GMP+ International

Assessment and Certification Criteria for GMP+ Certification - Process Certification

GMP+ C 6

Version EN: 11 May 2020

GMP+ Feed Certification scheme

Feed Safety Worldwide

gmpplus.org

History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0 / 09-2010	Previous versions can be found in History		01-01-2011
1.0 / 09-2011			01-01-2012
2.0 / 11-2012			01-03-2013
2.0 / 06-2014	Editorial changes: All editorial changes are listed in a factsheet	Entire document	01.01.2015
	Extension of the timeframe of temporary acceptance	Paragraph 2.2	
	Additional requirement for stricter supervision	Paragraph 2.6	
	Clarification audit rotation	Paragraph 2.7	
		Paragraph 2.8	
	Additional requirement for assessing	Paragraph 2.11	
	Added an additional requirement for the GMP+ contract/agreement	Annex 1 Annex 2	
	New assessment criteria and measures	Annex 3	
	New audit times for Gatekeeper files and additional scopes.	Annex 4	
	Adjustment report model	Annex 5	
	Extension audit times for additional activities Multi-Site	Annex 6	
	Changes in the normative documents		
	Adding products and process stages/services		
	Some extra corrections	Annex 1	
4.0 / 09-2016	"approval" can be replaced by "acceptance" "company can be replaced by "participant" "streamlining the type of audits" "should can be replaced by must"	Entire document	01.09.2016
	Expansion of scopes	Paragraph 2.2	01.09.2016
	Reducing size of sampling	Paragraph 2.3	01.09.2016
	Unannounced surveillance audit	Paragraph 2.4	01.09.2016
	Special audits	Paragraph 2.7	01.09.2016
	Rotation of auditors	Paragraph 2.8	01.09.2017
	Certification template	Paragraph 2.10	01.01.2017
	Submitting the form Audit Finding Notification Critical Nonconformity	Paragraph 2.11	01.09.2016
	Assessment criteria and measures	Annex 1	01.09.2016
	Audit time reductions requirements Audit time unannounced surveillance audit Audit time for assessing Gatekeeper files	Annex 2	01.09.2016

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
	Audit objectives	Annex 3	01.09.2016
	Multisite for Feed Responsible Management System	Annex 4	01.09.2016
	Normative documents	Annex 5	01.09.2016
5.0 / 11-2017	Editorial changes & clarification related by "through the Certification Body"	Paragraph 1.4 & entire document	01.07.2018
	New requirements unannounced surveillance audit.	Paragraph 2.4	22.02.2018
	Adaptation of stricter supervision regime	Paragraph 2.7	01.07.2018
	For an inland waterway vessel inspection the loading compartment must be empty	Paragraph 2.9	01.07.2019
	Criteria new checklist regarding GMP+ B4.3	Paragraph 2.9	01.07.2018
	No logo of Critical-, Non-Critical location and Outsourcing Parties on GMP+ certificates	Paragraph 2.10	01.07.2018
	Use of Unique Certification Agreements/Certification Agreement Template	Paragraph 2.12	01.07.2018
	Mandatory to close a Major NC or a follow up. Compliance audit regarding a Critical NC has been deleted	Annex 1	01.07.2018
	Audit time for PO Boxes and Qqualim audits can be combined	Annex 2	01.07.2018
	It must be clear in the report what has been assessed and concluded by the auditor	Annex 3	01.07.2018
6.0 / 05 2018	Editorial changes, conformity audit/inspection/assessment/new GMP+ database etc.	Entire document	01.07.2018
	A certified company who moves to another location must be audited	Paragraph 2.1	01.07.2018
	The scope of a certified company cannot be extended during the voluntary add on unannounced surveillance audit	Paragraph 2.2	04.06.2018
	Reinstallation of the voluntary add on unannounced surveillance audit	Paragraph 2.4	04.06.2018
	Rotation requirements for an inspector	Paragraph 2.7	01.07.2018
	Changes related to the new GMP+ database	Paragraph 2.8	01.07.2018
	For a Minor nonconformity an extra announced surveillance audit is not necessary	Annex 1	01.07.2018
	Once a company is excluded from participation of the GMP+ FC scheme the company cannot also not participate under all Gatekeeper protocols	Annex 1	01.07.2018
	Specific measures if a company cannot fulfill the financial obligation to the Certification Body	Annex 1	01.07.2018

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
	Audit times for both unannounced audits, for GMO controlled, reducing audit times when combined with Pastus+ and number of employees for transport are based on FTE	Annex 2	01.07.2018
	Audit report/inspection checklist has been added	Annex 3	01.07.2018
	For each Multi Site location the nonconformities must be uploaded in the new GMP+ database	Annex 4	01.07.2018
	An update by adding the GMP+ Appendices (BA documents) and new standards.	Annex 5	01.07.2018
	Expansion of the table of GMP+ standards who cannot be brought under accreditation	Annex 5	01.07.2018
	Streamlining GMP+ activities with the GMP+ new database	Annex 6	01.07.2018
	Production area has been replaced by working area	Annex 7	01.07.2018
6.1 / 08 - 2018	Addition of Inspection Checklist processed in the Audit app	Annex 3	15.08.2018
	Addition in option 1: uploading of a GMP+ audit report/checklist in the GMP+ database for all multi-site locations in which only nonconformities will be described for a multi-site location. Was already mentioned in option 2.	Annex 4	
6.2 / 09 – 2018	Correction text in title Correction text: 'the repeat audit' has to be 'audits'	Annex 7 2.9	26.09.2018
6.3 / 12 – 2018	Correction GMP+ C3 into GMP+ C6. Only English version.	2.12	27.12.2018
6.4 / 01 - 2019	Compliance audit is replaced by Conformity audit	Entire document	23.01.2019
7.0 / 03 – 2019	Implementation of the unannounced surveillance audit in Germany and other countries in Europe	2.4	21.03.2019
	BCN-IP Specific requirements Iberian Peninsula has been added as a normative document and cannot be brought under accreditation	Annex 5	BCN-IP: 15.05.2019
8.0 / 05 - 2019	Implementation of audit times FRA	Annex 2	14.06.2019
	Segregation for GMO Controlled, trade, storage and transshipment and transport is allowed	Annex 4	14.06.2019
	Audit times for Multi Site FRA	Annex 4	14.06.2019
	Specific GMO Controlled scopes for certificates	Annex 6	14.06.2019
9.0 / 04 - 2020	Removal of voluntary add on unannounced surveillance audit	Article 2.4	15.11.2019
	Duration for audits may increase if EWS, complaint, exemptions, incidents, etc, have to be investigated by the Certification Body	Annex 2	11.05.2020
	New gatekeeper files and times accordingly GMP+ BA10	Annex 2	11.05.2020

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
	Audit times auditing GMO Controlled	Annex 2	11.05.2020
	Adding two additional production scopes for GMO Controlled	Annex 6	11.05.2020

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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 was published. For this purpose, two modules have been 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 with standards 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 standards, such as requirements for a feed safety management system, for application of HACCP principles, for traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

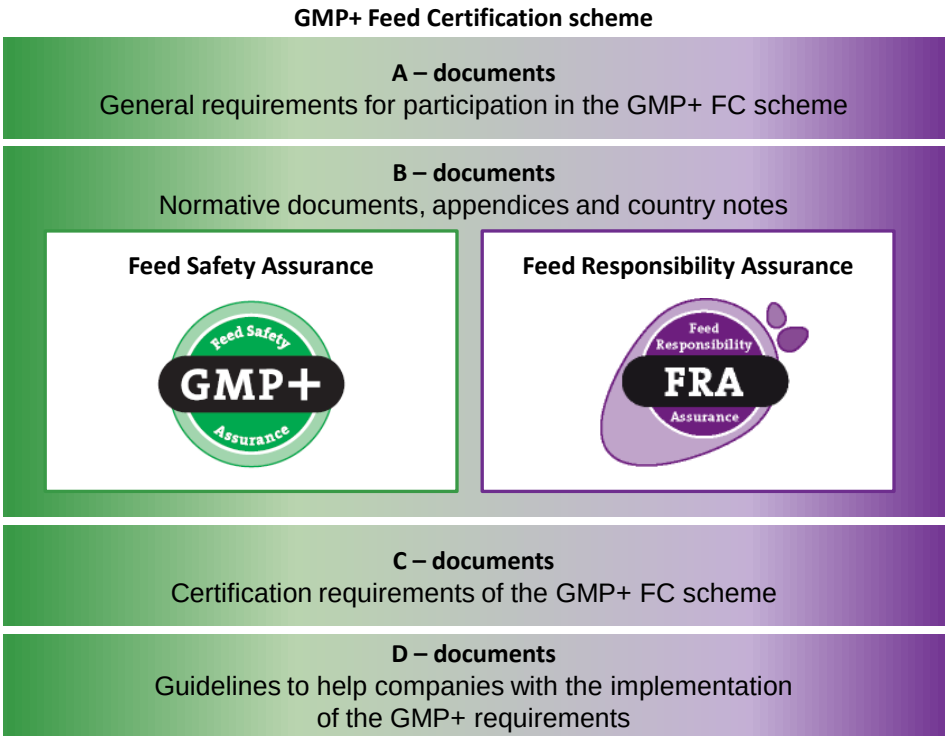
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and 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. GMP+ International facilitates via independent certification the demands from the market.

Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. 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:



All these documents are available via the website of GMP+ International (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.

In addition to this, reference to a number of other appendices is made as well. These appendices are only part of this standard, and are attached to it. To indicate them, only the word ‘annex’ is used.
Throughout this document the terminology “through the Certification Body” is used indicating that all activities performed by critical-, non-critical locations and outsourcing party are conducted under the responsibility/liability of the GMP+ accepted Certification Body.

2 Assessment programme

2.1 General

A Certification Body accepted 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 audits are provided for:
a. Initial certification audit
b. Announced surveillance audit
c. Unannounced surveillance audit
d. Recertification audit.

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

In case a participant changes during the certification cycle their activities to another location the new location must be audited by the Certification Body. This is applicable for production, transport and storage & transhipment. The GMP+ audit times shall apply. It is up to the Certification Body to decide if the initial- or surveillance audit must be performed.

2.2 Initial Certification audit

An initial certification audit in order to assess whether the company meets the criteria for the relevant GMP+ standard will be carried out through the Certification Body.

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

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

a. Assessment of the quality documentation
   There will be an investigation 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 (paragraph 2.6).

It is possible, based on a positive assessment of the quality documentation, to issue a temporary acceptance by the Certification Body (maximum 4 months) for an initial certification audit at a company that is starting its GMP+ activities in the feed sector.

The purpose of this assessment of the quality documentation is:
a. Verification 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 certification audit.

It means that the audit has to be executed through the Certification Body preferably within three months in order to ensure that nonconformities detected can be closed within the four months mentioned above.

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 four months the additional initial on-site audit must 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 (paragraph 2.6). The entire certification process must be finished within these four months including the updating of GMP+ International's company database (including status and certificate dates) by the Certification Body.

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

Companies that are already GMP+ certified are not eligible for a temporary acceptance. This also applies to companies that were previously GMP+ certified or which had a temporary acceptance.

<u>Expansion of scopes:</u>
If a participant wishes to expand the range of his already granted certification with an additional scope(s) and the expansion cannot wait until the next unannounced/announced surveillance- and/or recertification audit, the application and determination of the possibility whether or not to approve the expansion must be assessed through the Certification Body. The scope of a participant cannot be expanded during the temporary voluntary add on unannounced surveillance audit (see article 2.4.A).

The following applies through the Certification Body:

- Preform an expansion audit (stage 1 and stage 2) which shall only be focused on activities for which and expansion is applicable.

As a result of positive assessment of the expansion the Certification Body has to add the additional scope(s) to the GMP+ certificate and GMP+ company database. The validity of the original GMP+ certificate may not be extended. The Certification Body can also grant the participant a new GMP+ certificate for the additional scope.

