



# GMP+ Feed Certification scheme

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## GMP+ C6

### Assessment and Certification Criteria for GMP+ Certification - Process Certification

6

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EN

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## History of the document

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0.0 / 09-2010	Transfer of the document from PDV to GMP+ International	Entire document	01-01-2011
1.0 / 09-2011	Introduction has been updated Textual adjustments  Sharpen the classification: category 1;  From standard to scope	1.1; 1.2 Entire document Appendix 1  Entire document	01-01-2012
1.1 / 11-2012	Editorial adjustments  Audits rotation  Assessment and reporting  Contracts/agreement  Adding and deleting GMP+ standards/scopes  Adjustment of Multi Site unprocessed goods.  Adding and deleting normative documents  Products and process stages/services  Requirements for certification of GMP+ B101 Production and trade of responsible Soy  New introduction and modified text regarding the Feed Certification scheme	Entire document  Paragraph 2.7  Paragraph 2.8  Paragraph 2.11  Appendix 2  Appendix 4  Appendix 5  Appendix 6  Various paragraphs  Entire document	01-03-2013

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# 1 Introduction

## 1.1 General

The GMP+ Feed Certification scheme was initiated and developed in 1992 by the Dutch feed industry in response to various more or less serious incidents involving contamination in feed materials. Although it started as a national scheme, it has developed to become an international scheme that is managed by GMP+ International in collaboration with various international stakeholders.

Even though the GMP+ Feed Certification scheme originated from a feed safety perspective, in 2013 the first feed responsibility standard has been published. For this purpose, two modules are created: GMP+ Feed Safety Assurance (focussed on feed safety) and GMP+ Feed Responsibility Assurance (focussed on responsible feed).

GMP+ Feed Safety Assurance is a complete module for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA module, such as requirements for the quality management system (ISO 9001), HACCP, product standards, traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests by GMP+ participants. The animal feed sector is confronted with requests on working responsibly. This includes, for example, the use of soy (including soy derivatives and soy products) and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance.

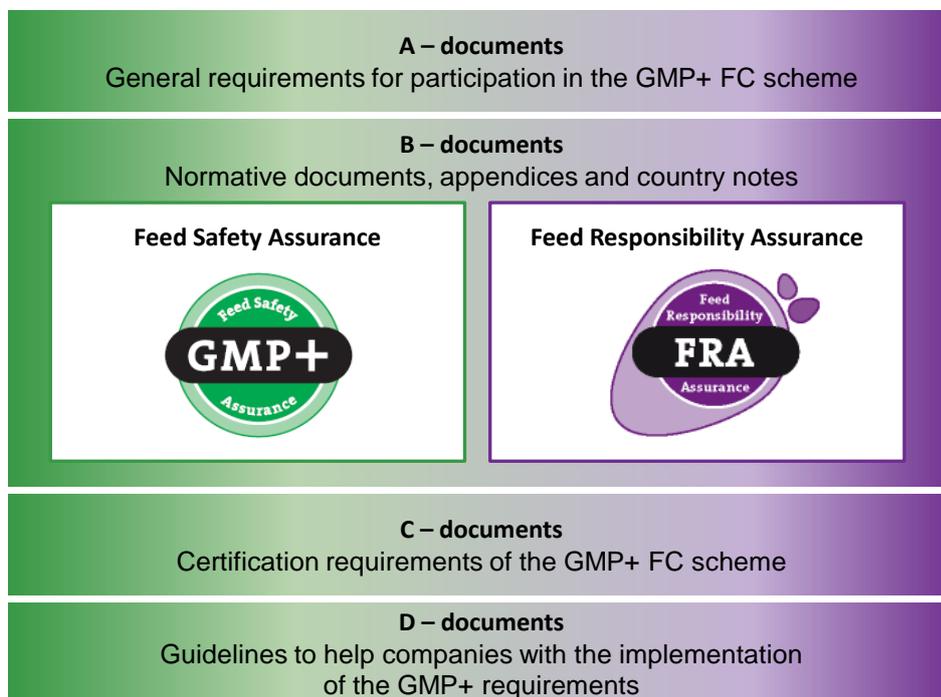
Together with the GMP+ partners, GMP+ International transparently sets clear requirements to guarantee feed safety & responsibility. Certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

## 1.2 Structure of the GMP+ Feed Certification scheme

The documents within the GMP+ Feed Certification scheme are subdivided into a number of series. The next page shows a schematic representation of the content of the GMP+ Feed Certification scheme:

### GMP+ Feed Certification scheme



All these documents are available via the website of GMP+ International ([www.gmpplus.org](http://www.gmpplus.org)).

This document is referred to as standard GMP+ C6 *Assessment and Certification Criteria for GMP+ Certification – Process Certification* and is part of the GMP+ Feed Certification 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+ FSA of GMP+ International,

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

### 1.4 Structure of the document

This standard has a structure of its own.

