more of the other GMP+ standards will not give any reduction in the time expenditure. The minimum time duration should always be applied for a GMP+ B10 audit.

¹⁷ The schemes must be audited during an associated audit. The following preconditions apply:

- Audit team:

An audit team consists of one or more auditors. If a combined audit is carried out by auditors from two or more certification bodies (joint audit) then all the auditors will be seen as members of a single audit team. Good internal communication is of great importance.

- o Within the audit team it must be clear which tasks, responsibilities and authority have been assigned to the individual members
- o The audit team must be sufficiently qualified (GMP+ C documents) to be able to audit all the relevant GMP+ standards.

- Carrying out of the audit:

- o GMP+ scheme is audited in an associated audit together with the complementary schemes
- o The audit planning must be such that all the requirements relevant for GMP+ are verified during the audit. The GMP+ checklist must be completed in full
- o It must be demonstrable how communication within the audit team works during the audit with respect to audit findings including nonconformities and agreed improvement measures
- o It must be demonstrable how decision-making takes place within the audit team and how the audit conclusion is arrived at.

- Audit reporting and handling:

- o It must be demonstrable how communication works within the audit team after the audit with respect to the handling of improvement measures.

Appendix 3: Reporting model

1 General details

Details of main location

Name of the company :
Address :
Postal code and location :
Telephone :
Fax :
E-mail :
Registration number :
Contact person :

Overview of all business locations (incl. head office) and GMP+ standards

Registration number	Name location	Address Postal code, Location	GMP+ standard(s) (incl. scope for GMP+ B1 and GMP+ B3) Incl. version date and additional product criteria	Expiry date of current certificate or temporary approval:

List of guaranteed brokers (if applicable)

Registration number of trader	Name of trader	Address Postal code, Location	Guaranteed products

List of locations in the event of multi-site certification (if applicable)

Registration number location	Name of location	Address Postal code, Location	Visit date

Audit details:

- Initial audit*
- Interim audit*
- Extension audit*
- Compliance audit*
- Repeat audit*
- Stricter supervision*
- Documents review (in the event of a temporary approval)*
- Other;*

Date of document assessment :

Date of audit inspection :

Report date :

Staff involved in inspection :
 Name Position
 Documents consulted :
 Certification body :
 Auditor(s) :
 Materials expert(s) :
 Name Signature

2 Scope company/locations

Specify the type of company and its activities. Describe the products and quantities. Specify the nature and the numbers of personnel (permanent, temporary) per location.

Describe the organisational structure. Also take note of other companies on the same site or under the same holding (with similar names or incompatible activities). Provide a brief summary of purchasing, production process and sales of main and subsidiary product streams (focusing on the relationship with the activities covered by the application). Also indicate whether the company applies the Gatekeeper principle and describe the activities.

3 Summary of the assessment and conclusion

Start with a standard phrase such as “The company was visited for a supervision audit of the GMP+ requirements. The company was checked for the requirements of the applicable GMP+ standards”.

Indicate whether the audit findings observed in the previous audit have been resolved.

Make a summary per company location and in total including products assessment. Give a brief summary of the general impression of the quality system of the company.

Possible postscript after a final assessment by the technical reviewer: review of additional documents and follow-up inspection.

Summary of the assessment and the number of audit nonconformities observed									
Location	During previous audit			During audit visit			At final assessment		
	Number of audit non-conformities			Number of audit non-conformities			Number of audit non-conformities		
	Cat. 1.	Cat. 2	Cat. 3	Cat. 1	Cat. 2	Cat. 3	Cat. 1	Cat. 2	Cat. 3

Audit conclusion: the company meets/fails to meet the requirements of the GMP+ standard.

Measures and sanctions: compliance audit, repeat audit, stricter supervision (including period of time), suspension, withdrawal.

4. Appendices

Checklists used, report forms for audit nonconformities.

Appendix 4: Multi-site certification

Option 1:

Multisite certification is possible:

- a. At a company with a main office with 100% subsidiaries, or
- b. At a group of companies which have joined together as a quality community.³

This applies for the activities:

- a. Transport
- b. Trade
- c. Storage
- d. Transshipment
- e. Collection

N.B. In a group of companies in which the above activities take place, then, in addition to the general requirements (see under A) which apply to a multi-site certification, there must also be compliance with the requirements under B.

Guidance

- a. For a definition of collection see GMP+ A2.
- b. If, for example, a group contains multiple production locations and storage locations then the production locations in this group can not be certified under multi-site but perhaps the storage locations can.
- c. If both collection and transport (incl. affreightment) takes place at locations then the certification of this may also be combined under the multi-site requirements.
- d. If a company or group of companies does not fully comply with the criteria then no use may be made of the following form of certification. A form of audit time reduction may possibly be requested. See GMP+ C3 Assessment and Certification Criteria for GMP+ Certification, appendix 2.
- e. These requirements do not exclude audits on the basis of reduced audit times. See GMP+ C3 Assessment and Certification Criteria for GMP+ Certification, appendix 2.

