

# CR1.0 - Acceptation requirements

Version EN: 1 January 2022







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#### Welcome

This Feed Certification scheme document supports you to contribute to feed safety worldwide. By assessing and complying with the requirements set by GMP+ International together with its stakeholders, we aim to provide safe and responsible feed for the GMP+ community. Please read the information in this document carefully.

Let's make this work together!

## 1. Scope of this document

This document contains the acceptation requirements and procedures for Certification Bodies who intend to certify applicant organizations/GMP+ Certified Companies. It also defines the compliance assessment towards Certification Bodies/Critical Locations performed by GMP+ International. In addition the audit times are expressed in days, 1 day equals 8 hours.

### 2. Normative references

The following documents, in whole or in part, are normatively referenced in this document and are mandatory to comply with. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including all amendments) applies.

- ISO/IEC 17021-1:2015 Conformity assessment requirements for bodies providing audit and certification of management systems.
- NPR-ISO/TS 22003:2013 Food safety management systems requirements for bodies providing audit and certification of food safety management systems.
- F 0.1 Rights and Obligations.
- F 0.2 Definition list.
- F 0.3 Scopes for certification.
- CR 2.0 Assessment and Certification.
- CR 3.0 Assessment and Certification of additional scopes.

## 3. Principles

Relevant requirements must apply	
ISO/IEC 17021-1:2015	Article 4.1



## 4. Acceptance

#### 4.1. General

A Certification Body that wishes to certify an applicant organization/GMP+ Certified Company according to 1 or more GMP+ scope(s) must demonstrably comply with the requirement laid down in this document in addition to chapter 2. If the Certification Body complies with the requirements GMP+ International will accept the Certification Body in question.

#### 4.2. Acceptation procedure

#### 4.2.1. Application

The applicant Certification Body submits an application using an application form (Appendix 1) to GMP+ International. The application will be considered when:

- the application form has been filled completely and all the requested documents have been received;
- the application fee for the handling the application has been paid (see CR 4.0 Tariffs);
- The applicant Certification Body must have 2 accepted GMP+ auditors/inspectors per scope(s) applied by the Certification Body. The applicant Certification Body must motivate and document its decision accordantly Appendix 2 and must keep all record available for assessment during the acceptation audit.

GMP+ International will confirm this application in writing. If the applicant Certification Body cannot be accepted by GMP+ International within the timeframe of 26 weeks after the first application, GMP+ International will terminate the acceptation procedure. The applicant Certification Body is then not allowed to start a new acceptation procedure within a year. For each additional acceptation audit to finalize the acceptation procedure GMP+ International will charge the applicant Certification Body.

#### 4.2.2. Desk assessment

Desk assessment of the requested documents will take at least 4 and a maximum of 6 weeks. The applicant Certification Body will be informed by GMP+ International about the results. Only after a positive result of the desk assessment an acceptation audit will be performed.

#### 4.2.3. Acceptation audit

An acceptation audit is only possible after a positive result of the desk assessment. The duration of the on-site acceptation audit is at least 1 day.

Audit findings will be addressed in the report to be drawn up and reviewed by GMP+ International. Only when the audit findings are resolved the applicant Certification Body can become accepted.



#### 4.2.4. Applicant Certification Bodies operating with Critical Locations

If, during the application procedure, it is established that the Certification Body operates with Critical Location(s) the following applies:

- Assessment of the Critical Location(s) will be part of the acceptation procedure of the applicant Certification Body.
- For on-site acceptation audit of the Critical Location GMP+ International will charge the applicant Certification Body.
- The acceptance of the applicant Certification Body can only be finalized if the Critical Location(s) complies with the requirements as stated in the GMP+ Feed Certification scheme.

#### 4.2.5. GMP+ Feed Certification scheme License Agreement

If the applicant Certification Body fulfils the requirements of acceptance then:

- GMP+ International will issue a GMP+ Feed Certification scheme License Agreement (Appendix 8 of this document) to the applicant Certification Body to be signed.
- After signing, the Certification Body will send 1 of the original copies back to GMP+ International. The acceptance is complete following receipt of the signed and dated Feed Certification scheme License Agreement.
- GMP+ International will publish the accepted Certification Body and if applicable its Critical Location(s) on the public section of the GMP+ Company Database with a specification for which scopes the acceptance applies (see Appendix 7).