Next to this, also reference to a number of other appendices is made. These appendices are only part of this standard, and are attached to it. To indicate them, only the word 'appendix' is used.

## 2 Assessment programme

### 2.1 General

A certification body approved by GMP+ International under the GMP+ FC scheme is entitled to certify companies who have an interest for one or more GMP+ standards/scopes for the feed sector as specified in GMP+ FC 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 whether what should be written down, according to the applicable GMP+ standards/scopes, 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/scopes is taking place in the correct manner. In addition, if applicable, there is a verification of process conformity (section 2.5).

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 a verification of process conformity ([section 2.5](#)). The total certification process must be finished off within these three months including the updating of GMP+ International's company 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 scope *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 a verification of process conformity (section 2.5).  
There will also be a check based on the marked products which means end products (bagged goods, bulk, etc.) on which there is a logo that the (production) process complies with the requirements.

## 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 company 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 management statement, 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 a verification of process conformity (section 2.5).

## 2.5 Verification of process conformity

### General

In order to be able to evaluate the (production) process the certification body should carry out a verification of process conformity by way of an assessment of the analyses results of the company. If there is any doubt then the certification body must carry out further verification by way of taking and analysing samples

### Verification of the company analysis results

The certification body will check whether the analysis results from the company comply with the norms as established in GMP+ FC scheme. The size of the random sample amounts per product to at least  $\sqrt{n}$ , where  $n$  = the number of analyses carried out for this product in the past year.

In addition to the check on analysis results, the certification body will assess:

- a. whether the sampling and the analysis methods used comply with the requirements set in the GMP+ FC scheme
- b. the reliability and completeness of the analysis results using its findings with respect to the analysis results, sampling and the analysis methods used.

A certification body may designate, on the basis of the assessment of reliability and completeness of the analyses results, one or more of the samples retained by the company for a verification analysis to be carried out by the company using the parameters specified by the certification body.

The results of any additional analysis will be used for the certification process of the company and entered by the company into GMP+ International's Feed Safety Database (Monitoring DOS).

### Verification through the taking of samples

If the certification body has any doubts following the verification of the company analyses results then this form of verification can be chosen. The certification body will take one sample from every product group at the company location.

Sampling will take place in accordance with the applicable protocol as stated in appendix-8. The certification body will have the samples analysed in accordance with the product norms defined in GMP+ BA1 *Product Standards* which are applicable to those products on the basis of the company's own risk analysis and GMP+ BA4 *Minimum Requirements for Sampling and Analysis*. The results of the analyses will be used for the certification process of the company and will also be made available by the certification body to GMP+ International's Feed Safety Database (Monitoring DOS).

### Analysis method

These analyses should be carried out by a laboratory which is ISO 17025 accredited with the right scope for the analysis in question (right combination product – performance).

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.

## **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+ FC 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 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 ~~three~~ ~~four~~ 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 from the six previous audits ~~less than four~~ ~~max. three~~ 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. 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.~~

The technical reviewer should check all the reports drafted by the auditors and provide with a final assessment. Reports related to audits during which shortcomings have been established, should, next to the mentioned final assessment, also be provided with any improvement measures.

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 company 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 2.4](#)).

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 a certificate

Name of the certification body:

GMP+ International registration number of the certification body:

GMP+ logo:

### PROCESS CERTIFICATE

Name, address, location of the business location

(Name of vessel + EU number of vessel)

Visit address

GMP+ International registration number of the business location

"=*name of CB*=" declares that it has justifiable confidence that the process(es) (1<sup>st</sup> and 2<sup>nd</sup> column of the table in appendix 6) at the company location =*name of company* = complies with the applicable requirements and conditions of the standard(s) GMP+ Bx =*name of standard* = (appendix 5), of the GMP+ FC scheme (based on GMP+ C6) of GMP+ International.

#### FREE SECTION

See appendix 6.

Registered office of the certification body

Certificate number

Begin and end date of certificate

Accreditation mark

(if applicable)

#### Notes:

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

## B text for a 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

"=*name of CB*=" declares that it has justifiable confidence that the quality documentation of the process(es) (1<sup>st</sup> and 2<sup>nd</sup> column of the table in appendix 6) at the company location =*name of company* = complies with the applicable requirements and conditions of the standard(s) GMP+ Bx =*name of standard* = (appendix 5), of the GMP+ FC scheme (based on GMP+ C6) of GMP+ International.

### FREE SECTION

See appendix 6.

Registered office of the certification body

Temporary approval number

Begin date and end date of temporary approval

### Notes:

- a. 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".
- b. It is not permitted to specify brand names in any way whatsoever on the temporary approval.

## 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 / agreements

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+ C6 *Assessment and Certification Criteria for GMP + Certification*. Reference to GMP+ C6 *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 costs.

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.

The GMP+ agreement entered into by the certification bodies and the GMP+ participants should provide the GMP+ participants with the possibility to terminate the GMP+ agreement before the end of the certification cycle.