A) General requirements:

1) General

- a. All locations fall under the same quality system which is managed centrally (referred to hereafter as the main office). This quality system complies with the relevant GMP+ standards and there must be compliance at all locations with the relevant GMP+ requirements (see also the guidance under C) Certification).
- b. The same methods and procedures are used at all the locations.
- c. Corrective measures may be imposed from the main office on all branches.
- d. There must be a written agreement between the participating subsidiaries and the main office. This agreement should be signed by all the participating parties and the signed agreement should be present at the main office and available to the auditor. The statement will include at least:

³ *Multisite certification is not to be used if various independent companies have joined together in a branch organisation, union, federation, association or similar and is also not to be used for trading companies where no physical handling of the feeds takes place.*

- e. a commitment by the company to the main office that it will comply with the requirements set in the quality system.
 - f. that corrective measures imposed by the main office are binding
 - g. that the above applies to all feed activities (and therefore those which are carried out more or less independently).
- a. All the locations are included in the programme of internal audits.
 - b. The main office must show that it is able to collect data from every location, to analyse the data and, where necessary, to implement changes with respect to:
 1. System documents and changes
 2. Management review
 3. Complaints handling
 4. Corrective measures
 5. Planning of internal audits and improvement measures.

Guidance

Central management of the training plan is one of the possibilities.

2) Requirements for the internal auditor:

The internal auditor must:

- a. Be independent and may not check his own daily activities
- b. Have demonstrable knowledge of feed safety systems through training or work experience
- c. Have demonstrable knowledge through training and/or work experience of the field of work which will be audited

3) Requirements for the internal audit:

- a. An internal audit will be carried out at least yearly (1 x per 12 months) at all locations.
- b. The internal auditor will have to carry out an internal audit in which all the aspects of the feed safety system are addressed. Use will preferably be made of the checklist used by the certification bodies (see GMP+ C5 Checklists).
- c. The internal audit reporting must be drawn up in such a way that the certification body can make use of this information.

B) Additional requirements:

The following additional requirements apply to a group of companies:

4) Trade

If not all feeds are traded via the main office but via a secondary location then this trade in feeds must be completely guaranteed by the main office. During the internal audit, (the trading of) these feeds will also be included.

5) Transport

A carrier can only be certified under multi-site requirements if the carrier carries out all the feed activities for the main office exclusively. If this is not the case then the carrier must be independently certified.

Guidance

A production company and a number of carriers may unite in a quality community, for example. The certification can then take place under multi-site requirements.

C) Certification

If a main office has a different GMP+ scope to one of the locations or companies then the main office must also additionally be certified for this scope.

Guidance

If the main office is a production company (GMP+ B1 Production, Trade and Services) and the other companies have a transport scope (GMP+ B4.1 Road Transport) and/or trading scope (GMP+ B3(2007) Trade, Collection and Storage & Transshipment) etc. then the production company must also be certified for this scope (transport and/or trade) because the management and control of the quality management system lies centrally with the production company.

In the event of multi-site certification the audit frequency for the locations (with the exception of the main office) is lowered where each location must be visited at least once per three years.

Guidance

In determining the locations which must be visited the certification body will use a random selection system. Account will be taken of:

- *the results of the internal audit as carried out by the main office*
- *the activities which take place at the various locations.*

Before an initial audit can take place, the contracts between the main office and the participating companies and also the internal audit report must be able to be handed over to the certification body for review.

In an initial audit the main office and then 1/3 of the locations should always be visited before a certificate can be issued.

If a new location joins a company or a group of companies then a verification of the relevant subjects must take place at the main office and the new location should be audited.

Minimum time to be spent per visit in hours:

Location	Number of employees*	Minimum time expenditure per visit
Main office	Time expenditure as recorded in the table of the GMP+ C3 increased with extra time per included multi-site location of 2 hours up to a maximum of 10 extra hours.	
Location / companies with only transport	≤ 5	2.0
	6-15	3.0
	>15	4.0
Storage only location		2.0
Location / companies with both storage and transport	≤ 5	2.0
	6-15	3.0
	>15	4.0
Location / companies with storage and/or transport and limited trading		4.0

*By the number of employees is meant the sum of the number of employees per audited branch per year.

As all locations / companies must work in accordance with the same methods and procedures and under the same quality system, the review of the documentation can remain limited to verification of the presence of up to date documentation and the completeness of the HACCP documentation with respect to the audited location.

During audits of locations where storage is done the following GMP+ requirements must assessed:

- a. verification and administration of received products
- b. process control: Good Housekeeping, control measures with respect to critical points
- c. tracking & tracing
- d. delivery, verification of loading compartments
- e. inspections and records
- f. delivery of feeds
- g. if transport activities also take place then the operational aspects should also be assessed
- h. complaints and nonconformities

During audits of locations where transport is done the following GMP+ requirements must assessed:

- a. reception of transport orders incl. product category classification
- b. journey sheets; identification of loading compartments, products, cleaning, loading and unloading addresses, etc.
- c. inspection of the trucks present
- d. administration, use of third parties, instructions with respect to GMP+ product categories
- e. if storage activities also take place then the operational aspects should also be assessed
- f. complaints and nonconformities

During audits of locations where trading is done the following GMP+ requirements must assessed:

- a. trading methods with respect to purchasing and delivery of feeds (possibly including the review of contracts)
- b. method of verification and administration
- c. tracking & tracing
- d. inspections and records
- e. complaints and nonconformities

An overview should be included in the GMP+ report showing when all the locations / companies were visited.