#### 4.3. Acceptation requirements

#### 4.3.1. Accreditation requirements

A Certification Body must be accredited for ISO/IEC17021 and NPR-ISO/TS22003 for the relevant scopes for which they are accepted for by GMP+ International. This accreditation has to be finalized by an accreditation body not later than 1 year after the date of acceptance including Critical Location. To add a Critical Location the Certification Body must assure that the Critical Location(s) are included in the accreditation of the Certification Body within 1 year after publication in the GMP+ Company Database.

The accreditation body must be either part of the European Accreditation (EA) Multilateral Agreement (MLA) or member of the International Accreditation Forum Multilateral Agreement (IAF MLA).

On request, the Certification Body must allow GMP+ International to inspect reports of audits carried out by an accreditation body within the framework of the accreditation for the GMP+ Feed Certification scheme.



### CR1.0 - Acceptation requirements

If the Certification Body cannot be accredited for the relevant scopes within a year after acceptance by GMP+ International, the Certification Body including Critical Location(s) must prove that it has an accredited food/feed quality management system for the relevant activity to ensure their processes.

#### 4.3.2. Management of impartiality

Relevant requirements must apply	
ISO/IEC 17021-1:2015	Article 5.2

#### 4.3.3. Confidentiality

Relevant requirements must apply	
ISO/IEC 17021-1:2015	Article 8.4

#### 4.3.4. Liability and Financing

Relevant requirements must apply	
ISO/IEC 17021-1:2015	Article 5.3

In addition article 12 of GMP+ Feed Certification scheme License Agreement must apply.

#### 4.3.5. Structural requirements

Relevant requirements must apply	
ISO/IEC 17021-1:2015	Article 6

#### 4.3.6. Resource requirements

#### 4.3.6.1. Competence of personnel

Relevant requirements must apply	
ISO/IEC 17021-1:2015	Article 7.1 up to and including 7.4
NPR-ISO/TS22003:2013	Article 7.1 up to and including 7.4

Additional requirements for the GMP+ coordinator, GMP+ auditor, GMP+ Inspector and GMP+ technical reviewer are mentioned in Appendix 2; Certification Bodies must ensure that these requirements are met. The Certification Body must motivate and document its decision according to Appendix 2 and must keep all records available for assessment during the Certification Body audit.

A GMP+ auditor may only conduct GMP+ audits once the GMP+ auditor is accepted for the relevant scope in the GMP+ database.



The Certification Body must appoint 1 person as GMP+ coordinator for the certification who acts as contact person to GMP+ International. Application for the acceptance of a GMP+ coordinator must be submitted to GMP+ International by using the application form, as stated in Appendix 5 of this document.

#### 4.3.6.2. Outsourcing

Relevant requirements must apply			
ISO/IEC 17021-1:2015	Article 7.5		
NPR-ISO/TS22003:2013	Article 7.5		

In addition the relevant articles of the GMP+ Feed Certification scheme License Agreement must apply.

#### 4.3.6.3. Responsibilities of GMP+ coordinator

The responsibilities are:

- Contact person to GMP+ International,
- Coordination of examination,
- Responsible for internal harmonization, physical harmonization is mandatory with a minimum of once per 2 years. Participation must be documented. Internal harmonization must be demonstrated by means of a presentation/minutes.
- Responsible for ensuring that GMP+ Company Database is up to date (see Appendix 7).
- Acceptance of GMP+ auditor, inspector and technical reviewer.
- Responsible for issuing audit time reduction.

The Certification Body must establish a procedure in case the GMP+ coordinator delegates responsibilities to an authorized person.

#### 4.3.7. Information requirements

#### 4.3.7.1. Public information

Relevant requirements must apply	
ISO/IEC 17021-1:2015	Article 8.1

Upon concluding a GMP+ Certification Agreement with a applicant organization, the Certification Body and/or Critical Location must immediately enter the following company details in the GMP+ Company Database (see Appendix 7):

- the official Company name, the Company's registered office address (including the
  official registration number in Chamber of Commerce or similar formal business
  registration), postal address, phone number, fax number, e-mail address, website, a
  company emergency telephone number, ship name, EU number of ship and all other
  information, as set out in the GMP+ CR documents,
- the Business Location where the Company conducts its activities;



- In case of a multisite certification or a certification for a tractionair which is included in the GMP+ Certified Companies quality manual, the main office has to be registered in the GMP+ Company Database and linked to the multi-site location/ traction unit.
- After a successful initial audit the scopes of certification must be added.