#### **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

### GMP+ FSA scheme

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><b>Conclusion</b></p>	<ul style="list-style-type: none"> <li>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.</li> </ul>
<p><b>Nonconformity</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>Some required element is not completely described in the documentation.</li> <li>An element previously described is not updated, while this is required as a consequence of amended requirements and regulations.</li> <li>Quality records have been overlooked or are out of date (&lt; 2 months), clearly of an incidental nature.</li> <li>An element is not being properly implemented, but this will have only a limited negative effect on the basic quality of the product.</li> <li>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.</li> <li>It is reasonable to assume that the nonconformity is an incident.</li> <li>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.</li> </ul>	<p><b>Measures</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>If the nonconformity is not or not fully resolved then it will be converted to a Category 2 nonconformity.</li> </ul>
<ul style="list-style-type: none"> <li>10 or more Category 3 nonconformities</li> </ul>	<ul style="list-style-type: none"> <li>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).</li> </ul>

**Classification: Category 2**

<b>Conclusion</b>	<ul style="list-style-type: none"> <li>The company does not meet the requirements for GMP+ certification or temporary approval.</li> <li>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.</li> </ul>
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<b>Nonconformity</b>	<b>Measures</b>
<ul style="list-style-type: none"> <li>A Category 3 nonconformity was observed earlier and inadequate or no improvement has taken place.</li> <li>An element is absent or is very incompletely described in the documentation, such that the functioning of the quality system is put in question.</li> <li>Quality records are very out of date (&gt; 2 months).</li> <li>An element is not being properly implemented and is possibly critical for the feed safety of the product.</li> <li>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.</li> <li>Internal audits not carried out or are late or incomplete</li> <li>In addition it is reasonable to assume that there is <i>no</i> case of gross negligence, fraudulent actions or economic malpractice.</li> </ul>	<ul style="list-style-type: none"> <li>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).</li> <li>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.</li> </ul>
<b>Nonconformity</b>	<b>Measures</b>
<ul style="list-style-type: none"> <li>A serious nonconformity relating to critical GMP+ requirements.<sup>1</sup></li> <li>A serious nonconformity of an incidental nature without direct consequences for the subsequent links in the chain.</li> <li>Feed additives or feed medicines are not processed in accordance with the requirements.</li> <li>It is reasonable to assume that there is <i>no</i> case of gross negligence, fraudulent actions or economic malpractice.</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> <li>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).</li> </ul>

<sup>1</sup> 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 GMP+ Monitoring database, d) non-compliance with the feed legislation. This will be detailed in the checklists.

Nonconformity	Measures
	<ul style="list-style-type: none"> <li>The company will be given at least one compliance audit within 3 months. This may be handled administratively except in those cases where assessment in practice is necessary.</li> </ul>
<ul style="list-style-type: none"> <li>During the compliance audit a previously observed Category 2 nonconformity is not put right in time or not completely.</li> <li>Any recall is not carried out properly or (due to own negligence) is not carried out in time.</li> </ul>	<ul style="list-style-type: none"> <li>This nonconformity will be converted into a Category 1 nonconformity.</li> </ul>

**Classification: Category 1**

<p><b>Conclusion</b></p>	<ul style="list-style-type: none"> <li>• The company does not meet the requirements for GMP+ certification or temporary approval.</li> <li>• 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.</li> </ul>
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<b>Nonconformity</b>	<b>Measures</b>
<ul style="list-style-type: none"> <li>• A structural nonconformity relating (regularly practice) to critical GMP+ requirements. This relates in any event to               <ul style="list-style-type: none"> <li>a) incorrect cleaning and disinfections, loading sequence, with a forbidden pre-load, for GMP+ transport,</li> <li>b) no risk assessment for a feed material,</li> <li>c) purchasing from a non-GMP+ supplier,</li> <li>d) intended, on purpose or regularly practice non-compliance with a product standard</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• The certification body will immediately withdraw the certificate or temporary approval.</li> <li>• The company or natural persons involved are excluded for a period of at least 1 year from participation in the GMP+ FSA scheme.</li> </ul>

<b>Nonconformity</b>	<b>Measures</b>
<ul style="list-style-type: none"> <li>• There has been a previous Category 2 nonconformity but only inadequate or late improvement measures have been implemented.</li> </ul>	<ul style="list-style-type: none"> <li>• 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).</li> <li>• The company will be given at least one compliance audit.</li> <li>• The company will be placed under stricter supervision for a period of at least 3 and maximum 6 months.</li> <li>• 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.</li> <li>• 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.</li> </ul>