2.3 Announced surveillance audit

Through the Certification Body, an announced surveillance audit will be carried out during the period of validity of the GMP+ certificate, to assess whether the participant continues to meet the requirements for certification. This announced surveillance audit is announced. The frequency of the announced surveillance audit is specified for each GMP+ standard as in annex 2.

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

An announced surveillance audit aimed at all areas of the certification requirements consists of:

a. Assessment of the quality documentation
   There will be an assessment of those sections which based on 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 participant, it will be investigated whether the requirements of the GMP+ standards are being implemented correctly. In case of the scope *Road Transport,* this audit can also take place at a branch that is not the official registered address of the participant instead. See the requirements in annex 7. In addition, if applicable, process conformity will be verified (paragraph 2.6).

In principle, all requirements and obligations of the GMP+ FC scheme must be assessed, in order to do so the Certification Body is allowed reduce the sampling size.

2.4 Unannounced surveillance audit

~~Option A: Temporary reinstallation of the **voluntary** add on unannounced surveillance audit, valid until 15th November 2019.~~

~~The purpose of the unannounced surveillance audit is to gather extra objective evidence allowing the participant to demonstrate that its feed safety system works consistently and correctly in accordance with the GMP+ requirements. The unannounced surveillance audit only applies to the participants certified for the scopes:~~

- ~~Production of compound feed,~~
- ~~Production of premixtures,~~
- ~~Production of additives,~~
- ~~Production of feed materials,~~
- ~~Production of pet food.~~

~~Topics to be audited must be based on a risk assessment of the Certification Body, but must in any case cover the production facility.~~

~~The unannounced surveillance audit is an extra audit carried out during the certification cycle which can be requested by the participant and must be secured in the contract. It is recommended to refrain from scheduling the unannounced surveillance audit within 2 months prior to or following the execution of other audits (initial, extension and announced surveillance audits). The unannounced surveillance audit cannot be used to certify additional scopes. The unannounced surveillance audit cannot replace other audits. Per certification cycle, the participant may request one unannounced surveillance audit.~~

~~As soon as the participant chooses to have unannounced surveillance audits, it becomes compulsory during the certification cycle. A participant may - in principle - not refuse the conduction of an unannounced surveillance audit. The participant can only refuse the unannounced surveillance audit by means of a legitimate motivation. It's up to the Certification Body to decide whether the legitimate motivation to refuse the unannounced surveillance audit, is justified.~~

~~Examples of legitimate refusal of the unannounced surveillance audit are:~~

- ~~The Certification Body cannot visit the site of the participant because its flooded or there are other extreme weather conditions.~~
- ~~The location of the participant is closed (yearly closing) or the location of the participant is not conducting GMP+ activities (seasonal work).~~

~~Should the Certification Body be unable to carry out the unannounced surveillance audit, the Certification Body must document and motivate the reason of not performing the unannounced surveillance audit.~~

~~The minimum required audit times for the unannounced surveillance audits are determined in annex 2.~~

Option A: **Mandatory** unannounced surveillance audit

The purpose of the unannounced surveillance audit is to gather objective evidence allowing the participant to demonstrate that, at any given moment, its feed safety system works consistently and correctly in accordance with the GMP+ requirements. The unannounced surveillance audit is for participants located in the Netherlands, Germany and in other countries of Europe certified for one of the following scopes:

- Production of compound feed,
- Production of premixtures,
- Production of feed additives,
- Production of feed materials,
- Production of pet food.

The unannounced surveillance audit will replace one of the announced surveillance audits during the certification cycle and must be secured in the contract between the participant and the Certification Body. Once the unannounced surveillance audit is secured in the contract between the participant and the Certification Body registration in the GMP+ database is mandatory.
The following dates apply for securing the unannounced surveillance audit in the contract between the participant and the Certification Body:

- Participants (producers) located in the Netherlands, the unannounced surveillance audit became mandatory as from 22nd February 2018.
- Participants (producers) located in Germany at the latest 31st December 2019.
- Participant (producers) located in other countries of Europe* at the latest 31st December 2020.

Other countries in Europe:

Albania, Andorra, Austria, Belarus, Belgium, Bosnia Herzegovina, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Iceland, Italy, Kosovo, Croatia, Latvia, Liechtenstein, Lithuania, Luxembourg, Nord – Macedonia, Malta, Moldavia, Monaco, Montenegro, Norway Ukraine, Poland, Portugal, Romania, San Marino, Serbia, Slovenia, Slovakia, Spain, Czech Republic, Vatican City, United Kingdom, Sweden and Switzerland.

Guidance for transition period:

Participants that already apply the voluntary unannounced audit will be changing to the mandatory unannounced audit in the new certification cycle.

It is recommended to refrain from scheduling the unannounced surveillance audit within 2 months prior to or following the execution of other audits (initial, recertification and announced surveillance audits).
Every twelve months, each participant can specify 15 days in that year during which the unannounced surveillance audit cannot be performed. If not indicated in advance the unannounced surveillance audit cannot be refused. It is up to the Certification Body to decide whether the legitimate motivation to postpone the unannounced surveillance audit, is justified.

Examples of legitimate postponing of the unannounced surveillance audit are:

- The Certification Body cannot visit the site of the participant because its flooded or there are other extreme weather conditions.
- The location of the participant is closed (yearly closing, maintenance, holiday) or the location of the participant is not conducting GMP+ activities (seasonal work).

The following prior notice periods to perform the unannounced surveillance audit are applicable:

- Participants (producers) located in the Netherlands: **not allowed**.
- Participants (producers) located in Germany: one working day.
- Participants (producers) located in other countries in Europe: two working days.

The minimum obliged audit times for the unannounced surveillance audits and the frequency are determined in annex 2.

In principle, all requirements and obligation of the GMP+ FC scheme must be assessed, in order to do so the Certification Body is allowed reduce the sampling size.

Option B: European* participants (including participants located in the Netherlands and Germany) certified for a service scope and all participants outside Europe certified for any GMP+ scope.

The purpose of the **voluntary** unannounced surveillance audit is to gather objective evidence allowing the participant to demonstrate that, at any moment, its feed safety system works consistently and correctly in accordance with the GMP+ requirements. The unannounced surveillance audit is for European participants certified for one of the following scopes:

- Trade,
- Storage & Transshipment,
- Transport of feed, road- and rail transport,
- Affreightment,
- Short sea shipping and inland waterway transport.

And all participants outside Europe certified for at least one GMP+ scope, any scopes.

Guidance:

European participants (including participants located in the Netherlands and Germany) who are certified for one of the production scopes and therefore obligatory participate in the unannounced surveillance audit for the production scope, can decide whether they want to apply the unannounced surveillance audit also for one of the service scopes mentioned under C.

The unannounced audit will be carried out on a voluntary basis. Those who apply for the unannounced audit, will be obliged to participate during the certification cycle. This must be secured in the contract between the participant and the Certification Body.
In this case, the unannounced surveillance audit shall replace one of the announced surveillance audits during the certification cycle. Once the unannounced surveillance audit is secured in the contract between the participant and the Certification Body registration in the GMP+ database is mandatory. It is recommended to refrain from scheduling the unannounced surveillance audit within 2 months prior to or following the execution of other audits (initial, recertification and announced surveillance audits).

Guidance for transition period:

Participants that already apply voluntary add on unannounced audit will be changing to the replacement unannounced surveillance audit in the new certification cycle.

Every twelve months, each participant can specify 15 days in that year during which the unannounced surveillance audit cannot be performed. If not indicated in advance the unannounced surveillance audit cannot be refused. It is up to the Certification Body to decide if the legitimate motivation to postpone the unannounced surveillance audit, is justified.

Examples of legitimate postponing of the unannounced surveillance audit are:

- The Certification Body cannot visit the site of the participant because its flooded or there are other extreme weather conditions.
- The location of the participant is closed (yearly closing, maintenance, holiday) or the location of the participant is not conducting GMP+ activities (seasonal work).

The following prior notice periods to perform the unannounced surveillance audit are applicable:

- Participants located in the Netherlands: **not allowed**.
- Participants located in Germany: one working day.
- Participants located in other countries in Europe: two working days.

The minimum obliged audit times for the unannounced surveillance audits and the frequency are determined in annex 2.

In principle, all requirements and obligation of the GMP+ FC scheme must be assessed, in order to do so the Certification Body is allowed reduce the sampling size.

2.5 Recertification audit

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

Prior to the extension of validity of a certificate, a recertification audit must be carried out to assess whether the participant 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 including the updating of GMP+ International's participant database (including status and data certificate) through the Certification Body. The recertification audit is a comprehensive assessment of the quality system.
If a recertification audit is not carried out before the expiry of the period of validity of the certificate, then an initial certification audit must be carried out. The participant is in the intervening period not GMP+ certified.

A recertification 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 recorded as such in a quality manual or in a book of work or procedural instructions.

b. On-site audit
   At the participant locations it will be assessed whether the requirements of the GMP+ standards are being correctly implemented. In addition, if applicable, process conformity will be verified (paragraph 2.6).

2.6 Verification of process conformity

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

Verification of the participant analysis results
The Certification Body will check whether the analysis results from the participant comply with the limits as established in GMP+ FC scheme. The size of the random sample amounts per product to at least √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 following applies: 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.

Through the Certification Body it may be designated, based on the assessment of reliability and completeness of the analyses results, one or more of the samples retained by the participant for a verification analysis to be carried out by the participant using the parameters specified through the Certification Body.

The results of any additional analysis will be used for the certification process of the participant and entered by the participant into GMP+ Monitoring database. Through the Certification Body the analysis results must be entered in the GMP+ Monitoring database and share this anonymously with the GMP+ community.

Verification through the taking of samples
If the Certification Body has any doubts following the verification of the participant analyses results then this form of verification can be chosen. The Certification Body will take one sample from every product group at the participant location.

Sampling will take place in accordance with the applicable protocol as stated in annex 8. The Certification Body will have the samples analysed in accordance with the product norms defined in GMP+ BA1 *Specific feed safety limits* which are applicable to those products based on the participant'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 participant and will also be made available through the Certification Body to the GMP+ Monitoring Database.

Analysis method
These analyses must 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 participant.

2.7 Special audits

If the results of the audit indicate so, a special audit must be carried out. These special audits are mentioned here below. The circumstances in which this would be appropriate are indicated in Annex 1.

Conformity audit
If one or more Major Nonconformities are observed, a conformity audit may be carried out. 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 Major Nonconformity can also be handled administratively based on conformity measures formulated by the participant.

Stricter supervision
If one or more Critical nonconformities are observed through the Certification Body, the participant must at least be placed under stricter supervision. The Certification Body may also decide to suspend/withdraw the certificate or temporary acceptance. The stricter supervision will take place for the period determined in Annex 1, with a minimum of 3 months and a maximum of 6 months. One stricter supervision audit must be conducted on site. After the first stricter supervision audit it is up to the Certification Body to decide if further stricter supervision audits are necessary. This decision must be motivated and documented.

Repeat audit/inspection
In special circumstances, there may be a repeat audit/inspection. The reason for a repeat audit/inspection may be an EWS alert, complaints or incidents, or something else. In principle the repeat audit/inspection is aimed on these reason(s) but can also be aimed at all requirements of the GMP+ FC scheme.

a. GMP+ International may ask the Certification Body to carry out a repeat audit/inspection in the short term in the presence of a GMP+ International ~~lead~~ auditor and/or a technical expert from GMP+ International. The deadline for conducting the repeat audit/inspection audit will be assessed per case but ultimately determined by GMP+ International. This repeat audit/inspection will consist of at least an onsite audit/inspection. 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 participant by the Certification Body in consultation with GMP+ International.
   The GMP+ International auditor, during the repeat audit/inspection can carry out a witness audit and will report to GMP+ International and the involved Certification Body the results of the assessment (in accordance with article 2.2 of the GMP+ C11).