If serious nonconformities are observed at the main office then the whole company or quality community does not meet the requirements for GMP+ certification. If a nonconformity is observed at the level of a location then this can influence the location and/or the main office. This is to be assessed by the certification body.

A checklist should be completed only at the level of the main office. Audit findings which are observed at one of the storage locations / companies should be reported in the checklist and the GMP+ report.

Only one certificate (or temporary approval where appropriate) will be issued for multi-site. This certificate will have an annex with the companies which belong to the multi-site. An individual location or company can also receive a certificate.

Option 2:

For companies which apply GMP+ B3.2 *Trade to Livestock Farms* and which have extra storage locations and/or extra sales points or sales outlets, it is possible to make use of this option of multi-site certification.

Two types are distinguished for Distribution Centre (DC):

- a. DC acts as the only supplier of the brokers. In this case DC can be seen as a part of the sales points and therefore falls under certification for GMP+ 3.2. Option 2 for multi-site certification is possible.
- b. DC is one of the suppliers of the brokers. DC acts much more independently with respect to the brokers (and vice versa) than in option 1. In this case DC is seen as an “ordinary” trader and should apply at least GMP+ B3(2007) *Trade, Collection and Storage & Transshipment*. Option 2 for multi-site certification is **not** possible.

To be eligible for multi-site certification under GMP+ B3.2 *Trade to Livestock Farms* the company should comply with the following criteria:

- a. The company has a main office from which activities are planned and directed
- b. The company has a network of storage locations and/or sales points
- c. All storage sites and/or sales points fall under the same quality system which is managed from the main office. This quality system must be based on the GMP+ standard and all the locations must meet the GMP+ requirements;
- d. The same methods and procedures are used at all the locations.
- e. All the locations are included in the programme of internal audits
- f. Corrective measures may be imposed from the main office on all storage locations and/or sales points
- g. The company must show that it is able to collect data from every location, to analyse the data and, where necessary, to make changes with respect to:
 1. System documents and amendments
 2. Complaints handling
 3. Corrective measures
 4. Planning of internal audits and improvement measures
- h. If the main office is not the owner of the extra storage locations and/or extra sales points then the main office should have a written statement from the participants (storage locations and/or sales points) in which they undertake:
 1. to sell GMP+ certified feeds directly to the livestock farmer. Selling to other GMP+ certified companies is not permitted;
 2. That the purchase of GMP+ certified feeds will only take place via the main office;
 3. To provide full cooperation to the main office with respect to the activities which are described in all the above points of this option 2.

This statement should be signed by all the brokers participating in this multi-site certification and the signed declaration must be present at the main office and must be available for inspection by the auditor.

In addition, all the participants which have signed a declaration must be known to the certification body. The size of the random sample can be determined on the basis of this data.

In the event of multi-site certification for GMP+ B3.2 *Trade to Livestock Farms* the audit frequency for the extra storage locations or extra sales points (with the exception of the main office) may be lowered in accordance with the following schedule where each location must be visited at least once per three years.

Initial audit / extension audit / *supervision audit*

Number of locations /sales points (without main location)	1	2	≥3
Number of locations to be visited	1x / 3 years	1x / 3 years	33%

Minimum time to be spent per visit in hours:

	Minimum time expenditure per visit
Extra storage location	1.0
Extra retail outlet	1.5

As all storage locations and/or sales points must work in accordance with the same methods and procedures and under the same quality system, the review of the documentation can remain limited to verification of the presence of up-to-date documentation and the completeness of the documentation with respect to the location.

During audits of storage locations and/or sales points the following GMP+ requirements must be assessed:

- a. verification and administration of received products
- b. process control: Good Housekeeping, control measures with respect to critical points
- c. tracking & tracing
- d. delivery, possible verification of loading compartments for packaged goods
- e. inspections and records

If audit nonconformities are observed at company level then the whole company does not meet the requirements for GMP+ certification. If at the level of storage site or sales point audit nonconformities are observed then only this location is in non-compliance.

A checklist should only be completed at company level. Audit nonconformities which are observed at one of the storage locations and/or sales points should be reported in the checklist.

Only one certificate or temporary approval will be issued. This certificate or temporary approval only lists those storage locations and/or sales points which participate in the multi-site certification. All storage locations and/or sales points should be visited for an audit (in accordance with the above schedule).