Nonconformity	Measures
<ul style="list-style-type: none"> <li>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.</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ul>
<ul style="list-style-type: none"> <li>Any recall is not carried out properly or (due to own negligence) is not carried out in time.</li> </ul>	<ul style="list-style-type: none"> <li>The certification body will immediately withdraw the certificate or temporary approval.</li> <li>The company or natural persons involved are excluded for a period of at least 1 year from participation in the GMP+ FC scheme.</li> </ul>
<ul style="list-style-type: none"> <li>The participant does not cooperate in audits or in the supervision by the certification body.</li> </ul>	<ul style="list-style-type: none"> <li>The certification body suspends the certificate or temporary approval for a maximum period of three months.</li> <li>The suspension can only be released if suitable measures for improvement have been taken.</li> <li>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.</li> </ul>
<ul style="list-style-type: none"> <li>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.</li> </ul>	<ul style="list-style-type: none"> <li>The certification body will immediately withdraw the GMP+ certificate or temporary approval.</li> <li>The company or natural persons involved are excluded for a period of 1 year from participation in the GMP+ FC scheme.</li> </ul>

### GMP+ FRA scheme

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	
Nonconformity	Measures
<ul style="list-style-type: none"> <li>The auditor might identify the early stages of a problem which does not lead to serious non-conformities (category 2 or 1), but may lead to future non-conformities. These findings should be recorded in the checklist, but does not lead to any consequences for the participant yet.</li> </ul>	<p>The findings can benefit participants in order to prevent bigger non-conformities (category 2 or 1) in the future. There are no consequences at this point.</p>

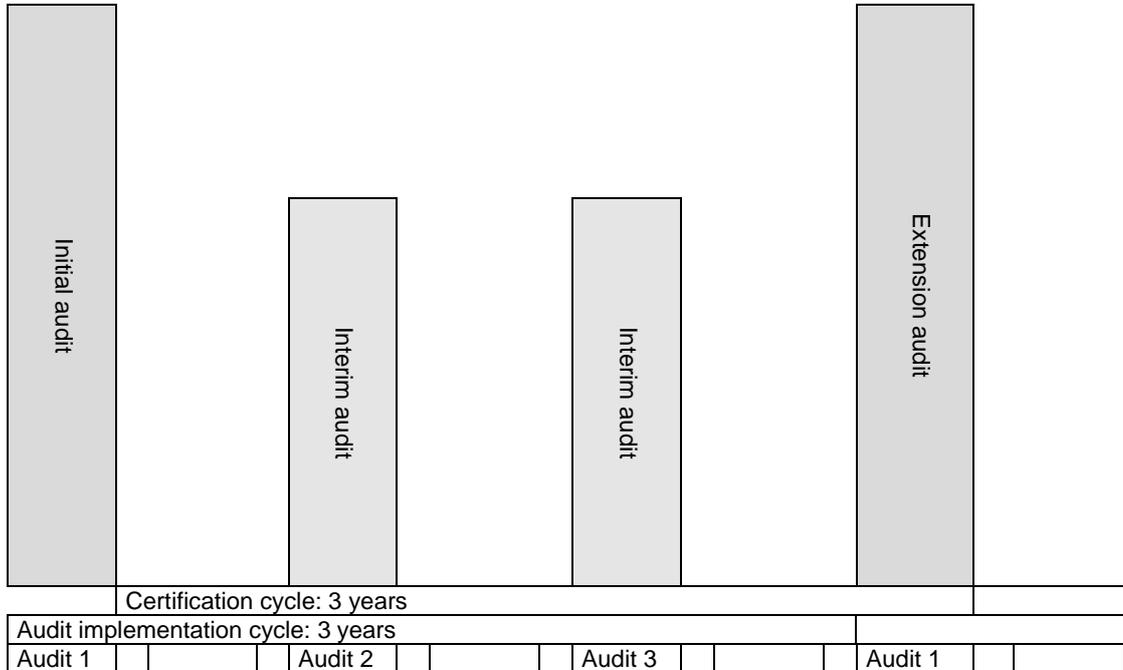
Classification: Category 2	
Nonconformity	Measures
<ul style="list-style-type: none"> <li>A nonconformity should be considered as category 2 if;               <ol style="list-style-type: none"> <li>It is a temporary lapse, or</li> <li>It is unusual / non-systematic, or</li> <li>If the impacts of the nonconformity are limited in their temporal and organizational scale and</li> <li>It does not result in a fundamental failure to achieve the objective of the relevant requirement</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>The participant is obliged to present an Action Plan which adequately describes how the non-conformity shall be addressed.</li> <li>The participant will fully address the nonconformity within 1 year.</li> <li>If the participant does not take improvement measures within the period of time established then the certification body will convert the nonconformity into a Category 1 nonconformity.</li> </ul>

Classification: Category 1	
Nonconformity	Measures
<ul style="list-style-type: none"> <li>A nonconformity should be considered as category 1 if the failure;               <ol style="list-style-type: none"> <li>continues over a long period of time, or</li> <li>is repeated or systematic, or</li> <li>is not corrected or adequately responded by the responsible managers once they have been identified.</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>The participant is obliged to present an Action Plan which adequately describes how the non-conformity shall be addressed.</li> <li>The participant will fully address the nonconformity within 3 months.</li> <li>The participant will be subjected 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.</li> <li>If the company does not take improvement measures within the period of time established then the certification body will withdraw the certificate.</li> </ul>