The repeat audit/inspection must be carried out by a GMP+ auditor/inspector. The involved Certification Body shall motivate the choice of the GMP+ auditor/inspector and document its decision.

The costs of the repeat audit will, in principle, be borne by GMP+ International. However, if it appears that one or more Critical or Major nonconformities are observed, the costs will be charged to the participant.

2.8 Duration of audits/inspection and rotation of auditors/inspectors

The minimum frequency and *duration* for the completion of the various audits/inspections (including the assessment of documentation) and reporting is stated in annex 2 of this document. The duration of the audit/inspection depends on the size of the participant and the number of activities requiring certification
Once the certification cycle of three years is finalized, a new auditor has to be deployed through the Certification Body for the start of the new certification cycle.
For GMP+ B4.3 *Inland Waterways Transport* a new inspector has to be deployed after three consecutive inspections.

Should an alternative auditor not be available, an exemption can be made and the period can be extended for a maximum of one extra certification cycle and for GMP+ B4.3 *Inland Waterways Transport* it can be extended for another three consecutive inspections. The decision shall be motivated and documented.

Guidance :

First GMP+ certification cycle:

Initial certification audit + surveillance audit 1 + surveillance audit 2, auditor A.

Second GMP+ certification cycle:

Re-certification audit + surveillance audit 1 + surveillance audit 2, auditor B (if motivated and documented the Certification Body may decide to use auditor A).

Interrupted GMP+ certification cycle:*

1) Initial certification audit + surveillance audit 1 auditor A, surveillance audit 2 auditor B, it is allowed for auditor A (or auditor B) to audit the second GMP+ certification cycle.

2) Initial certification audit auditor A, surveillance audit 1 auditor B, surveillance audit 2 auditor A, it is allowed for auditor A (or auditor B) to audit the second GMP+ certification cycle.

** It is not allowed to use auditor A or B to audit the third certification cycle.*

2.9 Assessment and reporting

Through the Certification Body, an assessment will take place at the participant for conformity with the general criteria as specified in Annex 1 of this document and the additional assessment criteria in the checklists. If, through the Certification Body it is established in some way that the participant does not comply fully or partly with the stipulations of the GMP+ FC scheme the measures and sanctions as specified in Annex 1 are applicable.
In the event of a temporary acceptance it is mandatory to work with the GMP+ checklists during the audit or assessment of the quality documentation. These checklists indicate the minimum frequency for assessment of each element of the GMP+ standard.
For an inspection for GMP+ B4.3 *Short Sea Shipping and Inland Waterways Transport* a loading compartment must be empty for assessment.
In a repeat audit as specified above, deviations from this are permitted, in consultation with GMP+ International.

All deviations which are observed during the audits or review of the quality documentation in the event of a temporary acceptance, must be documented in writing on a nonconformity form (NCR). The auditor will leave a copy of this form at the participant.

The participant representative will provide the corrective actions report (CAR) and the result of the internal verification through the Certification Body within the agreed and recorded period of time.

In the event of temporary acceptance, reporting with respect to the GMP+ audit or assessment of the quality documentation, will take place through the Certification Body, in accordance with the sample report in Annex 3 of this document. The reporting must be fully detailed and the checklist must be uploaded to the GMP+ database.

A checklist has to be completed for the standard GMP+ B4.3 *Short Sea Shipping and Inland Waterways Transport*. Assessment must be done in accordance with the checklist.
If a "Not Conform" with a description is observed, a GMP+ certificate cannot be issued. The GMP+ certificate can only be issued if the "Not Conform" with a description is resolved.
For GMP+ B3.2 *Trade to Livestock Farms* only a checklist has to be completed.

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

For the standards GMP+ B3.2 *Trade to Livestock Farms and* GMP+ B4.3 *Short Sea Shipping and Inland Waterways Transport* the review of the checklists by the technical reviewer is mandatory.

Data is to be stored in conformity with the accreditation requirements (where applicable). The Certification Body is responsible for the decision with respect to GMP+ certification.

Within 6 weeks after finishing the audit, the final report must be sent to the participant (for the standards GMP+ B3.2 *Trade to Livestock Farms and* GMP+ B4.3 *Inland Waterways Transport* the final audit checklist) together with any data from the certificate or the temporary acceptance. In the event of a repeat audit/inspection, GMP+ International must have received the audit report within 5 working days.

The Certification Body/critical location keeps the participants details up to date using the GMP+ database. Every business location that is given certification or temporary acceptance must have its own GMP+ International registration number.
The information from the audit checklists must be uploaded to GMP+ International's company database within a maximum of 2 weeks of the end of the audit.

If GMP+ International requests the audit reports then the Certification Body will make these available immediately.

2.10 Certification and temporary acceptance

Temporary acceptance will be granted for a period of a maximum of four months. Certificates will be issued for a maximum period of three years (GMP+ B4.3 *Short Sea Shipping and Inland Waterways Transport*: two years). A GMP+ certificate or temporary acceptance will only be issued by the Certification Body which GMP+ International has entered into a Feed Certification scheme License Agreement. A certificate will only be issued if there is full conformity with the requirements for certification taking into account the Annex 1. The classification of the nonconformities must take place in both cases in accordance with the specified criteria and interpretations.

Through the Certification Body, the data specified in Article 4 of GMP+ A1 *General Regulations* is provided. GMP+ International administers the publicly accessible GMP+ database.

The Certification Body must put the following text on the certificate or temporary acceptance:

A Text for a every certificate Feed Safety Assurance or temporary acceptance

Name of the Certification Body:
GMP+ International registration number of the Certification Body:

Process Certificate / Temporary Acceptance

Name, address, location of the business location
(Name of vessel + EU number of vessel)
Visit address
GMP+ International registration number of the business location

FIXED SECTION
"=*name CB*= declares that there is justifiable confidence that the processes (1st and 2nd column of the table in *annex 6*) at the participant =*name of participant* = comply with the applicable requirements and conditions of the standard(s) GMP+ Bx = name of standard = (annex 5), of the GMP+ FC scheme (based on GMP+ C6) of GMP+ International.

FREE SECTION
See annex 6

Registered office of the Certification Body Accreditation Mark (if applicable)

Certificate number / temporary acceptance number

Begin date and end date of certificate / temporary acceptance

Notes:

a. It is not permitted to use the GMP+ logo or accreditation mark on a temporary acceptance. In addition, the document may not be called a "certificate" but must be designated as a "temporary acceptance".
b. It is not permitted to specify brand names in any way whatsoever on the certificate or temporary acceptance.

c. It is mandatory to show the GMP+ logo and the Accreditation Mark (if applicable)-on the certificate.
d. The begin date of the certificate/temporary acceptance is a date which is in any event equal or after the date of the positive certification decision.
e. The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
f. It is not permitted to use the logos of critical location, non-critical location and outsourced party on the GMP+ certificate and temporary acceptance other than the GMP+ accepted Certification Body.

B Text for a certificate Feed Responsibility Management System

Name of the Certification Body:
GMP+ International registration number of the Certification Body:

FRA logo:

Name, address, location of the business location
Visit address
GMP+ International registration number of the business location

"=*name CB*= states that there is justifiable confidence that =*name participant*= meets the applicable requirements and conditions for (1st and 2nd column of the table in annex 6).

Therefore =*name participant*= is certified for the standard(s) GMP+ Mx =*name of standard* = (annex 5), of the GMP+ FC scheme (based on GMP+ C6) of GMP+ International.

Registered office of the Certification Body

Certificate number

Begin and end date of certificate

Notes:
a) It is not permitted to specify brand names in any way whatsoever on the certificate.
b) It is mandatory to show the FRA logo on the certificate.
c) The begin date of the certificate is a date which is in any event equal or after the date of the positive certification decision.
d) The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
e) It is not permitted to use the logos of critical location, non-critical location and outsourced party on the GMP+ certificate and temporary acceptance other than the GMP+ accepted Certification Body.

2.11 Suspension or withdrawal of a certificate or temporary acceptance

If it is established that a GMP+ certified or temporary accepted participant no longer complies with the requirements, measures and sanctions must be imposed immediately, through the Certification Body, in accordance with Annex 1.

The auditor must report a Critical nonconformities as specified in Annex 1 immediately to the responsible coordinator and/or authorized person. The responsible coordinator and/or authorized person will immediately inform GMP+ International by using the form Audit Finding Notification Critical Nonconformity.

If a Certification Body decides to suspend and/or withdraw the certificate/temporary acceptance of the participant because of nonconformity of GMP+ requirements, GMP+ International has to be informed immediately. In these cases the Certification Body must submit the form Audit Finding Notification Critical Nonconformity within the same timeframe as mentioned above.

~~2.12~~ Unique Certification Agreement/ Certification Agreement Template

Unique Certification Agreements/Certification Agreement Template must be issued by the GMP+ accepted Certification Body. The critical location, non-critical location and outsourced party must use the Certification Agreement Template issued by the GMP+ accepted Certification Body.

In the agreements (or quotations which are part of the agreements) through the Certification Body and companies the GMP+ minimum obliged audit/inspection time must be specified. This audit/inspection time must at least comply with the minimum audit/inspection time expenditure as laid down in GMP+ C6 *Assessment and Certification Criteria for GMP+ Certification - Process Certification*, Annex 2. Reference to GMP+ C6 *Assessment and Certification Criteria for GMP+ Certification - Process Certification* is insufficient. It is not permitted to deviate from the minimum obliged audit/inspection times by way of invoicing based on re-calculation. If based on the auditor's/inspector's findings, a longer audit time should be used then this can be done in consultation with the participant.

The Certification Body will establish in the agreements that the GMP+ certified participant may use the GMP+ logo and that it undertakes strict compliance with conditions set for this by GMP+ International. Companies that have a temporary acceptance are not permitted to make any use whatsoever of the GMP+ logo.

In the agreements the obligation for the companies to provide cooperation in the carrying out of witness audits, parallel audit (as stated in GMP+ C11 *Method of and Criteria for the Compliance Assessment of Certification Bodies*) and special audits (conformity audits, stricter supervision and repeat audits/inspections) must be established.

If applicable, the agreements (or quotations which are part of the agreements) must stipulate the unannounced surveillance audit, including the minimum obliged audit times. It is not permitted to deviate from these minimum obliged audit times by way of invoicing based on re-calculation.

The Unique Certification Agreements and Certification Agreement Template must provide the participants with the possibility to terminate these agreements before the end of the certification cycle.

If applicable, the agreements will stipulate, that, in case of a determined nonconformity of a permitted level of a contaminant, the participant is obliged to notify an EWS report within 12 hours after confirmation of the contamination, to its Certification Body competent authority, and GMP+ International.

An Initial Certification Audit/Inspection must be conducted within 3 months after concluding an Agreement with Participant(s).

2.13 Exclusion of *GMP+ International* liability

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

2.14 Tariffs

The Certification Body will use its own rates. On behalf of GMP+ International, through the Certification Body, relevant rates as listed in GMP+ C4 *Tariffs* are charged.

2.15 Disputes between certification bodies and participants

Disputes between certification bodies and participants 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 can be handled in accordance with the GMP+ A4 *Disputes Procedure.*

Annex 1: Assessment criteria and measures and sanctions for audits GMP+ FSA module

Nonconformities are to be classified based on the general assessment criteria stated below. In addition the specific assessment criteria shown in the checklists remain in force. With reference to the chapter 8 of the GMP+ A1 document, the measures and sanctions specified shall be imposed as a minimum. Imposing stricter measures and sanctions, through a Certification Body, is permitted, but deviation by means of less stricter measures and sanctions is not.