The Certification Body and/or Critical Location must inform GMP+ International (through the GMP+ Database) within 2 weeks of any change to the information specified above.

If the name, address, and/or registered office of the Certification Body or its Critical Location change, or in the event of closure, the Certification Body is obliged to inform GMP+ International accordingly 1 month in advance.

#### 4.3.7.2. Information exchange between Certification Bodies and its clients.

Relevant requirements must apply		
ISO/IEC 17021-1:2015	Article 8.5.1 and 8.5.2	

The Certification Body must retain all relevant certification documentation/information for at least 6 years.

#### 4.3.8. GMP+ International harmonization.

GMP+ International organises a harmonization meeting 2 times per year. For each meeting the GMP+ coordinator (or authorized person) of the accepted Certification Body must be present. If there are insufficient relevant agenda items for a Certification Body then GMP+ International may decide to issue an individual dispensation from the mandatory attendance.

Each Certification Body is obliged to provide GMP+ International with at least 1 case study in a timely manner each year to be discussed during the harmonisation meeting.

#### 4.3.9. Procedures and Documents for GMP+ certification

The Certification Body must have an up to date documented procedure(s) describing the way in which GMP+ certification will take place (application through to issuing of the certificate). This procedure(s) must be part of the quality management system of the Certification Body.

In the event of changes in the certification requirements the Certification Body must implement these at the latest on the implementation date.



## 5. Compliance assessment

#### 5.1. General

GMP+ International supervises if the Certification Bodies comply with that what is laid down in the relevant CR documents and F documents.

The criteria as laid down in this document are used for compliance assessment audits and for determining sanctions.

In addition the accreditation bodies ensure that the Certification Bodies comply with the requirements of accreditation with respect to the implementation of the GMP+ Feed Certification scheme.

## 5.2. Compliance assessment of Certification Bodies, Critical Location(s) and GMP+ auditors/inspectors

The compliance assessment of the Certification Bodies and Critical Location(s) that GMP+ International carries out consists of:

#### 5.2.1. Compliance Desk Assessment

Compliance Desk Assessment is to determine whether the Certification Body and Critical Location(s) comply with the requirements laid down in the GMP+ Feed Certification scheme.

#### 5.2.2. Compliance Audits

The Compliance Audits are risk based selected except for the Certification Body office audit, Critical Location(s) audit and the ad hoc audit.

#### 5.2.2.1. Witness Audits (WA report)

GMP+ International supervises the GMP+ auditors / inspectors by assessing their work method and the way they classify their findings during the execution of their audit. If the GMP+ International auditor observes that a feed safety risk is not identified during the audit, the GMP+ auditor will be informed by the GMP+ International auditor before the closing meeting in order to confirm whether there is a feed safety risk. During a repeat audit/inspection GMP+ International can decide to carry out a witness audit of the auditor/inspector involved.



#### **5.2.2.2.** Parallel Audits (PA report)

GMP+ International carries out parallel audits at GMP+ Certified Companies to verify the method by which an audit is planned, executed and reported through the Certification Body. The parallel audit will take place after the audit has been carried out through the Certification Body. Reference document for the description of findings for GMP+ Certified Companies is applicable (Appendix 6.3).

#### 5.2.2.3. CB office Audits (CB report)

GMP+ International will carry out an audit at the Certification Bodies at least once a year to assess implementation of the requirements laid down in the GMP+ Feed Certification scheme. This audit is a full assessment of all requirements. The minimum audit time is 1 day. Reference document for the description of NCR's is applicable (Appendix 6.2).

#### **5.2.2.4.** Critical Location(s) Audit (CL report)

GMP+ International will carry out an audit at the Critical Location(s) at least once every 2 years to assess implementation of the requirements laid down in the GMP+ Feed Certification scheme. The minimum audit time is 1 day.