## Appendix 2: Frequency and time expenditure from 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+ C6 *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 2.6](#), 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

GMP+ FSA scheme	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours <sup>1</sup>			Comment
			Initial or exten- sion audit	Supervision audit		
<b>GMP+ B1 Production, Trade and Services</b> Scope: Production of compound feeds						
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
<b>GMP+ B1 Production, Trade and Services</b> Scope: Production of compound feeds <b>without the use of critical feed additives and critical veterinary medical products.</b>						
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
<b>GMP+ B1 Production, Trade and Services</b> Scope: Production of premixes						
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

GMP+ FSA scheme	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours <sup>1</sup>			Comment
			Initial or exten- sion audit	Supervision audit		
<b>GMP+ B1 Production, Trade and Services GMP+ B2 (2010) Production of feed ingredients</b> Scope : production 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		
<b>GMP+ B1-Production, Trade and Services GMP+ B2 (2010) Production of feed ingredients</b> Scope: production 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		
<b>GMP+ B2 Quality control foreign suppliers</b>	Number of products					
	≤ 5	1x / year	<del>6.5 + 1.5X</del>	5.0 + 1.5X		
	6-15	1x / year	<del>8.0 + 1.5X</del>	5.5 + 1.5X		
	>15	1x / year	<del>9.5 + 1.5X</del>	6.5 + 1.5X		
Feed additives gatekeeper	1.5 hours per dossier					2
<b>GMP+ B3Trade (except forage trade) or GMP+ B1 Production, Trade and Services</b> Scope: trade in feed (except forage 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

GMP+ FSA scheme	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours <sup>1</sup>			Comment
			Initial or exten- sion audit	Supervision audit		
<b>GMP+ B3 Trade (forage trade) or GMP+ B1 Production, Trade and Services; scope: Trade (forage trade) or GMP+ B3 (2007) Trade, Collection and Stor- age &amp; Transhipment (forage trade)</b> scope: Trade in feed	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		
<b>GMP+ B3(2007) Trade, Collection and Storage &amp; Transhipment</b>						
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.	Number of products					4
	≤ 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
<b>GMP+ B3.2 Trade to Livestock Farm</b>						
Administrative trade		1x / year	2.5	2.0		5, 6, 7
(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 retail outlet		1x / year	See appendix 4: Multisite certifica- tion for .2 (option 2)			

GMP+ FSA scheme	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours <sup>1</sup>			Comment
			Initial or extension audit	Supervision audit		
<b>GMP+ B4 Transport, scope rail transport</b>			To be defined	To be defined		
<b>GMP+ B4.1 Road transport/GMP+ B4 Transport</b> Scope: transport feed, road transport and organisation of affreightment feed, road transport	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		
<b>GMP+ B4.1 Tractionair/GMP+ B4 Tractionair</b>						
With own manual		1x / year	4.0	2.0		8
Included in customers manual		1x / year	2.5	2.0		
<b>GMP+ B4.2 affreightment of Short Sea Shipping and Inland Waterways Transport, GMP+ B4.4 Sea Transport affreightment, GMP+ B4.5 Rail Transport affreightment, GMP+ B4, scope affreightment.</b>		1x / year	5.5	5.5		
<b>GMP+ B4.3 Inland Waterways Transport Short Sea Shipping and Inland Waterway</b>		1x / 2 year	2.0			
<b>GMP+ B4.4 Sea Transport Affreightment//GMP+ B4, scope affreightment</b>		1x / year	5.5	5.5		
<b>GMP+ B4.5 Rail Transport Affreightment/GMP+ B4, scope affreightment</b>		1x / year	5.5	5.5		
<b>GMP+ B5 Storage &amp; transhipment or GMP+ B1 Production, Trade and Services GMP+ B3(2007) Trade, Collection and Storage &amp; Transhipment</b> Scope: storage & transhipment	Number of employees					

GMP+ FSA scheme	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours <sup>1</sup>			Comment
			Initial or extension audit	Supervision audit		
	≤ 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		
<b>GMP+ B6 Feed Materials Cultivation</b>						
	Number of products					9
	≤ 5	1x / 3 years	6.5			
	6-15	1x / 3 years	8.0			
	>15	1x / 3 years	9.5			
<b>GMP+ B8 Production of and Trade in Pet food</b>						
Scope: production 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		
<b>GMP+ B8 Production of and Trade in Pet food</b>						
Scope: trade in pet food						
	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		
<b>GMP+ B10 Laboratory Testing</b>						
	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		
Partially ISO17025 accredited	≤ 5	1x / year	5.5	5.5		
	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		

GMP+ FSA scheme	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours <sup>1</sup>			Comment
			Initial or extension audit	Supervision audit		
	>20	1x / year	12.0 + 12.0	9.5 + 9.5		15
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		
<b>Combined audit GMP+ 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)</b>		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+ FC scheme audit			16, 17