Classification: Minor Nonconformity	
Definition:	• Any nonconformity which does not adversely affect the health or safety of a product.
Minor nonconformity	**Measures and sanctions**
• This relates to a nonconformity where there is no direct risk for feed safety for the subsequent links in the chain. • An element previously described is not updated, while this is required as a consequence of amended requirements and regulations. • Quality records have been overlooked or are out of date (< 2 months), clearly of an incidental nature (not related to EWS or traceability). • A requirement of the normative document is incompletely described in the documentation.	• The participant is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The participant is obliged to send the planned correction and corrective actions to the Certification Body for reviewing and acceptance for the certification decision (initial certification- and recertification audits) and within 6 months after the unannounced-,announced surveillance audit. • The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (at the latest during the next on site audit). Nonconformities can be handled administratively by the Certification Body unless an extra assessment is necessary. • If the nonconformity is not or not fully resolved then it will be converted to a major nonconformity.
Conclusion	
• 10 or more minor nonconformities during an initial-, re-certification audit or during the assessment of the quality documentation.	• The Certification Body is not allowed to issue GMP+ certification or temporary acceptance.
• 10 or more minor nonconformities during the announced surveillance-, additional-, unannounced surveillance audit	• The participant is obliged to take the necessary corrective actions to take care of the nonconformities (10 or more) within the period of time set by the Certification Body (maximum 6 weeks).

Classification: Major Nonconformity	
Definition:	• Any nonconformity other than critical, which may result in failure for health or safety and which cannot be completely eliminated by re-work or reduced to a minor nonconformity. • When a requirement of the GMP+ normative document has been addressed but there is insufficient evidence to demonstrate that it has been properly controlled or implemented.
Major Nonconformity	**Measures and sanctions**
• A minor nonconformity was also observed during the previous audit and inadequate or no corrective actions has taken place. • The Certification Body is unable to close a minor nonconformity within the deadline as agreed with the participant. • A requirement of the normative document is absent in the documentation. • Quality records are structural very out of date (> 2 months), (not related to EWS or traceability). • A requirement of the normative document is not being implemented and this can have an effect on the feed safety of the product.	• The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (maximum 6 weeks). • The participant is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The participant can be subjected to one conformity audit within a period of 3 months. This may be handled administratively except in those cases where an assessment on-site is necessary. It is mandatory to close the nonconformity or to do a follow up.
• A serious nonconformity related to GMP+ requirements excluding what is listed under Critical Nonconformity.[1]	• Immediate recall of all the products in question unless the participant can demonstrate, to the satisfaction of the Certification Body that the nonconformity has no harmful health effects for animals and/or humans and the existing legal standards for animal products are not breached. • The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (maximum 6 weeks). • The participant is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The participant can be subjected to one conformity audit within a period of 3 months. This may be handled administratively except in those cases where an assessment on-site is necessary. It is mandatory to close the nonconformity or to do a follow up.
• During the conformity audit a previously observed major nonconformity is not resolved in time or not completely. • Any recall is not carried out properly or (due to own negligence) is not carried out in time.	• This nonconformity will be converted into a critical nonconformity.
Conclusion	
• A Major nonconformity during an initial-, re-certification audit or during the assessment of the quality documentation.	• The Certification Body is not allowed to issue GMP+ certification or temporary acceptance.
• A Major nonconformity during the announced surveillance-, special-, unannounced surveillance audit.	• The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (maximum 6 weeks).

[1] *This includes in any event about a) inadequate entry checks of delivered feed ingredients, b) non-*conformity *with the feed legislation.*

Classification: Critical Nonconformity	
Definition:	• Any nonconformity which may result in hazardous or unsafe for individuals and animals. • A regulatory violation or a complete feed safety failure to implement a requirement of the GMP+ normative document.
Critical Nonconformity	**Measures and sanctions**
• There has been a previous major nonconformity but insufficient or late corrective actions have been implemented. • The Certification Body is unable to close major nonconformity within the deadline as agreed with the participant.	• The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (maximum 2 weeks). • The participant is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The participant will be placed under stricter supervision for a period of at least 3 and maximum 6 months. • If the participant does not take corrective actions within the period of time established and feed safety is at risk then the Certification Body will suspend the certificate or temporary acceptance for a maximum of 3 months. • Lifting of suspension is only possible if the Certification Body has established during a conformity audit that proper corrective actions have been taken. The participant will be placed under stricter supervision for at least 3 to a maximum of 6 months. • If the participant does not take corrective actions within the period of time established then the Certification Body will withdraw the certificate or temporary acceptance. The participant will be excluded for a period of at least 1 year from participation in the GMP+ FC scheme. The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.
• A serious nonconformity, incidental, with a direct or possible hazard to the safety of humans, animals or the environment and direct consequences for the subsequent links in the chain. • The participant did not send an EWS to the Certification Body and competent authority (if applicable) and GMP+ International within the time frame as determine in the GMP+ BA5.	• The participant is obliged to undertake an immediate recall of all the products in question unless the participant can show to the satisfaction of the Certification Body that the nonconformity has no harmful health effects for animals or humans and the existing standards are not breached. • The participant is obliged to take improvement measures immediately (within 24 hours). The participant will be placed under stricter supervision for a period of at least 3 and maximum 6 months. • If the participant does not take improvement measures immediately then the Certification Body will suspend the certificate or the temporary acceptance for a maximum of 3 months. • Lifting of suspension is only possible if the Certification Body has established during a conformity audit that proper improvement measures have been taken. The participant will be placed under stricter supervision for at least 3 to a maximum of 6 months. • If the participant does not take corrective actions within the period of time established then the Certification Body will withdraw the certificate or temporary acceptance. The participant will be excluded for a period of at least 1 year from participation in the GMP+ FC scheme.

	The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.
• The participant refuses and/or does not cooperate in (planning/conducting) audits for (stricter) supervision by the Certification Body. • For the period of time when a participant is under impending prosecution related to feed safety. • It is reasonable to assume that there is case of gross negligence, fraudulent actions or economic malpractice related to feed safety. • The participant does not respect the criteria as defined in the Agreement with the involved Certification Body. • The participant refuses and/or does not cooperate in (planning/conducting) compliance assessment of GMP+ International. • Customers involved in a EWS are not demonstrably informed within the time frames established in the specific GMP+ B standards.	• The Certification Body suspends the certificate or temporary acceptance for a maximum period of three months. • Lifting of suspension is only possible if the Certification Body has established during a conformity audit that proper corrections and corrective actions have been taken. The participant will be placed under stricter supervision for at least 3 to a maximum of 6 months. • The participant is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • If the participant does not take corrective actions within the period of time established then the Certification Body will withdraw the certificate or temporary acceptance. The participant will be excluded for a period of at least 1 year from participation in the GMP+ FC scheme. The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.
• The participant does not respect the financial criteria as defined in the Agreement with the involved Certification Body.	• The Certification Body suspends the certificate or temporary acceptance for a maximum period of three months. • Lifting up the suspension is the responsibility of the Certification Body. A conformity audit in not necessary. • If the Certification Body is unable to lift up the suspension within three months the Certification Body must withdraw the certificate or temporary acceptance. The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.

• A structural nonconformity related to critical GMP+ requirements. This relates in any event to: a) incorrect cleaning and disinfections, loading sequence, with a forbidden pre-load, for GMP+ transport, b) no risk assessment for a feed material, c) purchasing feed products and services not in accordance with the purchase requirements, d) intended, on purpose or regularly practice non-compliance with specific feed safety limits. • Within a time frame of two year after the same first offence the participant did not send an EWS to the Certification Body and competent authority (if applicable) and GMP+ International within the time frame as determine in GMP+ BA5. • Customers involved in an EWS are not demonstrably informed. • A requirement of the normative document is not being implemented and is critical for the feed safety of the product. • Quality records related to EWS, traceability and tracking and trace are not implemented. • Previously observed critical nonconformities are not properly fixed after a 3 months suspension of the GMP+ certificate or the temporary acceptance has not been properly released or other such nonconformities are established. • Delivery of products from non- GMP+ (or equivalent) certified source(s) , under the implicit or explicit suggestion that has been produced in compliance with the GMP+ requirements.	• The Certification Body will immediately withdraw the certificate or temporary acceptance. • The participant or natural persons involved are excluded for a period of at least 1 year from participation in the GMP+ FSA module. The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.
Conclusion	
• A Critical nonconformity during an initial-, re-certification audit or during the assessment of the quality documentation.	• The Certification Body is not allowed to issue GMP+ certification or temporary acceptance.
• A Critical nonconformity during the announced surveillance-, additional-, chain oriented-, unannounced surveillance audit	• The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (maximum 2 weeks). • The Certification Body suspends the certificate or temporary acceptance for a maximum period of three months. • The Certification Body will immediately withdraw the GMP+ certificate or temporary acceptance. • The participant or natural persons involved are excluded for a period of 1 year from participation in the GMP+ FSA module. The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.

Annex 1: Assessment criteria and measures and sanctions for audits GMP+ FRA module

Nonconformities are to be classified based on the general assessment criteria stated below. In addition the specific assessment criteria shown in the checklists remain in force. With reference to the chapter 8 of the GMP+ A1 document, the measures and sanctions specified shall be imposed as a minimum. Imposing stricter measures and sanctions, through a Certification Body, is permitted, but deviation by means of less stricter measures and sanctions is not.

Classification: Minor Nonconformity	
Nonconformity	**Measures**
• An element previously described is not updated, while this is required as a consequence of amended requirements and regulations. • Records have been overlooked or are out of date (< 12 months), clearly of an incidental nature (not related to traceability).	• The participant is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The participant is obliged to send the planned correction and corrective actions to the Certification Body for reviewing and acceptance for the certification decision (initial certification- and recertification audits) and within 6 months after the unannounced-, announced audit.. • The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (at the latest during the next on site audit). Nonconformities can be handled administratively by the Certification Body unless an extra assessment is necessary. • If the nonconformity is not or not fully resolved then it will be converted to a major nonconformity.
Conclusion	
10 or more minor nonconformities during an initial-, re-certification audit or during the assessment of the documentation.	The Certification Body is not allowed to issue GMP+ certification or temporary acceptance.
10 or more minor nonconformities during the surveillance- or additional(s) audit	The participant is obliged to take the necessary corrective actions to take care of the nonconformities (10 or more) within the period of time set by the Certification Body (maximum 6 weeks).