#### 5.2.2.5. Ad-hoc Audit (AH report)

GMP+ International can carry out ad hoc audits at GMP+ Certified Companies as a result of an EWS warning, complaints or incidents. This audit focuses on the specific topics related to the EWS warning, complaints or incidents. But all requirements of the GMP+ Feed Certification scheme can be assessed.

#### 5.2.3. Analysis

#### **5.2.3.1.** Retrospective analysis

Retrospective analysis of the GMP+ Certified Company/GMP+ auditor, which is based on special events and not on a regular basis:

- a. Retrospective analysis of certification process (RAC report)
   It is an analysis of the reports of all Certification Audits and, if available, also of Compliance Audits, conducted at a specific company during the last 36 months.
- b. Retrospective analysis of a GMP+ Auditor (RAA report) It is an analysis of the reports of all Certification Audits conducted by a certain GMP+ auditor for a number of reports to be determined by GMP+ International and related to the relevant scope(s).



#### 5.2.3.2. Overall analysis

Overall analysis of the performance of certification (OA report).

It is an annual analysis of performance of a Certification Body during the last 3 calendar years, based on at least:

- a. Identified nonconformities per GMP+ auditor
- b. Findings/NCR's of GMP+ Compliance audits;
- c. Participation and input in harmonization meetings;
- d. Exam results of the GMP+ auditors;
- e. Compliance assessment of the Critical Location(s), if applicable.

The final result of the overall analysis can result in additional compliance assessment for the Certification Body and/or Critical Location(s). The cost for the additional compliance assessment can be charged to the Certification Body. If an action/improvement plan is requested by GMP+ International the Certification Body is obliged to send in such an action/improvement plan within the timeframe requested by GMP+ International.

#### 5.2.4. Examination

Examination of GMP+ auditors, technical reviewers and inspectors is a tool to measure knowledge and application of the knowledge of the GMP+ auditors, GMP+ technical reviewers and GMP+ inspectors in accordance with the requirements of the GMP+ Feed Certification scheme, including the classification of nonconformities.

#### 5.2.5. Report assessment

Based on random samples, GMP+ International will assess GMP+ audit report/checklist on audits carried out through Certification Bodies under the GMP+ Feed Certification scheme. The Certification Body must provide the information immediately on request.

### 5.3. Identifying and recording findings

Additional to Appendix 6 for the articles 5.2.1, 5.2.2., 5.2.3.1 and 5.2.5 the following applies:

After the compliance assessment has been carried out by GMP+ International the NCR(s) is prepared by the GMP+ International auditor and handed over to the GMP+ coordinator and/or authorized person of the Certification Body. GMP+ International is responsible if the observed NCR(s) are justified and well classified. Nonconformities determined during the Critical Location audit will always be issued to the liable Certification Body.



NCR(s) can only be closed if the Certification Body involved conducts a root cause analysis, implements corrective and/or preventive actions and, if applicable, the Certification Body involved must submit objective evidence to GMP+ International.

GMP+ International refers to this actions as Corrective Action Report (hereunder: CAR). Minor and/or Major nonconformities:

The GMP+ International auditor and GMP+ International (technical) reviewer are responsible for finalizing the compliance report and for assessing the CAR(s) and closing the NCR(s).

#### Critical nonconformities:

GMP+ International is responsible to make the decision to close and/or upgrade / downgrade the NCR(s) and to make the compliance assessment report final.

#### 5.4. Reporting

For all assessment types as mentioned under Article 5.2 (5.2.4 excluded) a report will be provided to the Certification Body in the English language. In addition the compliance report for all audit types as mentioned in article 5.2. (5.2.4. excluded) can be provided to the Certification Body also in the German or Dutch language.

#### 5.5. Measures and Sanctions

If GMP+ International determines that a Certification Body does not comply with the requirements and obligations of the GMP+ Feed Certification scheme, or the GMP+ Feed Certification scheme, or the GMP+ Feed Certification scheme License Agreement, it will impose one of the measures or sanctions under a) up to and including e) on the Certification Body. The Certification Body will be informed if necessary by means of an official letter.