GMP+ FRA scheme	Audit frequency	Minimum time expenditure in hours <sup>1</sup>		Comment
		Initial or extension audit	Supervision audit	
<b>GMP+ B101 Production and trade of responsible soy.</b>				
In addition to a GMP+ FSA standard;				
Scope: RTRS mass balance system	1x / year	3	2	
Scope: RTRS Segregated system	1x / year	3	2	
<b>As a stand alone standard (without GMP+ FSA certification)</b>				
Scope: RTRS mass balance system	1x / year	8	4	
Scope: RTRS Segregated system	1x / year	8	4	

- <sup>1</sup> The basis is the main activity of the company. "X" is the number of additional activities and/or scopes to be certified at the same location.
- <sup>2</sup> All dossiers should be initially assessed and then on a random sample basis during the period of validity of the certificate.
- <sup>3</sup> 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.
- <sup>4</sup> The scopes within GMP+ B3(2007) *Trade, Collection and Storage & Transshipment* are: a) trade and collection, b) storage and c) transport of own products. Simple actions fall under collection.
- <sup>5</sup> In combination with other GMP+ standards/scopes, the audit times for these standards/scopes are counted with the times for GMP+ B3.2 *Trade to Livestock Farms*.
- <sup>6</sup> For the GMP+ B3.2 *Trade to Livestock Farms* no report needs to be drawn up, just an audit checklist.
- <sup>7</sup> 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 *Trade to Livestock Farms*.
  - 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 & Transshipment*.
- <sup>8</sup> 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.
- <sup>9</sup> 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.
- <sup>10</sup> Where the company produces wet pet foods the scope of the production should be converted using the dry matter content.
- <sup>11</sup> 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).
- <sup>12</sup> The most important analyses must be assessed during the initial audit. At least once during the audit cycle all analyses should be assessed.
- <sup>13</sup> 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.
- <sup>14</sup> If a laboratory is certified for both GMP+ B10 *Laboratory Testing* and ISO 9001; 2000 or ISO22000 then a 35% audit time reduction may be applied on the condition that the laboratory is included in the scope of the ISO certificate.
- <sup>15</sup> 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.
- <sup>16</sup> The correspondences between GMP+ B10 *Laboratory Testing* and the other GMP+ standards/scopes are so few that a combined audit for GMP+ B10 *Laboratory Testing* and one or more of the other GMP+ standards/scopes will not give any reduction in the time expenditure. The minimum time duration should always be applied for a GMP+ B10 audit.
- <sup>17</sup> 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 (C documents) to be able to audit all the relevant GMP+ standards/scopes.
  - Carrying out of the audit:
    - o GMP+ FC 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+FCA scheme are verified during the audit. The GMP+ checklist must be completed in full

- 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
  - 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:
  - 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. ver- sion date and additional product criteria	Expiry date of current certificate or tempo- rary 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 verification of the conformity of the products.

The evaluation of the marked products must also be described.

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:

Multi site 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.

*Note: 'A multi site organization need not to be a unique legal entity, but all sites must have a legal or contractual link with the main office of the organization and be subject to a common management system, which is laid down, established and subject to continuous surveillance and internal audits by the central office. This means that the central office has rights to require that the sites implement corrective actions when needed in any site. Where applicable this should be set out in a formal agreement between the central office and the sites'.<sup>2</sup>*

### **Guidance**

*Multi site certification is reserved for companies which are part of the feed sector. Companies, participating in a multi site organisation, should demonstrate this.*

*Multi site certification is not to be used if various independent companies have joined together in a branch organisation, union, federation, association, via an independent consultancy office or similar.*

This applies for the activities:

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

Note: In a group of companies in which the above activities take place, 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.

For **unprocessed goods** (i.e. grain, seeds and pulses) which are collected, handled, stored or transported with own transport, the minimum requirements for multi-site certification, as laid down in a separate section under Certification, can be used.

### **Guidance**

- a. For a definition of collection see GMP+ A2 *Definitions and Abbreviations*.
- b. If, for example, a group contains multiple production locations and storage locations, the production locations in this group cannot be certified under multi-site but perhaps the storage locations can.
- c. If both collection and transport (incl. affreightment) takes place at locations, the certification of this may also be combined under the multi-site requirements.

<sup>2</sup> IAF MD1:2007 - Document for the Certification of Multiple Sites Based on Sampling

- d. If a company or group of companies does not fully comply with the criteria, 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:
  - 1. a commitment by the company to the main office that it will comply with the requirements set in the quality system.
  - 2. that corrective measures imposed by the main office are binding
  - 3. that the above applies to all feed activities (and therefore those which are carried out more or less independently).
- e. All the locations are included in the programme of internal audits.
- f. 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, 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, 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 take place under multi-site requirements.*

## **C) Certification**

If a main office has a different GMP+ scope to one of the locations or companies, 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., 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 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, 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:

<b>Location</b>	<b>Number of employees*</b>	<b>Minimum time expenditure per visit</b>
<b>Main office</b>	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.	
<b>Location / companies with only transport</b>	≤ 5	2.0
	6-15	3.0
	>15	4.0
<b>Storage only location</b>		2.0
<b>Location / companies with both storage and transport</b>	≤ 5	2.0
	6-15	3.0
	>15	4.0
<b>Location / companies with storage and/or transport and limited trading</b>		4.0

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

### **Unprocessed goods (i.e. grain, seeds and pulses)**

This multisite construction is applicable for transport and storage for unprocessed goods. Trade is excluded, also as transport and storage of processed goods.