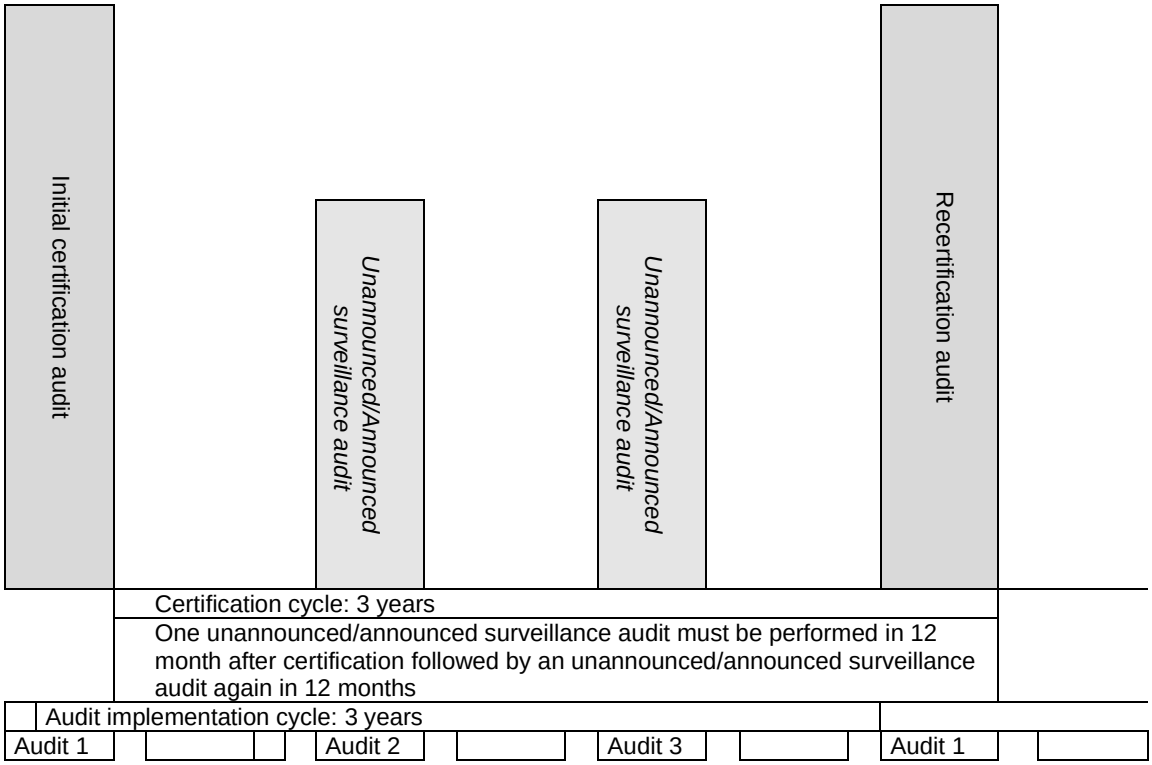
Classification: Major Nonconformity	
Nonconformity	**Measures**
• A minor nonconformity was also observed during the previous audit and inadequate or no corrective actions has taken place. • The Certification Body is unable to close minor nonconformity within the deadline as agreed with the participant. • A requirement of the normative document is absent in the documentation. • Records are structurally very out of date (> 12 months), (not related to traceability). • A requirement of the normative document is not being implemented and this can have an effect on the product.	• The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (maximum 6 weeks). • The participant is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The participant can be subjected to one conformity audit within a period of 3 months. This may be handled administratively except in those cases where an assessment on-site is necessary. It is mandatory to close the nonconformity or to do a follow up.
• The output and input of the material accounting system doesn't correspond with the sales and purchases found in for example contracts or invoices. • The material accounting system shows more output then input after closing the fixed inventory period of the participant. *Please note: if there is more input than output, the participant is in compliance with the requirements.* • In case of a continuous balancing system, sales are made without responsible feed available for allocation to outputs in the material accounting system.	• The participant is obliged to correct the material accounting system by purchasing the needed amount of responsible feed. • The participant is obliged to conduct a root cause analysis and to implement preventive actions. • The participant can be subjected toone conformity audit within a period of 3 months. This may be handled administratively except in those cases where an assessment on-site is necessary. It is mandatory to close the nonconformity or to do a follow up.
• During the conformity audit a previously observed major nonconformity is not put right in time or not completely.	• This nonconformity will be converted into a critical nonconformity.
Conclusion	
• A Major nonconformity during an initial-, recertification audit or during the assessment of the quality documentation.	• The Certification Body is not allowed to issue GMP+ certification or temporary acceptance.
• A Major nonconformity during the announced surveillance-, special-, unannounced surveillance audit	• The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (maximum 6 weeks).

Classification: Critical Nonconformity	
Nonconformity	**Measures**
• There has been a previous major nonconformity but insufficient or late corrective actions have been implemented. • The Certification Body is unable to close major nonconformity within the deadline as agreed with the participant. • The participant cannot demonstrate that there is a material accounting system. • In case of the use of the supply chain model segregation; no segregation of certified material is in place.	• The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (maximum 2 weeks). • The participant is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • The participant will be placed under stricter supervision for a period of at least 3 and maximum 6 months. • If the participant does not take corrective actions within the period of time established by the Certification Body, then the Certification Body will suspend the certificate or temporary acceptance for a maximum of 3 months. • Lifting of suspension is only possible if the Certification Body has established during a conformity audit that proper corrective actions have been taken. The participant will be placed under stricter supervision for at least 3 to a maximum of 6 months. • If the participant does not take corrective actions within the period of time established, the Certification Body will withdraw the certificate or temporary acceptance. The participant will be excluded for a period of at least 1 year from participation in the GMP+ FRA module. The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.
• The participant refuses and/or does not cooperate in (planning/conducting) audits for (stricter) supervision by the Certification Body. • For the period of time when a participant is under impending prosecution related to feed responsibility. • It is reasonable to assume that there is case of gross negligence, fraudulent actions or economic malpractice related to feed responsibility. • The participant does not respect the criteria as defined in the Agreement with the involved Certification Body. • The participant refuses and/or does not cooperate in (planning/conducting) compliance assessment of GMP+ International.	• The Certification Body suspends the certificate or temporary acceptance for a maximum period of three months. • Lifting of suspension is only possible if the Certification Body has established during a conformity audit that proper corrections and corrective actions have been taken. The participant will be placed under stricter supervision for at least 3 to a maximum of 6 months. • The participant is obliged to analyse the cause and describe the specific correction and corrective actions to be taken, to eliminate detected nonconformities. • If the participant does not take corrective actions within the period of time established then the Certification Body will withdraw the certificate or temporary acceptance. The participant will be excluded for a period of at least 1 year from participation in the GMP+ FRA module. The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.
• The participant does not respect the financial criteria as defined in the Agreement with the involved Certification Body.	• The Certification Body suspends the certificate or temporary acceptance for a maximum period of three months. • Lifting up the suspension is the responsibility of the Certification Body. A conformity audit in not necessary.

Classification: Critical Nonconformity	
Nonconformity	**Measures**
	• If the Certification Body is unable to lift up the suspension within three months the Certification Body must withdraw the certificate or temporary acceptance. The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.
• A requirement of the normative document is not being implemented and is critical for product. • Records related to traceability and tracking and trace are not implemented. • Previously observed critical nonconformities are not properly fixed after a 3 months suspension of the GMP+ certificate or the temporary acceptance has not been properly released or other such nonconformities are established.	• The Certification Body will immediately withdraw the certificate or temporary acceptance. • The participant or natural persons involved are excluded for a period of at least 1 year from participation in the GMP+ FRA module. The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.
Conclusion	
A Critical nonconformity during an initial-, re-certification audit or during the assessment of the quality documentation.	The Certification Body is not allowed to issue GMP+ certification or temporary acceptance.
A Critical nonconformity during the surveillance-or, additional audits.t	• The participant is obliged to take the necessary corrective actions to take care of the nonconformity within the period of time set by the Certification Body (maximum 2 weeks). • The Certification Body suspends the certificate or temporary acceptance for a maximum period of three months. • The Certification Body will immediately withdraw the GMP+ certificate or temporary acceptance. • The participant or natural persons involved are excluded for a period of 1 year from participation in the GMP+ FRA module. The participant can also not participate in the GMP+ FC scheme under all Gatekeeper Protocols.

Annex 2: Frequency and time expenditure from GMP+ audits

Frequency
Audits must 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 minimum allocation of time in hours for GMP+ audits/inspections at participants. Deviation from these binding guidelines is possible where this can be justified by the nature of the participant. If there is a deviation from the minimum audits/inspections times then the Certification Body must motivate and document its decision. GMP+ International will check the reasoning and assess this during the annual Certification Body audit. The Certification Body must make clear to GMP+ International what the audits/inspections duration has to be according to the binding guidelines and their temporary deviation from these guidelines.

The Certification Body cannot issue audit/inspection time reduction if:

- It exceed more than 30% of the minimum obliged audit time.
- During the validity of the GMP+ certificate and taken into account that no changes as mentioned on the previous page occurred, only one audit time reduction can be applied for and given to the participant.
- During the last three audits at the participant one Critical non-conformity was established.
- During the last three audits at the participant one Major non-conformity was established with a structural character or the Major non-conformity resulted in feed safety hazard.

- During the last three audits at the participant twenty Minor non-conformities were established.

Through the Certification Body audit time reduction can only be granted on the initial certification audit if the Certification Body can demonstrate that they certified the company for another scheme as mentioned in this annex or properly documented and justified, a reduction can be made for a less complex company measured by number of employees, size of the company and/or the product volume (including a limited number of products).

Audit times reductions are not allowed to be used for re-calculation of the minimum obliged audit times, except when during the initial certification audit as stated above.

This temporary deviation from the audit times is valid as long as:
a. no changes take place in the activities and organisation of the participant
b. no changes are made to annex 2, GMP+ C6 *Assessment and Certification Criteria for GMP+ Certification*, frequency and time expenditure for GMP+ audits.
c. The participant does not transfer to another Certification Body. If the participant transfers to a new Certification Body, the Certification Body has to assess if an audit time reduction can be issued.

Document review and reporting is included in the period of time for the duration of the audit and must be filled in on the audit report/inspection checklist accordingly. The filled in audit/inspection time must comply with the audit/inspection times as mentioned in this Annex.

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 conformity audits, repeat audits and stricter supervision audits as specified in paragraph 2.7, the period of time will apply which is considered necessary through the Certification Body or GMP+ International. Duration for audits may increase if EWS, complaint, exemptions, incidents, etc, have to be investigated by the Certification Body.

A working day is 8 hours.

To determine the main activity of the participant the following ranking must be applied:
a. Production and Processing
b. Trade

Within these main categories the following classification must 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 module	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours [1]			
				Initial or recer-tification audit	Unan-nounced/An-nounced sur-veillance audit	Voluntary add on unan-nounced sur-veillance audit	Comment
GMP+ B1 Production, Trade and Services Scope: Production of compound feeds							
	Main office (incl. production)	≤ 50,000	1x / year	14.0 + 1.5X	13.5 + 1.5X	6 hours + 1.5X	
		> 50,000	1x / year	15.5 + 1.5X	15.5 + 1.5X	8 hours + 1.5X	
	Production location	≤ 50,000	1x / year	10.0 + 1.5X	8.5 + 1.5X	4 hours + 1.5X	
		> 50,000	1x / year	11.5 + 1.5X	11.0 + 1.5X	6 hours + 1.5X	
GMP+ B1 Production, Trade and Services Scope: Production of compound feeds **without the use of critical feed additives and critical veterinary medical products.**							
	Main office (incl. production)	≤ 50,000	1x / year	12.0 + 1.5X	11.5 + 1.5X	4 hours + 1.5X	
		> 50,000	1x / year	13.5 + 1.5X	13.5 + 1.5X	6 hours + 1.5X	
	Production location	≤ 50,000	1x / year	8.0 + 1.5X	6.5 + 1.5X	4 hours + 1.5X	
		> 50,000	1x / year	9.5 + 1.5X	9.0 + 1.5X	4 hours + 1.5X	
GMP+ B1 Production, Trade and Services Scope: Production of premixtures							
	Main office (incl. production)	≤20,000	1x / year	14.0 + 1.5X	13.5 + 1.5X	4 hours + 1.5X	
		> 20,000	1x / year	15.5 + 1.5X	15.5 + 1.5X	6 hours + 1.5X	
	Production location	≤20,000	1x / year	10.0 + 1.5X	8.5 + 1.5X	4 hours + 1.5X	
		> 20,000	1x / year	11.5 + 1.5X	11.5 + 1.5X	4 hours + 1.5X	
GMP+ B1 Production, Trade and Services **GMP+ B2 Production of feed ingredients** Scope : production of feed additives		Number of products					