Appendix 5: Normative documents

Product/service	Standard document	Normative document
Compound feed	GMP+ B1 <i>Production, Trade and Services</i> - assessment product(s)	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA scheme
Grass-fed chicken feed	GMP+ B1 <i>Production, Trade and Services</i> & GMP+ B9.1 <i>Special regulation for grass-fed chickens</i> - assessment product(s)	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA scheme
Compound feed for free-range animals	GMP+ B1 <i>Production, Trade and Services</i> & GMP+ B9.2 <i>Special regulation for free-range animals</i> - assessment product(s)	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA scheme
Premix	GMP+ B1 <i>Production, Trade and Services</i> - assessment product(s)	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA scheme
Feed material	GMP+ B1 <i>Production, Trade and Services</i> GMP+ B2 <i>Quality Control of Feed Materials</i> - assessment product(s)	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA scheme
Additive	GMP+ B1 <i>Production, Trade and Services</i> - assessment product(s)	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA scheme
Pet foods	GMP+ B1 <i>Production, Trade and Services</i> GMP+ B8 <i>Production of and Trade in Pet Foods</i> - assessment product(s)	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA scheme
Trade in feeds.	GMP+ B3(2006) <i>Trade</i> - assessment product(s)	appendices GMP+ BA1 and GMP+ BA3 of the GMP+ FSA scheme
Store and tranship animal feeds	GMP+ B5 <i>Storage & Transshipment</i>	Process requirements as specified in Chapter 7 of GMP+ B5 of the GMP+ FSA scheme
Road transport of animal feeds	GMP+ B4.1 <i>Road Transport</i> - assessment GMP+ BA 14	appendix GMP+ BA 14 of the GMP+ FSA scheme
Short sea shipping and inland waterways transport affreightment	GMP+ B4.2 <i>Short Sea Shipping and Inland Waterways Transport</i>	Process requirements as specified in Chapter 7 of GMP+ B4.2 of the GMP+ FSA scheme.

Product/service	Standard document	Normative document
Affreightment of sea transport	GMP+ B4.4 <i>Affreightment of sea transport</i>	Process requirements as specified in Chapter 7 of GMP+ B4.4 of the GMP+ FSA scheme
Affreightment of rail transport	GMP+ B4.5 <i>Affreightment of rail transport</i>	Process requirements as specified in Chapter 7 of GMP+ B4.5 of the GMP+ FSA scheme

Appendix 6: Products and process stages/services

On the certificate or temporary approval a distinction can be made for the description of feeds which must be quality assured between a so-called fixed part and a free part.

Fixed part:

Completion of the fixed section is mandatory. The description of the assured animal feeds on the GMP+ certificate or temporary approval should be formulated in combination with the activities as combinations of activities and feeds as summarised in the following table which is derived from the titles of the GMP+ standards (see appendix 5 for the complete titles). The scope of the products is specified next to the activity as specified in accordance with the standard name to which the certificate or temporary approval refers.

Activities	Animal feedstuffs
Production of	the animal feeds to be distinguished: feed additives feed materials premixes compound feeds feeds own products In addition to 'compound feeds' the following can be further specified: grass-fed chicken feeds compound feed for free-range animals There can also be a separate mention of: pet foods
Treatment of.....	
Cultivation of.....	
Trading in.....	
Storage and transshipment of....	
Collection of	
Road transport of	
Inland waterway transport of ...	
Afreightment of inland waterway transport for	
Afreightment of sea transport for	
Afreightment of rail waterway transport for	
Afreightment of short sea shipping for .	
Afreightment of road transport for....	

The standards applied by the participant are specified. (See appendix 5) followed by the product group.

Free part:

The completion of the free part is voluntary. In consultation with the certification body, the participant may show a further description of the activities and the animal feeds.

This description may not conflict with the fixed part.

There can, for example, be sub-processes of production which can be distinguished (bagging, packaging, extrusion, etc.). Processing may include activities such as collection, cleaning, drying, etc.

The animal feeds may also be further specified. For example, in the category compound feeds there may be mineral mixes, milk replacer feed or poultry feeds. Feed materials can also be detailed such as grains, grain by-products, etc. Or be more specific such as wheat, wheat grits.

- Examples: A milk replacer feed producer may specify his production of compound feeds as:
- production of milk replacer feed.
 - a collector of grains may specify his treatment of feed materials as collection, cleaning and drying of grains
 - a trader in grains may specify his trade in feed materials as trade in grains, etc.

It is not permitted to specify brand names in any way whatsoever on the certificate or temporary approval.

The validity of a certificate or temporary approval relates to the specified scope. Unspecified products or activities do not fall within the scope of the certificate or temporary approval.

Appendix 7: Guaranteed brokers

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Appendix 8: Supervision audit – not at company location

For road transport companies (GMP+ B4.1 *Road Transport*) a supervision audit may also take place at another location than the registered offices of the company.

The following requirements apply:

- a. The company falls into the category: 1-5 employees
- b. The company does not have its own production area
- c. The company offers at least one loading compartment which is used for GMP+ transport (trailer / semi-trailer, etc.) for checking;
- d. All the required GMP+ documentation for the previous 12 months should be present for a proper assessment, including:
 1. quality manual
 2. Cleaning validations
 3. Internal audit reports
 4. Management review
 5. Journey sheets
 6. Waybills
 7. Order faxes
 8. Specifications of cleaning and disinfectant agents, etc.
- e. The alternative location is suitable for carrying out audits:
 9. Checking of loading compartments causes no hazardous situations for those involved or bystanders
 10. If there is a collective check (multiple companies are invited for audit at the same time) then the privacy of individual companies should be guaranteed.

Audit nonconformities should be classified and handled at least using the general assessment criteria in appendix 1 and the specific assessment criteria in the checklist.

Appendix 9: Protocols for independent sampling by certification bodies

Sampling protocol M1: Sampling from tank storage and silos or sheds.