- a. Stating a period of time when the Certification Body/Critical Location must comply with the requirements of the GMP+ Feed Certification scheme. The Certification Body will be asked to provide a corrective action report within a determined timeframe
- b. Not to renew the GMP+ Feed Certification scheme License Agreement with a Certification Body;
- c. To suspend the GMP+ Feed Certification scheme License Agreement for a period of maximum 3 months which automatically results that Critical Location, Non-Critical Location and Outsourcing Party are not allowed to conduct any GMP+ activities for the same period;
- d. To terminate the GMP+ Feed Certification scheme License Agreement possibly after suspension which automatically results in the fact that the Critical Location and Non-Critical Location and Outsourcing Party are not allowed to conduct any GMP+ activities;
- e. To make the not renewing, suspension and termination as mentioned under b, c, and d publicly known.



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During a suspension as mentioned under item c the Certification Body must arrange that all its obligations under the GMP+ Feed Certification scheme are taken over by another GMP+ accepted Certification Body.

As a consequence of not renewing/termination as under item b and d, the concerned Certification Body will be excluded for a period of at least 1 year from participation in the GMP+ Feed Certification scheme. GMP+ International will inform the involved GMP+ Certified Companies.



## Appendix 1: Application form for acceptance of a Certification Body

To apply use the <u>application form</u> as published on the website of GMP+ International.





## Appendix 2: Competence of personnel

## **Appendix 2.1 GMP+ auditor FSA**

	Applicant	Accepted
Education	- Relevant agricultural, food	See applicant
	safety/technology, logistics, or transport at	
	least Bachelor level or at least an equivalent	
	level of experience.	
	* For the scopes laboratory testing and	
	registered laboratory a relevant laboratory	
	education at least at Bachelor or an	
	equivalent level or experience <sup>1</sup> .	
Knowledge of	- HACCP (in accordance with ISO/TS22003	See applicant
J	latest version), including the Pre-requisite	
	programs (PRPs); and	
	- Food Safety Management Systems	
	principles; and	
	- Feed legislation.	
	- coa logistationii	
	In addition:	
	* For the scope production and/or trade of	
	feed additives demonstrable knowledge of	
	relevant chemical processes.	
	relevant chemical processes.	
	* For the scopes laboratory testing and	
	registered laboratory knowledge of the	
Audit skills	assessment of laboratory analysis <sup>1</sup> .  -Lead assessor or FSSC Lead assessor	Coconnicant
Audit Skills		See applicant
	training (40 hours minimum, IRCA	
	recognized, or demonstrable equivalent).	
A 12	- Effective interviewing skills.	A. I
Audit experience	- Minimum of 3 audits as an observer for	- At least 5 audits per scope per yea
	the relevant GMP+ scope(s) (Appendix 3.1	for which the auditor has been
	of exemptions is applicable) or equivalent	accepted, Appendix 3.2 is applicable
	certification schemes as laid down in GMP+	- If the first requirement cannot be
	TS 1.2 Purchase and/or Appendix 3.2 are	met, 1 witness audit per scope must
	applicable.	be performed by an accepted
	and,	auditor of the Certification Body wit
	- at least 5 independently audits carried out	an acceptation for the relevant scop
	as lead auditor in equivalent certification	and complying with the first
	schemes as laid down in TS 1.2 Purchase or	requirement. The Certification Body
	schemes as mentioned in Appendix 2 of CR	must motivate and documents its
	2.0.	decision.
Working experience	- Working experience in the feed / food	See applicant
	sector in a relevant position (for example	
	quality assurance, production, consultancy	
	on feed safety management systems).	
	* For the scopes laboratory testing and	
	registered laboratory at least 2 years of	
	working experiences in the relevant field of	
	work <sup>1</sup> .	
	1	1





Position: GMP+ auditor FS	A	
Internal harmonization	Exception:  * For the scope Affreightment of animal feed: Demonstrable knowledge of transport. This knowledge to be obtained by demonstrably taking an internal or external course or demonstrable experience in the carrying out of audits or checks at relevant companies.  Each applicant GMP+ auditor must have demonstrably followed an initial training, focussed on the scope(s) in question.	- For each accepted scope the auditor must attend in 8 hours of harmonization to a maximum of 24 hours per calendar year organized by a Certification Body.  * Equivalent certification schemes as laid down in TS 1.2 <i>Purchase</i> and/or Appendix 3.2 are applicable.
Examination	Successfully pas the applicable exams. The GMP+ examination regulation and Appendix 3.1 are applicable.	See applicant