	GMP+ FSA module	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours [1]			
				Initial or recer-tification audit	Unan-nounced/An-nounced sur-veillance audit	Voluntary add on unan-nounced sur-veillance audit	Comment
	Main office (incl. production)	≤ 5	1x / year	14.0 + 1.5X	13.5 + 1.5X	4 hours + 1.5X	
		> 5	1x / year	15.5 + 1.5X	15.5 + 1.5X	6 hours + 1.5X	
	Production location	≤ 5	1x / year	10.0 + 1.5X	8.5 + 1.5X	4 hours + 1.5X	
		> 5	1x / year	11.5 + 1.5X	11.0 + 1.5X	4 hours + 1.5X	
GMP+ B1-Production, Trade and Services GMP+ B2 Production of feed ingredients Scope: production of feed materials		Number of products					
	Main office (incl. production)	≤ 5	1x / year	9.0 + 1.5X	8.0 + 1.5X	4 hours + 1.5X	
		> 5	1x / year	10.0 + 1.5X	9.0 + 1.5X	6 hours + 1.5X	
	Production location	≤ 5	1x / year	7.0 + 1.5X	6.0 + 1.5X	4 hours + 1.5X	
		> 5	1x / year	8.0 + 1.5X	7.0 + 1.5X	4 hours + 1.5X	
GMP+ B1 Production, Trade and Services 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		
GMP+ B1 Production, Trade and Services; scope: Trade (forage trade) or GMP+ B3 Trade, Collection and Storage & Transshipment (forage trade) scope: Trade in feed		Number of products					2
		≤ 5	1 x / year	6.5 + 1.5X	2.5 + 1.5X		
		6-15	1 x / year	8.0 + 1.5X	4.0 + 1.5X		
		>15	1 x / year	9.5 + 1.5X	6.5 + 1.5X		

	GMP+ FSA module	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours [1]			
				Initial or recertification audit	Unannounced/Announced surveillance audit	Voluntary add on unannounced surveillance audit	Comment
GMP+ B3 Trade, Collection and Storage & Transshipment		Number of products					
	This is the audit time for one scope of GMP+ B3. For each additional scope of GMP+ B3 the audit time is extended by 1.5 hours.	≤ 5	1x / year	6.5 + 1.5X	6.5 + 1.5X		3
		6-15	1x / year	8.0 + 1.5X	8.0 + 1.5X		
		>15	1x / year	9.5 + 1.5X	9.5 + 1.5X		
GMP+ B3.2 Trade to Livestock Farm							
	Administrative trade		1x / year	2.5	2.0		
	(Administrative) trade + storage of packaged products and/or transport of packaged products.		1x / year	3.0	2.5		
	Extra storage for packaged products		1x / year	See annex 4: Multi-site certification for GMP+ B3.2 (option 2)			4, 5, 6
	Extra retail outlet		1x / year	See annex 4: Multi-site certification for .2 (option 2)			
GMP+ B4 Transport, scope rail transport				5,5	5,5		
GMP+ B4 Transport Scope: road transport or animal feed (including the organisation of affreightment of road transport)		Number of Employees [16]					
		≤ 2	1x / year	4.0 + 1.5X	2.5 + 1.5X		
		3-5	1x / year	6.5 + 1.5X	4.0 + 1.5X		
		6-15	1x / year	8.0 + 1.5X	7.0 + 1.5X		
		>15	1x / year	9.5 + 1.5X	9.0 + 1.5X		
GMP+ B4 Tractionair(s)							7
	With own manual		1x / year	4.0	2.0		

	GMP+ FSA module	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours [1]			
				Initial or recertification audit	Unannounced/Announced surveillance audit	Voluntary add on unannounced surveillance audit	Comment
	Included in customers manual		1x / year	2.5	2.0		
GMP+ B4, scope affreightment.			1x / year	5.5	5.5		
GMP+ B4.3 Short Sea Shipping and Inland Waterways			1x / 2 year	2			
GMP+ B1 Production, Trade and Services **GMP+ B3 Trade, Collection and Storage & Transshipment** Scope: storage & transshipment		Number of products					
		≤ 5	1x / year	6.5 + 1.5X	6.5 + 1.5X		
		6-15	1x / year	8.0 + 1.5X	8+ 1.5X		
		>15	1x / year	9.5 + 1.5X	9.5 + 1.5X		
GMP+ B8 Production of and Trade in Pet food Scope: production pet food							8, 9
	Main office (incl. production)	≤ 10,000	1x / year	14.0 + 1.5X	12.0 + 1.5X	6 hours + 1.5X	
		> 10,000	1x / year	15.5 + 1.5X	14.0 + 1.5X	8 hours + 1.5X	
	Production location	≤ 10,000	1x / year	10.0 + 1.5X	7.5 + 1.5X	4 hours + 1.5X	
		> 10,000	1x / year	11.5 + 1.5X	9.5 + 1.5X	6 hours + 1.5X	

	GMP+ FSA module	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours [1]				
				Initial or recertification audit	Unannounced/Announced surveillance audit	Voluntary add on unannounced surveillance audit	Comment	
GMP+ B8 Production of and Trade in Pet food 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			
GMP+ B10 Laboratory Testing		Number of analyses						
	ISO 17025 accredited	≤ 5	1x / year	2.0			10, 11, 12	
		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			
		>20	1x / year	12.0 + 12.0	9.5 + 9.5			
	Secondary location (analyses)	≤ 5	1x / year	5.0	5.5			
		6-20	1x / year	6.5	7.5			13
		>20	1x / year	8.0	9.5			
Audit time PO Boxes		N.A.	1x / year	1.0	1.0			

	GMP+ FSA module	Tonnage/ Number of products / Number of employees / Number of actions	Audit frequency	Minimum time expenditure in hours [1]			
				Initial or recertification audit	Unannounced/Announced surveillance audit	Voluntary add on unannounced surveillance audit	Comment
	Combined audit GMP+ FC-scheme with valid versions of: ISO 9001 and/or ISO 22000, scope feed and ISO22002-6 and/or HACCP and/or IFS Food and/or BRC Production and/or GMP-Feed Chain Alliance and/or FAMI-QS and/or FSSC 22000 and/or EFISC-GTP and/or Oqualim and/or Pastus+		1x / year	Time expenditure ISO 9001, ISO 22000 scope feed and ISO22002-6 and/or HACCP food audit and/or IFS Food and/or BRC Production and/or GMP- Feed Chain Alliance and/or FAMI-QS and/or FSSC 22000 and/or EFISC-GTP and/or Oqualim and/or Pastus+ plus half of the time expenditure for GMP+ FC scheme audit.		14, 15
	GMP+ B1.2 *Production, trade and services* All scopes integrated in GMP+ B1 *Production, trade and services.*			Time expenditure is half of the time expenditure for GMP+ B1 audits, relevant scope. Participant must be certified for ISO22000, scope feed and ISO22002-6.			

[1] The basis is the main activity of the participant. "X" is the number of additional activities and/or scopes to be certified at the same location.

[2] A forage participant is a trading participant 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.

[3] The scopes within GMP+ B3*Trade, Collection and Storage & Transshipment* are: a) trade and collection, b) storage. Simple actions fall under collection.

[4] 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*.

[5] For single GMP+ B3.2 *Trade to Livestock Farms* certification, just an audit checklist must be uploaded.

[6] 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. *Trade, Collection and Storage & Transshipment*.

[7] Time expenditure is charged to the tractionair(s). For reasons of efficiency the audit of the tractionair(s) may take place at the same time as the audit of the customer. A separate GMP+ audit report must be drawn up for both the customer and the tractionair(s) and entered into the GMP+ International database.

[8] Where the participant produces wet pet foods the scope of the production must be converted using the dry matter content.

[9] Based on the classification it should be assumed in the case of a participant 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).
[10] The most important analyses must be assessed during the initial certification audit. At least once during the audit cycle all analyses must be assessed.
[11] 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.

[12] 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.
[13] 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.
[14] 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 must always be applied for a GMP+ B10 audit.
[15] 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.
  - Within the audit team it must be clear which tasks, responsibilities and authority have been assigned to the individual members
  - 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:
  - GMP+ FC scheme is audited in an associated audit together with the complementary schemes
  - 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.

[16] Number of employees is including part-time workers calculated as percentage of FTE.

Audit time for assessing Gatekeeper files

No. Gatekeeper files	minimum of files to be reviewed per 3 years	GMP+ BA 10: ~~Annex 3, 6~~: 4.3.3 ~~Gatekeeper protocol for purchase of additives / - Gatekeeper protocol for purchase of (former) foodstuffs~~ Purchase of feed additives, foodstuffs, pharma products 4.3.4 Purchase of former foodstuffs 4.3.8 Purchase of processed feed materials	GMP+ BA 10: ~~Annex 4, 5, 7, 8, 9, 10~~: 4.3.1 ~~Gatekeeper protocol for purchase of unprocessed agricultural products from the grower~~ Purchase of unprocessed agricultural products from grower for use in or as feed 4.3.2 ~~Gatekeeper protocol for purchase of grains, seeds and legumes~~ Purchase of unprocessed grains, (oil)seeds and legumes out of a collect chain for use in feed 4.3.5 ~~Gatekeeper protocol for purchase of GMQ Palm Oil~~ Purchase of palm oil 4.3.7 Purchase of herbs and spices 4.3.9 Purchase of feed for feed trial ~~- Gatekeeper protocol for purchase of straw~~ 4.4.1 ~~Gatekeeper protocol for road transport~~ Purchase of road transport 4.4.2 Purchase of inland waterway transport 4.4.3 ~~Gatekeeper protocol for storage and transshipment~~ Purchase of storage and transshipment
1 to 5	all	1h per file	0,5 h per file
6 to 10	5	1h per file	0,5 h per file
11 to 15	6	1h per file	0,5 h per file
16 to 30	7	1h per file	0,5 h per file
31 to 50	8	1h per file	0,5 h per file
51 to 100	9	1h per file	0,5 h per file
> 100	10	1h per file	0,5 h per file

	GMP+ B100 *Feed Responsible Management System*	Audit frequency	Minimum time expenditure in hours		
			Initial- or recertification audit	Unannounced/Announced surveillance audit	Comment
GMP+ MI101 *Production and trade of RTRS* soy					
GMP+ MI102 *Responsible pig and poultry feed*					
GMP+ MI103 *Responsible dairy feed*					
GMP+ MI105 *GMO Controlled*					
	In addition to a GMP+ FSA standard (or equivalent as mentioned in chapter 3 of GMP+ BA10);				
	Segregation Additional audit time per production location	1x / year 1x / year	2*+ 1,5X 2*+ 1,5X	2*+ 1,5X 2*+ 1,5X	
	Mass Balance	1x / year	2*+ 1,5X	2*+ 1,5X	
	Responsible pig and poultry feed	1x / year	2*+ 1,5X	2*+ 1,5X	
	Responsible dairy feed	1x / year	2*+ 1,5X	2*+ 1,5X	
~~1~~	Production of Compound Feed GMO Controlled ~~feed~~	1x / year	~~4~~ 2*+ 1,5X	~~4~~ 2*+ 1,5X	
	Production of Premixtures GMO Controlled	1x / year	2*+ 1,5X	2* + 1,5X	
	Production of Feed Additives GMO Controlled	1x / year	2*+ 1,5X	2* + 1,5X	
	Production of Feed Materials GMO Controlled	1x / year	2*+ 1,5X	2* + 1,5X	
	Trade in GMO Controlled feed	1x / year	2*+ 1,5X	2*+ 1,5X	
	Storage & Transshipment of GMO Controlled feed	1x / year	2*+ 1,5X	2*+ 1,5X	
	Transport of GMO Controlled feed	1x / year	2*+ 1,5X	2*+ 1,5X	
	As a stand-alone standard (without GMP+ FSA certification)				
	Segregation Additional audit time per production location	1x / year 1x / year	6 + 1,5X 2	6 + 1,5X 2	
	Mass Balance	1x / year	6 + 1,5X	6 + 1,5X	
	Responsible pig and poultry feed	1x / year	6 + 1,5X	6 + 1,5X	
	Responsible dairy feed	1x / year	6 + 1,5X	6 + 1,5X	
~~1~~	Production of Compound Feed GMO Controlled	1x / year	~~8~~ 4 + 1,5X	~~8~~ 4 + 1,5X	
	Production of Premixtures GMO Controlled	1x / year	4 + 1,5X	4 + 1,5X	
	Production of Feed Additives GMO Controlled	1x / year	4 + 1,5X	4 + 1,5X	
	Production of Feed Materials GMO Controlled	1x / year	4 + 1,5X	4 + 1,5X	
	Trade in GMO Controlled feed	1x / year	~~6~~ 4 + 1,5X	~~6~~ 4 + 1,5X	
	Storage & Transshipment of GMO Controlled feed	1x / year	~~6~~ 4 + 1,5X	~~6~~ 4 + 1,5X	
	Transport of GMO Controlled feed	1x / year	~~6~~ 4 + 1,5X	~~6~~ 4 + 1,5X	

The basis is the main activity of the participant for FSA certification (if applicable). "X" is the number of additional FRA scopes to be certified at the same location.
* Audit time for the first FRA scope in combination with FSA.
~~1. For auditing GMO controlled the production is the main activity to start with the calculation of the audit times.~~

Annex 3: Reporting Model or Audit Report/Inspection Checklist

Reporting Model:

1 General details

Details of main location
Name of the participant :
Address :
Postal code and location :
Telephone :
Fax :
E-mail :
GMP+ registration number :
Legal business registration number :
Contact person :

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

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

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

GMP+ registration number location	Name of location	Address Postal code, Location	Visit date

Audit details:

- ☐ *Initial certification audit*
- ☐ *Announced surveillance audit*
- ☐ *Recertification audit*
- ☐ *Unannounced surveillance audit*
- ☐ *Conformity audit*
- ☐ *Repeat audit*
- ☐ *Stricter supervision*
- ☐ *Documents review (in the event of a temporary acceptance)*
- ☐ *Other;*

Date of document assessment :

Date of audit :

Report date :

Staff involved in
Name Position :

Documents consulted :
Certification Body :
Auditor(s) :
Materials expert(s) :

Name Signature

2 Scope participant/locations

Specify the type of participant 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 participant applies the Gatekeeper principle and describe the activities.