Purpose

To obtain in a uniform fashion a sample from the batch in the event of an emergency or an incident.

Implementation

1. Sample material

Use can be made when taking a sample of a scoop, a hand scoop or sample drill. The sample drill must be adjusted to the depth of the product in the shed. The samples can be collected in a plastic bucket or an equivalent receptacle. The sampling equipment and the sample bags or pots must be clean, dry and free of odours foreign to the product.

2. Sampling location

During turning over from one silo to another or at the location where the batch is stored. If this is technically not possible then it must be established how this will be implemented.

3. Sampling

The sample is taken by collecting a number of sub-samples and making a collective sample from these and then preparing a final sample. The number of sub-samples depends on the quantity of product in storage. See the table.

Product	Form	Quantity in tons	Number of sub-samples	Minimum quantity of collective sample	Minimum quantity of final sample
Feed materials	Dry	up to 50 tons	2	2 kg	600 g
		from 50 to 500 tons	1 per 25 tons	20 kg	600 g
		the part of the batch in excess of 500 tons	1 per 50 tons	1 kg per sub-sample	600 g
Compound feeds	Dry	up to 50 tons	2	2 kg	600 g
		from 50 to 500 tons	1 per 25 tons	20 kg	600 g
		the part of the batch in excess of 500 tons	1 per 50 tons	1 kg per sub-sample	600 g
Pre-mixtures	Dry	up to 50 tons	2	2 kg	200 g
		from 50 to 500 tons	1 per 25 tons	20 kg	200 g
		the part of the	1 per 50	1 kg per sub-	200 g

Product	Form	Quantity in tons	Number of sub-samples	Minimum quantity of collective sample	Minimum quantity of final sample
		batch in excess of 500 tons	tons	sample	
Feed additives	Dry	up to 50 tons	2	2 kg	200 g
		from 50 to 500 tons	1 per 25 tons	20 kg	200 g
		the part of the batch in excess of 500 tons	1 per 50 tons	1 kg per sub-sample	200 g
Feed materials	Liquid	up to 50 tons	1	500 g	600 g
		Above 50 tons	1 per 50 tons	7 kg	600 g
Compound feeds	Liquid	up to 50 tons	1	500 g	600 g
		Above 50 tons	1 per 50 tons	7 kg	600 g
Premixtures	Liquid	up to 50 tons	1	250 g	200 g
		Above 50 tons	1 per 50 tons	7 kg	200 g
Feed additives	Liquid	up to 50 tons	1	250 g	200 g
		Above 50 tons	1 per 50 tons	7 kg	200 g

Sub-samples

The individual sub-samples should be of the same size. If the sample is taken during turning over from one silo to another silo then the sub-samples must be spread over the whole time of turning over. If the samples are taken using the sample drill then the sub-samples should be spread across the whole batch.

Aggregate sample

The sub-samples which are taken are collected into a collection receptacle (a bucket for example). The product which is present is well mixed to produce a collective sample.

Final sample

A final sample is made from the collective sample.

4. Sample sealing and storage

The sample should be labelled such that it can easily be identified. This means that at least the following records must be made, if applicable, on the sample using a clearly linked form of registration: date of sampling, product identification, batch identification, sampler, supplier, production unit where the sample was taken. The sample must be kept in such a way that damage to and deterioration of the sample is avoided. The sealing should be such that opening the sample inevitably leads to an irrevocable break in the seal on the sample.

Sampling protocol M2: Dry and wet feed materials delivery by inland waterways vessel or coaster¹

Purpose

Taking a sample from the batch in a uniform fashion.

Implementation

1. Sample material

Use can be made when taking a sample of a scoop, a hand scoop or sample drill consisting of one or more compartments. The sample drill must be adjusted to the depth of the product in the hold. In addition, use can be made of automatic sampling equipment. Automatic sampling equipment must be able to take samples over the whole production flow or to the extent that this is possible. The sampling equipment must be able to be adjusted to the size of the subsamples and the frequency of sampling.

In the event of manual sampling the sub-samples can be collected in a plastic bucket or an equivalent bin. All parts of the sampling equipment and the storage facilities for the collective sample, sampling tools and sample bags or pots must be clean, dry and free of odours foreign to the product. The sampling equipment must be easily accessible for inspection, cleaning, maintenance, repair and for sample verification.

2. Sampling location

In the hold of the vessel before the vessel is unloaded if the sample drill is used for sampling. The whole load must be accessible. If it is not possible to sample the hold then the sampling must be done from the flow during unloading. If use is made of automatic sampling equipment then the sample must be taken as close as possible to the point where the transfer of ownership of the product takes place (just after intake). Samples must be taken such that contamination of the samples, equipment and containers in which the samples are stored with, for example rain or dust, is prevented.

3. Sampling

The sample is taken by collecting a number of sub-samples and making a collective sample from these and then preparing a final sample. The number of sub-samples depends on the quantity of product delivered, see the table.