If a multisite company consists of more than 20 sub locations and there are only unprocessed goods involved, another method to calculate the minimum frequency and audit times can be used:

- The requirements as laid down for the internal audit will be the same as in a regular multisite certification; the internal audit program must cover all sites every year, including sites that are not used the whole year round.
- All sites with unprocessed goods must be located in the same country or in the bordering regions of neighbouring countries.
- The sampling programme for the external audit can be risk based. All sites, including sites that are not used the whole year round, must be part of the sampling programme of the external audit. For the external audit the main office will be audit every year. The sub locations will be audited during the certification period (3 years) as follows:
  - a. up to 20 sites; all sites
  - b. from the 21<sup>st</sup> site; every fifth site.

The sub locations will be chosen randomly. The certification body may divide the sub locations into groups or districts.

## **Guidance**

### **Regular multisite**

The main office (certified for GMP+ B4.1, scope: Road Transport; 3 – 5 employees and GMP+ B3 (2007), scope: Storage) and 10 sub locations with:

5 sub locations only transport ( $\leq 5$  employees), calculated audit time is 2 hours per sub location;

5 sub locations with storage and transport (6-15 employees), calculated audit time is 3 hours per sub location.

The main office has to be audited every year in accordance to appendix 2 of this document.

For the sub locations 1/3 of the total calculated audit time every year.

Calculation audit time for initial/extension audit of the main office:

GMP+ B4.1, scope: Road Transport (3 – 5 employees = 6,5 hours) and GMP+ B3, scope: Storage (extra 1,5 hour) = 8,0 hours (see appendix 2 of this document) +10 hours (additional audit time for the sub locations) makes a total of: 18 hours.

Calculation audit time for supervision audit of the main office: GMP+ B4.1, scope: Road Transport (3 – 5 employees = 4 hours) + GMP+ B3, scope: Storage (extra 1,5 hour) = 5,5 hours (see appendix 2 of this document) +10 hours (additional audit time for the sub locations) makes a total of: 16,5 hours

Calculation audit time for the transport sub locations ( $\leq 5$  employees)  $5 \times 2 = 10$  hours

Calculation audit time for the transport and storage sub location (6-15 employees)  $5 \times 3 = 15$  hours

1/3 of  $10+15 = 8,33$  hours audit time every year for the sub locations

### **Unprocessed goods (large multisite)**

The main office (certified for GMP+ B3 (2007), scope: Trade and Storage ( $\leq 5$  products)) and 100 sub locations which are all certified for Storage. The main office has to be audited every year in accordance to appendix 2 of this document.

100 sub locations only storage, calculated audit time is 2 hours per sub location.

Sub locations to be audited randomly chosen by the CB.

20 sub locations and from the 2<sup>1st</sup> sub location every 5<sup>th</sup> sub location has to be audited per 3 year (certification period).

Calculation audit time for initial/extension- and supervision of the audit main office:

GMP+ B3 (2007), scope: Trade ( $\leq 5$  products) is 6,5 hours and GMP+ B3 scope: Storage, extra 1,5 hour = 8,0 hours (see appendix 2 of this document) +10 hours (additional audit time for the sub locations) makes a total of: 18 hours

Calculation audit time for the 100 sub locations which are all certified for storage:  $20+80 \cdot 0,20 = 20 + 16 = 36$  audits per 3 year (certification period).

Sub locations average  $1/3 \times 36 \times 2 = 24$  hour per year.

## **Extra points of interests**

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 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, verification of loading compartments
- e. inspections and records
- f. delivery of feeds
- g. if transport activities also take place, the operational aspects should also be assessed
- h. complaints and nonconformities

During audits of locations where transport is done the following GMP+ requirements must be 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, the operational aspects should also be assessed
- f. complaints and nonconformities

During audits of locations where trading is done the following GMP+ requirements must be 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, the whole company or quality community does not meet the requirements for GMP+ certification. If nonconformity is observed at the level of a location, 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, 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

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

Minimum time to be spent per visit in hours:

	<b>Minimum time expenditure per visit</b>
<b>Extra storage location</b>	1.0
<b>Extra retail outlet</b>	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, 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, 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