3 Audit objectives

The audit objectives shall describe what is to be accomplished by the audit and must include the following topics:

a) *Determination of the conformity.*
b) *Evaluation of the ability of the Quality Management System to ensure the participant's organisation meets applicable statutory, regulatory and contractual requirements.*
c) *Evaluation of the effectiveness of the Quality Management System to ensure the participant's organisation is continually meeting its specified objectives.*

4 Which topics have been assessed and concluded

In general it must be clear in the report what has been assessed and what was the conclusion of the auditor.

5 Summary of the assessment and a general conclusion

Start with a standard phrase such as "The participant was visited for a surveillance audit of the GMP+ requirements. The participant was checked for the requirements of the applicable GMP+ standards".
Indicate whether the audit findings nonconformities observed in the previous audit have been resolved.
Make a summary per participant 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 participant.
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**		
	Critical	*Major*	*Minor*	*Critical*	*Major*	*Minor*	*Critical*	*Major*	*Minor*

Audit conclusion: the participant meets/fails to meet requirements of the GMP+ standard. Measures and sanctions: conformity audit, repeat audit, stricter supervision (including period of time), suspension, withdrawal.

6 Appendices

Checklists used, report forms for audit nonconformities.
Note: non-conformities observed must also be recorded in the English/German or Dutch language.

Audit Report/Inspection Checklist

(This is an impression of the Audit Report/Inspection Checklist, consult for the latest version always the Audit Report/Inspection Checklist processed in the GMP+ Database/Audit app)

Company Details			
GMP+ Registration Nr.			
Company Name			
Company Relation	Main site		
Company Address			
Postal Address			
Legal Business Registration No.			
24/7 Number			
Email Address			
Production in tons			
Number of products			
Number of employees			
Gatekeeper files	☐	Number of gatekeeper files - BA10 Annex 3.6	
		Number of gatekeeper files - BA10 Annex 4,5,7-10	
Vessel Name			
Vessel Owner			
Vessel Registration Number/EU Number			
Vessel Size in Tons			
Total Cubic Content			
Number of Holds			
Type of Hatch Cover			
Floor Type (steel, wood)			

Contacts	
Full Name	**Position**

Certifications				
Scope	**Standard**	**Certified Since**	**Start Date**	**End Date**

Company Relation	
Connected To	**Company Relation**

Audit Details			
Audit Date			
Report Date			
Name Certification Body			
Name Auditor			
Name Co-Auditor			
Name Observer			
Name Technical/Material Expert			
Audit Type*			
Audit/Inspection Time			
Combined Audit			
Certificate Combined Scheme	☐	Validity	26-4-2018

* Initial Certification audit (ICA), Surveillance audit (SA), Unannounced Surveillance audit (USA), Recertification audit (RCA), ~~Compliance~~ Conformity audit (CA),
Stricter Supervision audit (SSA), Repeat audit (RPA), Document assessment (DA).

Scope of the Audit	Standard to be assessed

Audit Objectives

The audit objectives shall describe what is to be accomplished by the audit and must include the following topics:
a) Determination of the conformity.
b) Evaluation of the ability of the Quality Management System to ensure the participant's organization meets applicable statutory, regulatory and contractual requirements.
c) Evaluation of the effectiveness of the Quality Management System to ensure the participant's organization is continually meeting its specified objectives.

All Audit Requirements					
Article	**Scope**	**Standard**	**Requirement**	**Assessment**	**Evidence**

All Non Conformities										
Article	**Scope**	**Standard**	**Requirement**	**Classification**	**Description Non-Conformity**	**Based on**	**Deadline NCR**	**Corrective / Preventive Actions**	**NCR Solved On**	**Final Classification**

Audit conclusion:

Final assessment:
Approved or Disapproved

Date, place

Signature Auditor,
(not mandatory)

Date, place

Signature Reviewer,
(not mandatory)

Annex to the report NCR form

yes/no

Annex 4: Multisite certification

Option 1:
Multisite certification is possible:
a. At a participant with a main office with 100% subsidiaries, or
b. At a group of companies which have joined together as a quality community.

Note: *'A multisite organization does not have 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 announced 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'.*[2]

Guidance
Multisite certification is reserved for companies which are part of the feed sector. Companies, participating in a multisite organisation, must 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 following FSA (including Country Notes) and FRA activities:
a. Transport
b. Trade
c. Storage
d. Transshipment
e. Collection
f. Affreightment

It is not allowed to bring production within FSA (including country notes) and within FRA under Multi-site certification.
It is not allowed to bring segregation under Multi-site certification except for the activities trade in feed GMO Controlled, storage & transshipment of feed GMO Controlled and transport of feed, road transport GMO Controlled.

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.

[2] IAF MD1:2007 - Document for the Certification of Multiple Sites Based on Sampling

d. If a participant 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 applicable. See GMP+ C6 Assessment and Certification Criteria for GMP+ Certification, annex 2.
e. These requirements do not exclude audits based on reduced audit times. See GMP+ C6 Assessment and Certification Criteria for GMP+ Certification, annex 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 actions 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 must be signed by all the participating parties and the signed agreement must be present at the main office and available to the auditor. The statement will include at least:
    1. a commitment by the participant to the main office that it will comply with the requirements set in the quality system.
    2. that corrective actions 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 actions
    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 annually (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 audit report used by the certification bodies.

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 participant and a number of carriers may unite in a quality community, for example. The certification can take place under multisite 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 participant (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 Trade, Collection and Storage & Transshipment) etc., the production participant must also be certified for this scope (transport and/or trade) because the management and control of the feed safety management system lies centrally with the production participant.

In the event of multisite 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 certification audit can take place, a unique certification agreement/certification agreement template 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 ⅓ of the locations must always be visited before a certificate can be issued.

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

Minimum time to be spent per visit in hours:

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

*By the number of employees is meant the sum of the number of employees (including part time employees as percentage of FTE) per audited branch per year.

Unprocessed products (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 participant consists of more than 20 multi sites 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 multi-site 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 random 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 random sampling 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 21st site; every fifth site.

The multi sites will be chosen randomly. The Certification Body may divide the multi sites into groups or districts.

Guidance

Regular multisite

The main office certified for GMP+ B3 scope storage & transshipment, (6–15 products) and certified for GMP+ B4 road transport.
5 Multi-site locations are certified for storage and transshipment (< 5 products for each Multi-site location).
5 Multi-site locations are certified for road transport (≤ 5 employees for each Multi-site location)

Calculation audit time for initial certification/recertification/surveillance audit of the main office:
GMP+ B3, scope storage & transshipment 8 hours for all type of audits (see annex 2 of this document) plus 1,5 hours for the additional scope road transport plus 10 hours (additional audit time for the Multi-sites locations) makes a total of: 19,5 hours for all type of audits at the main office.

5 Multi-site locations are certified for storage and transshipment (< 5 products for each Multi-site location) is 2 hours per location so the total is 10 hours per 3 years.
5 Multi-site locations are certified for road transport (≤ 5 employees for each Multi-site location) is 2 hours per location so the total is 10 hours per 3 years.

Total audit times are 19,5 for all type of audits at the main office is: 58,5 hours. Plus 10 hours for the Multi-site locations storage & transhipment plus 10 hours for the Multi-site location transport is a total of 78,5 hours for the certification cycle.
The main office has to be audited every year in accordance to annex 2 of this document.

Unprocessed goods (large multisite)

The main office (certified for GMP+ B3 scope: Trade and Storage (≤5 products)) and 100 sub locations which are all certified for Storage. The main office has to be audited every year in accordance to annex 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 21st sub location every 5th sub location has to be audited per 3 year (certification period).

Calculation audit time for initial certification/recertification- and announced/unannounced surveillance of the audit main office:
GMP+ B3, scope: Trade (≤5 products) is 6,5 hours and GMP+ B3 scope: Storage, extra 1,5 hour = 8,0 hours (see annex 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*0,20 = 20 + 16 = 36 audits per 3 year (certification period).*
Sub locations average 1/3 x 36 x 2 = 24 hour per year.

Total audit time for this construction is 42 hours 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 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 take place as well, the operational aspects must also be assessed
h. complaints and nonconformities

During audits of locations where transport is done the following GMP+ requirements must assessed:
a. reception of transport orders incl. product category classification
b. journey sheets; identification of loading compartments, products, cleaning, loading and unloading addresses, etc.
c. inspection of the trucks present
d. administration, use of third parties, instructions with respect to GMP+ product categories
e. if storage activities take place as well, the operational aspects must also be assessed
f. complaints and nonconformities

During audits of locations where trading is carried out 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 must be included in the GMP+ audit report showing when all the locations / companies were visited.

If serious nonconformities are observed at the main office, the whole participant 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 GMP+ audit report/checklist must be uploaded in the GMP+ database for all multi-site locations in which only nonconformities will be described for a multi-site location.

Only one certificate (or temporary acceptance where appropriate) will be issued for multi-site. This certificate will have an annex with the companies that belong to the multisite. An individual location or participant 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 must apply at least GMP+ B3 *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 participant must comply with the following criteria:
a. The participant has a main office from which activities are planned and directed
b. The participant 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 actions may be imposed from the main office on all storage locations and/or sales points
g. The participant must demonstrate 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 actions
    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 must 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 must be signed by all the brokers participating in this multisite 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 based on this data.

In the event of multisite 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 reduced in accordance with the following schedule where each location must be visited at least once per three years.

Initial certification audit / recertification audit / *announced-/unannounced surveillance audit*

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

Minimum time to be spent per visit in hours:

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

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

During audits of storage locations and/or sales points the following GMP+ requirements must 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 participant level, the whole multisite 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 GMP+ audit report/checklist must be uploaded in the GMP+ database for all multi-site locations in which only nonconformities will be described for a multi-site location.

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

Feed Responsible Management System (Segregation excluded)

If a multi-site participant consists of more than 20 sub locations 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 multi-site certification; the internal audit program must cover all sites every year, including sites that are not used the whole year round.
- All sites must be located in the same country or in the bordering regions of neighbouring countries.
- The random sampling 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 random sampling 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 21st site; every fifth site.

The multi sites will be chosen randomly. The certification body may divide the sub locations into groups or districts.
Segregation/Production sites cannot be included in the Multi-site certification except for the activities trade in feed GMO Controlled; storage & transshipment of feed GMO Controlled and transport of feed, road transport GMO Controlled.