Quantity in tons	Number of sub-samples	Minimum quantity of collective sample	Final sample
up to 5,000 tons: for each 500 tons	minimum 5	for each 500 tons minimum 1.0 kg	300 g
5,000 – 10,000 tons for each 1000 tons	minimum 10	for each 1000 tons minimum 1.0 kg	300 g
More than 10,000 tons for each 5,000 tons	minimum 5	for each 5000 tons minimum 1.0 kg	300 g

Sub-samples

The individual sub-samples should be of the same size. If the sample is taken during unloading of the vessel then the sub-samples must be spread over the whole time that the vessel is being unloaded. If the samples are taken using the sample drill then the sub-samples should be spread across the whole load.

If use is made of automatic sampling equipment then the samples must be taken over as wide a cross-section as possible of the product flow such that nearly every part of the batch has a chance of flowing into the sampling machine.

The sub-samples can be taken by allowing a small part of the batch to flow continuously into the sampling equipment or by taking a series of sub-samples at a determined interval. If the sub-samples are taken at intervals then samples must be taken throughout the whole time that the batch is flowing past the sampling equipment.

In the event of manual sampling the sub-samples which are taken should be collected on a clean, flat base where contamination by the environment is prevented or collected in a collection bin (such as a bucket).

Aggregate sample

The sub-samples which are taken are collected into a collection receptacle (a bucket for example). The product which is present is well mixed to produce a collective sample.

Final sample

A final sample is made from the collective sample. This refers to the retained samples.

If inspection of the batch is desired then two or more final samples should be taken from the collective sample.

4. Sample sealing and storage

The sample should be labelled such that it can easily be identified. This means that at least the following records must be made, if applicable, on the sample using a clearly linked form of registration: date of sampling, product identification, batch identification, sampler, supplier, production unit where the sample was taken. The sample must be kept in such a way that damage to and deterioration of the sample is avoided. The sealing should be such that opening the sample inevitably leads to an irrevocable break in the seal on the sample.

¹ *Customers may, if desired, make use of demonstrably recorded and agreed use of sampling in the port which takes place on the basis of Fosfa, Gafta and make use of simpler sampling at their own company.*

Sampling protocol M3: Feed materials, compound feeds, premixes and feed additives in bags, drums, big-bags, etc.

Purpose

Taking a sample from the batch in a uniform fashion.

Implementation

1. Sample material

Use can be made when taking a sample of a scoop, a hand scoop or sample drill. The samples can be collected in a plastic bucket or an equivalent receptacle. The sampling equipment and the sample bags or pots must be clean, dry and free of odours foreign to the product.

2. Sampling location

Contamination from the environment is prevented by using a clean, dry location

3. Sampling

The sample is taken by collecting a number of sub-samples and making a collective sample from these and then preparing a final sample. The number of units (for example bags or big bags) that must be sampled depends on the size of the batch. Per unit, in the case of sacks and big bags, should if possible be sampled at the top of the bag, big bag etc., in the middle and at the bottom. If this is not possible then open the unit at the top and take a sample from the top.

Product	Quantity	Number of sub-samples	Minimum quantity of collective sample	Minimum quantity of final sample
Feed materials	up to 50 tons (for example up to 2000 units of 25 kg)	2	2 kg	300 g
Feed materials	more than 50 tons (for example more than 2000 units of 25 kg)	1 per 25 tons	1kg per sub-sample	300 g
Compound feeds	All quantities	1	500 g	300 g
Premixtures	All quantities	1	250 g	100 g
Feed additives	up to 50 tons (for example up to 2000 units of 25 kg)	2	1 kg.	100 g
Feed additives	more than 50 tons (for example more than 2000 units of 25 kg)	1 per 25 tons	500 g per sub-sample	100 g

Sub-samples

The individual sub-samples should be of the same size.

Aggregate sample

The sub-samples which are taken are collected into a collection receptacle (a bucket for example). The product which is present is well mixed to produce a collective sample.

Final sample

A final sample is made from the collective sample. This refers to the retained samples. If inspection of the batch is desired then two or more final samples should be taken from the collective sample.

4. Sample sealing and storage

The sample should be labelled such that it can easily be identified. This means that at least the following records must be made, if applicable, on the sample using a clearly linked form of registration: date of sampling, product identification, batch identification, sampler, supplier, production unit where the sample was taken. The sample must be kept in such a way that damage to and deterioration of the sample is avoided. The sealing should be such that opening the sample inevitably leads to an irrevocable break in the seal on the sample.

Sampling protocol M4: Compound feeds, dry feed materials, premixes and feed additives in bulk, transport per vehicle (for both the delivery and removal of these products) or in the event of bagging

Purpose

Taking a sample from the batch in a uniform fashion.

Implementation

1. Sample material

Use can be made when taking a sample of a scoop, a hand scoop or sample drill consisting of one or more compartments. The sample drill must be adjusted to the depth of the product in the vehicle. In addition, use can be made of automatic sampling equipment. Automatic sampling equipment must be able to take samples over the whole production flow or to the extent that this is possible. The sampling equipment must be able to be adjusted to the size of the subsamples and the frequency of sampling.

In the event of manual sampling the subsamples can be collected in a plastic bucket or

An equivalent receptacle.

All the parts of the sampling equipment and the storage facilities for the collective sample, sample tools and sample bags or pots must be clean, dry and free of odours foreign to the product.

The sampling equipment must be easily accessible for inspection, cleaning, maintenance, repair and for sample verification.