Standard GMP+ FSA scheme	Name of the Standard
GMP+ B1	Production, trade and services
GMP+ B2	Quality Control of Feed Materials
GMP+ B2(2010)	Production of feed ingredients
<del>GMP+ B3(2006)</del>	<del>Trade</del>
GMP+ B3(2007)	Trade, collection and storage & transhipment
GMP+ B3.2	Trade to livestock farms
<del>GMP+ B4</del>	<del>Transport</del>
GMP+ B4.1	Road transport
GMP+ B4.2	Affreightment of short sea shipping and inland waterway transport
GMP+ B4.3	<del>Inland waterways transport</del> Short Sea Shipping and Inland Waterway
GMP+ B4.4	Sea transport affreightment
GMP+ B4.5	Rail transport affreightment
<del>GMP+ B5</del>	<del>Storage &amp; Transhipment</del>
GMP+ B6	Feed materials cultivation
GMP+ B8	Production of and trade in pet foods
GMP+ B10	Laboratory testing
Standard GMP+ FRA scheme	Name of the Standard
GMP+ B101	Production and trade of responsible soy

standard GMP+ FSA →	B1	B2 **	B2- 2010	B3- 2006 *	B3 2007	B3.2	B5*	B4 From 1-2- 2012	B4.1 Appli- cable until 31-12- 2015	B4.2 Appli- cable until 31-12- 2015	B4.3	B4.4 Appli- cable until 31-12- 2015	B4.5 Appli- cable until 31-12- 2015	B6	B8	B10
↓ scope of process																
Production of compound feed	x															
Production of premixes	x															
Production of feed additives	x		x													
Production of feed materials	x	x	x													
Trade of feed.	x	x		✖	x											
Trade to livestock farms	x	x			x	x										
Storage and transhipment of feed	x	x			x		✖									
Road transport								x	x							
Affreightment of road transport								x	x							
Railtransport								x								
Affreightment of short sea shipping and inland waterway transport								x		x						
<del>Inland waterway transport</del> Short Sea Shipping and Inland Waterway											x					
Affreightment of sea transport								x				x				
Affreightment of rail transport								x					x			
Feed materials Cultivation														x		
Production of pet food	x														x	
Trade in pet food	x														x	
Laboratory Analyses of feed																x

\* After 01-01-2010 no longer certifiable, disappears per 31-12-2012

\*\* After 01-01-2011 no longer certifiable, disappears per 31-12-2013

## Accreditation

All standards / scopes can be brought under accreditation with the exception of the following standards /scopes:

Process	Normative document
<b>Not yet able to be brought under accreditation:</b>	
Trade, collection, storage and transshipment, transport of own products	GMP+ B3(2007) <i>Trade, Collection and Storage &amp; Transshipment</i>
Affreightment of the road transport of feed	GMP+ B4.1 <i>Road Transport</i>
Transport	GMP+ B4 <i>Transport</i>
<b>Not able to be brought under accreditation:</b>	
Distributive trades with direct delivery to livestock farmers	GMP+ B3.2 <i>Trade to Livestock Farms</i>
Inland waterway shipping	GMP+ B4.3 <del><i>Inland Waterways Transport</i></del> <del><i>Short Sea Shipping and Inland Waterway</i></del>
Cultivation	GMP+ B6 <i>Feed Materials Cultivation</i>
Laboratory	GMP+ B10 <i>Laboratory Testing</i>
Production and trade of responsible soy	GMP+ B101 <i>Production and trade of responsible soy</i>

## 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.

<i>GMP+ Feed Safety Assurance</i>	
<i>Activities</i>	<i>Animal feedstuffs</i>
Production of .....	the animal feeds to be distinguished: ..... feed additives ..... feed materials ..... premixes ..... compound feeds ..... feeds ..... own products  There can also be a separate mention of: ..... pet foods
Processing of .....	
Cultivation of .....	
Trade in.....	
Storage and transhipment of ...	
Collection of .....	
Road transport of ....	
Rail transport of .....	
Inland waterway transport Short Sea Shipping and Inland Waterway of ...	
Affreightment of inland waterway transport for ....	
Affreightment of sea transport for ....	
Affreightment of rail transport for ....	
Affreightment of short sea shipping for ...	
Affreightment of road transport for....	

<i>GMP+ Feed Responsibility Assurance</i>	
<i>Activities</i>	<i>Product</i>
Production of .....	- RTRS mass balance responsible soy - RTRS segregated responsible soy
Trade in.....	

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. A milk replacer feed producer may specify his production of compound feeds as: production of milk replacer feed.
- b. a collector of grains may specify his treatment of feed materials as collection, cleaning and drying of grains
- c. 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: Supervision audit – not a 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:
  1. Checking of loading compartments causes no hazardous situations for those involved or bystanders
  2. 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 8: 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

Product	Form	Quantity in tons	Number of sub-samples	Minimum quantity of collective sample	Minimum quantity of final sample
		the part of the batch in excess of 500 tons	1 per 50 tons	1 kg per sub-sample	200 g
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 coaster<sup>1</sup>

### 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.

<sup>1</sup> 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 cannot 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.