Annex 5: Related documents

GMP+ activity	Normative document	Related ~~Appendices~~ documents
Production of Compound Feed	GMP+ B1/GMP+ B1.2 *Production, Trade and Services*	~~Appendices~~ GMP+ BA1, GMP+ BA2, GMP+ BA3, GMP+ BA4, GMP+ BA5, GMP+ BA6, GMP+ BA7, GMP+ BA10 and GMP+ BA13 of the GMP+ FSA module.
Production of Premixtures	GMP+ B1/GMP+ B1.2 *Production, Trade and Services*	~~Appendices~~ GMP+ BA1, GMP+ BA2, GMP+ BA3, GMP+ BA4, GMP+ BA5, GMP+ BA6, GMP+ BA7, GMP+ BA10 and GMP+ BA13 of the GMP+ FSA module.
Production of Feed Material	GMP+ B1/GMP+ B1.2 *Production, Trade and Services* GMP+ B2 *Production of feed ingredients*	~~Appendices~~ GMP+ BA1, GMP+ BA2, GMP+ BA3, GMP+ BA4, GMP+ BA5, GMP+ BA6, GMP+ BA7, GMP+ BA10 and GMP+ BA13 of the GMP+ FSA module.
Production of Additives	GMP+ B1/GMP+ B1.2 *Production, Trade and Services* GMP+ B2 *Production of feed ingredients*	~~Appendices~~ GMP+ BA1, GMP+ BA2, GMP+ BA3, GMP+ BA4, GMP+ BA5, GMP+ BA6, GMP+ BA7, GMP+ BA10 and GMP+ BA13 of the GMP+ FSA module.
Pet foods	GMP+ B1 *Production, Trade and Services* GMP+ B8 *Production of and Trade in Pet Foods*	~~Appendices~~ GMP+ BA1, GMP+ BA2, GMP+ BA3, GMP+ BA4, GMP+ BA5, GMP+ BA6, GMP+ BA7, GMP+ BA10 and GMP+ BA13 of the GMP+ FSA module.
Trade in feed	GMP+ B3 *Trade, Collection and Storage & Transhipment* GMP+ B1 *Production, Trade and Services* GMP+ B8 *Production of and Trade in Pet Foods*	~~Appendices~~ GMP+ BA1, GMP+ BA2, GMP+ BA3, GMP+ BA4, GMP+ BA5, GMP+ BA6, GMP+ BA7, GMP+ BA10 and GMP+ BA13 of the GMP+ FSA module.
Storage & Transhipment of feed	GMP+ B3 *Trade, Collection and Storage & Transhipment* (GMP+ B1 *Production, Trade and Services)*	~~Appendices~~ GMP+ BA1, GMP+ BA2, GMP+ BA3, GMP+ BA4, GMP+ BA5, GMP+ BA6, GMP+ BA7, GMP+ BA10 and GMP+ BA13 of the GMP+ FSA module.

GMP+ activity	Normative document	Related ~~Appendices~~ documents
Trade to Livestock farms	GMP+ B3.2 *Trade to Livestock Farms*	~~Appendices~~ GMP+ BA1 and GMP+ BA6.
Road transport of feed (including af-freightment of road transport)	GMP+ B4 *Transport* Assessment IDTF	IDTF of the GMP+ FSA module, GMP+ BA5, GMP+ BA6, GMP+ BA10 and GMP+ BA13.
Rail transport of feed	GMP+ B4 *Transport*	IDTF of the GMP+ FSA module, GMP+ BA5, GMP+ BA6, GMP+ BA10 and GMP+ BA13.
Short sea shipping and inland water-ways transport af-freightment	GMP+ B4 *Transport*	Process requirements as specified in Chapter 7 of GMP+ B4 and GMP+ BA5, GMP+ BA6, GMP+ BA10 and GMP+ BA13.
Affreightment of sea transport	GMP+ B4 *Transport*	Process requirements as specified in Chapter 7 of GMP+ B4 and the GMP+ BA5 and GMP+ BA6.
Affreightment of rail transport	GMP+ B4 *Transport*	Process requirements as specified in Chapter 7 of GMP+ B4 and the GMP+ BA5 and GMP+ BA6.
Short sea shipping and inland water-ways transport	GMP+ B4.3 *Short sea shipping and inland waterways transport*	GMP+ BA5 and GMP+ BA6.
Laboratory testing	GMP+ B10 *Laboratory testing*	
Registered laboratory	GMP+ B11 *Protocol for GMP+ registration for laboratories*	GMP+ BA11
Assuring suppliers of feed ingredients and services for China	GMP+ BCN-CN1 *Supplier assurance for China*	
Antibiotics-free feed produced at an antibiotics-free production site or Antibiotics-free feed produced on antibiotics-free production line(s)	GMP+ BCN-NL1 *Antibiotics free feed*	
Dioxin-monitoring in laying hens (rearing) feeds	GMP+ BCN-NL2 *Dioxin monitoring in laying hens (rearing) feeds*	
QM-Milch	GMP+ BCN-DE1 QM-Milch	

GMP+ activity	Normative document	Related ~~Appendices~~ documents
Production of compound feed and premixtures in Central and Eastern Europe.	GMP+ BCN-CEE Additional requirements for Central & Eastern Europe	
Specific requirements for Italy.	GMP+ BCN-IT specific requirements for Italy	
Specific requirements for Vietnam	GMP+ BCN-VN *specific requirements for Vietnam*	
Specific requirements for Iberian Peninsula	GMP+ BCN-IP *specific requirements for Iberian Peninsula*	
RTRS Mass Balance	GMP+MI101 *Production and trade of RTRS soy*	GMP+ B100 Feed Responsible Management system
RTRS Segregation	GMP+MI101 *Production and trade of RTRS soy*	
Responsible pig & poultry feed	GMP+MI102 *Responsible pig & poultry feed*	
Responsible diary feed	GMP+MI103 *Responisble diary feed*	
GMO Controlled	GMP+ MI105 *GMO Controlled*	

standard GMP+ FSA → ↓ scope of process	B1/ B1.2	B2	B3	B3.2	B4	B4.3	B8	B10	B11
Production of compound feed	x								
Production of premixtures	x								
Production of feed additives	x	x							
Production of feed materials	x	x							
Trade of feed.	x		x						
Trade to livestock farms	x		x	x					
Storage and transshipment of feed	x		x						
Road transport					x				
Affreightment of road transport					x				
Rail transport					x				
Affreightment of short sea shipping and inland waterways transport					x				
Short Sea Shipping and Inland Waterways						x			
Affreightment of sea transport					x				
Affreightment of rail transport					x				
Production of pet foods	x						x		
Trade in pet foods	x						x		
Laboratory Analyses of feed								x	
Registered Laboratory									x

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Accreditation

If possible, all standards / scopes can be brought under accreditation with the exception of the following standards /scopes:

Process	Normative document
Not able to be brought under accreditation:	
Distributive trades with direct delivery to livestock farmers	GMP+ B3.2 *Trade to Livestock Farms*
Inland waterways shipping	GMP+ B4.3 *Short Sea Shipping and Inland Waterways*
Laboratory testing	GMP+ B10 *Laboratory Testing*
Registered laboratory	GMP+ B11 *Protocol for GMP+ registration for laboratories*
Assuring suppliers of feed ingredients and services for China	GMP+ BCN-CN1 *Supplier assurance for China*
Antibiotics-free feed produced at an antibiotics-free production site or Antibiotics-free feed produced on antibiotics-free production line(s)	GMP+ BCN-NL1 *Antibiotics free feed*
Dioxin-monitoring in laying hens (rearing) feeds	GMP+ BCN-NL2 *Dioxin monitoring in laying hens (rearing) feeds*
QM-Milch	GMP+ BCN-DE1 *QM-Milch*
Production of compound feed and premixtures in Central and Eastern Europe.	GMP+ BCN-CEE *Additional requirements for Central & Eastern Europe*
Specific requirements for Italy.	GMP+ BCN-IT *specific requirements for Italy*
Specific requirements for Vietnam	GMP+ BCN-VN *specific requirements for Vietnam*
Specific requirements for Iberian Peninsula	GMP+ BCN-IP *specific requirements for Iberian Peninsula*
Production and trade of RTRS soy	GMP+MI101 *Production and trade of RTRS soy*
Responsible pig & poultry feed	GMP+MI102 *Responsible pig & poultry feed*
Responsible diary feed	GMP+MI103 *Responsible dairy feed*
GMP+ GMO Controlled	GMP+MI105 *GMO Controlled*

Annex 6: Products and process stages / services

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

Fixed part:
Completion of the fixed section is mandatory. The description of the assured feed on the GMP+ certificate or temporary acceptance must 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 annex 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 acceptance refers.

GMP+ Feed Safety Assurance	
Activities	*Feed*
Production of …… Trade in……	the feed to be distinguished: ….. feed additives ….. feed materials …...feed materials (pet foods) ….. premixtures ….. compound feed …...compound feed (pet foods) ….. feed
Storage and transshipment of	…..feed
Transport of feed	…..Road transport …..Rail transport …..Short Sea shipping and Inland Waterways transport
Affreightment of feed	…..Road transport …..Rail transport …..Inland waterways transport …..Sea transport …..Short sea shipping
Trade to	Livestock farms

GMP+ Feed Responsibility Management System	
Activities	*Product*
Production and/or trade of feed that complies with the scope:	RTRS Mass Balance RTRS Segregation Responsible pig & poultry feed Responsible diary feed

GMP+ Feed Responsibility Management System	
Main scope GMO Controlled, divided in the following activities*	*Product*
Production of	Compound feed GMO Controlled Feed materials GMO Controlled Premixtures GMO Controlled Feed additives GMO Controlled
Trade in Storage and Transshipment of	Feed GMO Controlled
Transport of feed, road transport	GMO controlled

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

Free part:
The completion of this 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 feed may also be further specified. For example, the category compound feeds may contain 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 its production of compound feeds as: production of milk replacer feed.
b. a collector of grains may specify its treatment of feed materials as collection, cleaning and drying of grains
c. a trader in grains may specify its 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 acceptance.
The validity of a certificate or temporary acceptance relates to the specified scope. Unspecified products or activities do not fall within the scope of the certificate or temporary acceptance.

Annex 7: Announced surveillance audit – not at participant location

For road transport companies (GMP+ B4 *Road Transport*) an announced surveillance audit may also take place at another location than the registered offices of the participant.

The following requirements apply:

a. The participant falls into the category: 1-5 employees
b. The participant does not have its own working area
c. The participant 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 must 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 must be guaranteed.

Audit nonconformities must be classified and handled at least using the general assessment criteria in Annex 1 and the specific assessment criteria in the GMP+ audit report.

Annex 8: Protocols for independent sampling though 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
Premixtures	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 additives	Dry	up to 50 tons	2	2 kg	200 g

Product	Form	Quantity in tons	Number of sub-samples	Minimum quantity of collective sample	Minimum quantity of final sample
		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 must 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 must 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 must 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 must 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[1]

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 must 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 must 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 must 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 must be taken from the collective sample.

4.Sample sealing and storage
The sample must 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 must be such that opening the sample inevitably leads to an irrevocable break in the seal on the sample.

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

Sampling protocol M3: Feed materials, compound feeds, premixtures 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, must 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 must 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 must be taken from the collective sample.

4.Sample sealing and storage
The sample must 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 must 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, premixtures 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 premixtures 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 must 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 must be taken.

4.Sample sealing and storage
The sample must 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 must 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 must 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 must 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) must 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 must 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 must 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 must 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 must 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 must be such that opening the sample inevitably leads to an irrevocable break in the seal on the sample.
Consignment of the sample must 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 must 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 must 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 must 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 must be taken from the collective sample.

4.Sample sealing and storage
The sample must 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 must be such that opening the sample inevitably leads to an irrevocable break in the seal on the sample.

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