2. Sampling location

Preferably during loading or unloading of the vehicle. If this is not possible then from the stationary vehicle auto where the whole load must be accessible. Sampling during the production process is also possible. It is important then that after sampling there are no more additives to or treatments of the product. If the product is bagged then a sample can be taken during bagging. If use is made of automatic sampling equipment then the sample must be taken just after intake or as close as possible during loading. In the event of sampling of compound feeds and premixes the samples can be taken as closely as possible beyond the mixer. Samples must be taken such that contamination of the samples, equipment or containers in which the samples are stored with, for example rain or dust, is prevented. If the delivery consists of two parts (vehicle and trailer) then they can both be considered to be one batch.

3. Sampling

The sample is taken by collecting a number of sub-samples and making a collective sample from these and then preparing a final sample. The number of sub-samples depends on the quantity of product supplied or to be delivered, see the table.

Product	Quantity in tons	Number of sub-samples	Minimum quantity of collective sample	Final sample
Feed materials	up to 50 tons	2	2 kg	300 g
Compound feeds	up to 50 tons	1	300 g	300 g
Premixtures	up to 50 tons	1	100 g	100 g
Feed additives	up to 50 tons	2	2 kg	100 g

Sub-samples

The individual sub-samples should be of the same size. If the sample is taken during loading or unloading of the vehicle or during the production process then the sub-samples must be spread over the whole time that the vehicle is being loaded or unloaded or the production time. If the samples are taken from the stationary vehicle then the samples must be spread across the whole batch using a sample drill. If applicable the sub-samples must be taken from multiple compartments or hatches.

If use is made of automatic sampling equipment then the samples must be taken over as wide a cross-section as possible of the product flow such that nearly every part of the batch has a chance of flowing into the sampling machine.

The sub-samples can be taken by allowing a small part of the batch to flow continuously into the sampling equipment or by taking a series of sub-samples at a determined interval. If the sub-samples are taken at intervals then samples must be taken throughout the whole time that the batch is flowing past the sampling equipment.

Aggregate sample

The sub-samples which are taken are collected into a collection receptacle (a bucket for example). The product which is present is well mixed to produce a collective sample.

Final sample

A final sample is made from the collective sample. This refers to the retained samples.

If inspection of the batch is desired then two or more final samples should be taken.

4. Sample sealing and storage

The sample should be labelled such that it can easily be identified. This means that at least the following records must be made, if applicable, on the sample using a clearly linked form of registration: date of sampling, product identification, batch identification, sampler, supplier, production unit where the sample was taken. The sample must be kept in such a way that damage to and deterioration of the sample is avoided. The sealing should be such that opening the sample inevitably leads to an irrevocable break in the seal on the sample.

Sampling protocol M5: Forage products

Purpose

Taking a sample from the batch in a uniform fashion.

Validity

This sampling protocol applies to the sampling of the following forage products:

- a. Green maize
- b. Grass hay
- c. Grass
- d. Grain maize
- e. Corn Cob Mix

Implementation

1. Sample material

Use can be made when taking a sample of the hands, a scoop, a hand scoop or sample drill consisting of one or more compartments. The sample drill must be adjusted to the depth of the product (for example in the silage or loading compartment). The samples can be collected in a plastic bucket or an equivalent receptacle. The sampling equipment and the sample bags or pots must be clean, dry and free of odours foreign to the product.

2. Sampling location

Preferably during loading or unloading of the vehicle. If this is not possible then from the stationary vehicle auto where the whole load must be accessible. If loading is done from a rick or silage then this is one unit.

3. Sampling

The sample is taken by collecting a number of sub-samples and making a collective sample from these and then preparing a final sample. The number of sub-samples depends on the quantity of product supplied or to be delivered, see the table.

Quantity in tons per unit	Number of sub-samples	Minimum quantity of collective sample	Minimum quantity of final sample
up to 50 tons	Minimum 5	500 grams	500 grams
> 50 tons	Minimum 10	500 grams	500 grams

Sub-samples

The individual sub-samples should be of the same size. If the sample is taken during loading or unloading of the vehicle (for example feed potatoes) then the sub-samples must be spread over the whole time that the vehicle is being loaded or unloaded. If the samples are taken from the stationary vehicle then the sub-samples should be spread across the whole batch using a sample drill if possible. In the event of packs or bales then 5 units (bales or packs) should be sampled from the batch spread across the batch (if possible at the top, middle and bottom of the batch). If the batch can only be accessed from one side then the samples may be taken from that side.

Collective sample / final sample

The sub-samples which are taken are collected into a bucket or bag. The product which is present will if necessary be reduced and well stirred or mixed to produce a collective sample. This collective sample can also serve as a final sample.

4. Sample sealing and storage

The sample should be labelled such that it can easily be identified. This means that at least the following records must be made, if applicable, on the sample using a clearly linked form of registration: date of sampling, product identification, batch identification, sampler, supplier, production unit where the sample was taken. The sample must be kept in such a way that damage to and deterioration of the sample is avoided. The sealing should be such that opening the sample inevitably leads to an irrevocable break in the seal on the sample.

Sampling protocol M6: Samples for microbiological examination

Purpose

The obtaining of a sample where the microbiological condition of the product is not changed.

Implementation

This sampling protocol may possibly be used in combination with other sampling protocols when sampling takes place for analysis of both microbiological and chemical characteristics.

1. Sample material

Use can be made when taking a sample of a scoop, a hand scoop or sample drill consisting of one or more compartments. The sample drill must be adjusted to the depth of the product in the vehicle. The sample materials used are disinfected (with 95% alcohol or another bactericidal agent) or are sterile.

2. Sampling location

Depends on the purpose of the sampling.

The following should be taken into consideration in the sampling of the bacteriological status of delivered feeds:

Preferably during loading or unloading of the vehicle. If this is not possible then from the stationary vehicle auto where the whole load must be accessible. If the product is bagged then a sample can be taken during bagging. Samples must be taken such that contamination, for example by rain or dust, of the samples or containers in which the samples are stored is prevented. If the delivery consists of two parts (vehicle and trailer) then they can both be considered to be one batch.

3. Sampling

Use sterile gloves, disinfect the hands. Do not cough, sneeze or talk during the sampling and, if necessary, take measures to avoid infection from clothing, hair, etc. Keep bags, pots and bottles, etc. open as short as possible and with the opening turned upwards at an angle of 45°. Do not touch the insides of bags, pots, covers and the sampling tools with the hands if the sample material could come in contact with it. Always hold spoons, etc., by the handles. Avoid sampling by pouring out. If this can not be avoided then disinfect the edge over which the pouring will be done prior to use. Avoid contact with heat / sunlight / damp / equipment. The sample size amounts to at least 60 grams which is sufficient for a duplicate determination. This is also the final sample.

4. Sample sealing, storage and consignment

The sample should be labelled such that it can easily be identified. This means that at least the following records must be made, if applicable, on the sample using a clearly linked form of registration: date of sampling, product identification, batch identification, sampler, supplier, production unit where the sample was taken. The sample must be kept in such a way that damage to and deterioration of the sample is avoided. The sealing should be such that opening the sample inevitably leads to an irrevocable break in the seal on the sample.

Consignment of the sample should be done in a sterile bottle or bag. Deliver samples of wet by-products to the laboratory within 24 hours. Other samples must be sent within two working days.

Sampling protocol M7: Liquid feed materials and wet liquid feeds and solids in bulk, transport per vehicle (for both the delivery and removal of these products)

Purpose

Taking a sample from the batch in a uniform fashion.

Implementation

1. Sample material

Use should be made, when taking a liquid sample, of the drain cock of the vehicle. Use can be made when taking a sample from a solid product of a scoop, a hand scoop or sample drill consisting of one or more compartments. When using a sample drill this must be adjusted to the depth of the product in the vehicle or after unloading. The samples can be collected in a plastic bucket or an equivalent receptacle. For mixing liquid product a mixing spoon is required. The sampling equipment and the sample bags or pots must be clean, dry and free of odours foreign to the product.

2. Sampling location

The following items for attention apply during the loading of the truck:

- there is no residual load in the truck
- after loading the product will be quickly delivered (meaning within a few hours) to the customer
- no additional loading will take place after the sampling
- for products which are collapsing or where lighter elements are drifting up it is desirable prior to and during the loading to stir it to obtain a good representative sample.

Solid products can be sampled after unloading. Liquid products can also be sampled during unloading.

3. Sampling

The sample is taken by collecting a number of sub-samples and making a collective sample from these and then preparing a final sample. The number of sub-samples depends on the quantity of product supplied or to be delivered, see the table.

Product	Quantity in tons	Number of sub-samples	Minimum quantity of collective sample	Final sample
Liquid	up to 50 tons	min 2	250	250 g
Solid	up to 50 tons	min 2	final sample	500 g

Sub-samples

When taking a sub-sample via a drain cock it is important always to allow the old material to drain out (not to use it as a sub-sample). In addition, the diameter of the ball valve must be enough to prevent the sieving out of solids.

The individual sub-samples should be of the same size. If the sample is taken during loading or unloading of the vehicle then the sub-samples must be spread over the whole time that the vehicle is being loaded or unloaded. For solid products a sample should be taken across the batch.

This is done by taking sub-samples across the batch using a sampling drill or a scoop. The liquid sub-samples which are taken are put in a sample pot or something like that and collected in a bucket or equivalent receptacle.

The other sub-samples are also put in a bucket or equivalent receptacle. If inspection shows that the product is insufficiently homogeneous then one sub-sample (=collective sample) is sufficient.

Aggregate sample

The sub-samples which are taken are collected into a collection receptacle (a bucket for example). The product which is present is well mixed to produce a collective sample.

Final sample

A final sample is made from the collective sample. If inspection of the batch is desired then two or more final samples should be taken from the collective sample.

4. Sample sealing and storage

The sample should be labelled such that it can easily be identified. This means that at least the following records must be made, if applicable, on the sample using a clearly linked form of registration: date of sampling, product identification, batch identification, sampler, supplier, production unit where the sample was taken. The sample must be kept in such a way that damage to and deterioration of the sample is avoided. The sealing should be such that opening the sample inevitably leads to an irrevocable break in the seal on the sample.