<sup>&</sup>lt;sup>1</sup> also applicable for the technical expert



## **Appendix 2.2 GMP+ auditor FRA**

Position: GMP+ audito		
	Applicant	Accepted
Education	<ul> <li>Relevant agricultural, food safety/technology, logistics, or transport at least Bachelor level or at least an equivalent level of experience.</li> </ul>	See applicant
Knowledge of	<ul> <li>Knowledge and skill with respect to methods and techniques aimed at the assessment of FSMS and,</li> <li>Mass Balancing and traceability over the production chain and,</li> <li>If an auditor successfully completed the RTRS endorsed training you can audit MI5.1, MI5.2 and MI5.3.</li> </ul>	See applicant
	* For auditing MI5.4 GMO Controlled the GMP+ auditor must have a valid VLOG "Ohne Gentechnik" training certificate, or The auditor must have followed a FRA training¹ for MI5.1, MI5.2, MI5.3 and MI5.4, consisting at least of:	
	<ul> <li>- The training must contain at least all topics as stated in the FRA training provided by GMP+ International in the past,</li> <li>- GMP+ FRA certification,</li> <li>- 5. FRMR</li> <li>- MI documents</li> <li>- Certification in practice &amp; cases</li> </ul>	
	<ul> <li>Equivalent topics as address in the VLOG "Ohne Gentechnik" training.</li> <li>* The duration of the FRA training MI5.1, MI5.2 en MI5.3 is at least 4 hours.</li> <li>* The duration of the FRA training MI5.4 is</li> </ul>	
Audit skills	at least 8 hours  -Lead assessor or FSSC Lead assessor training (40 hours minimum, IRCA recognized, or demonstrable equivalent).  - Effective interviewing skills.	See applicant
Audit experience	- Minimum of 3 audits as an observer for the relevant GMP+ scope(s) (Appendix 3.1 of exemption if applicable) or equivalent certification schemes as laid down in TS 1.2 <i>Purchase</i> and/or Appendix 3.2 are applicable and - at least 5 independently audits carried out as lead auditor in equivalent certification schemes as laid down in TS 1.2 <i>Purchase</i> or schemes as mentioned in Appendix 2 of CR 2.0.	- At least 5 audits per scope per year for which the auditor has been accepted, Appendix 3.2 is applicable If the first requirement cannot be met, 1 witness audit per scope must be performed by an accepted auditor of the Certification Body with an acceptation for the relevant scope and complying with the first requirement. The Certification Body must motivate and documents its decision.



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Position: GMP+ auditor FF	RA	
Working experience	- Working experience in the feed / food sector in a relevant position (for example quality assurance, production, consultancy on feed safety management systems).	See applicant
Internal harmonization	Each applicant GMP+ auditor must have demonstrably followed an initial training, focussed on the scope(s) in question. See knowledge of.	- For each accepted scope the auditor must attend in 8 hours of harmonization to a maximum of 24 hours per calendar year organized by a Certification Body.  * Equivalent certification schemes as laid down in TS 1.2 <i>Purchase</i> and/or Appendix 3.2 are applicable.
Examination	Not applicable	Not applicable

<sup>&</sup>lt;sup>1</sup> Requirements for the trainer:

The trainer must have a certificate of the FRA training provided by GMP+ International in the past and/or the trainer succeeded for the RTRS endorsed training (MI5.1, MI5.2 and MI5.3) and/or must always be in possession of a valid certificate VLOG "Ohne Gentechnik" (MI5.4).

- The trainer must have a Lead assessor Training of 40 hours (IRCA recognized or equivalent).
- The trainer must have performed of at least 5 FRA audits during the last 12 months.
- The trainer must have trainer experiences.



## **Appendix 2.3 GMP+ technical reviewer FSA/FRA**

Position: GMP+ techn	iical reviewer FSA/FRA	
	Applicant	Accepted
Education	- Relevant agricultural, food safety/technology, logistics, or transport at least Bachelor level or at least an equivalent level of experience.  * For the scopes laboratory testing and registered laboratory a relevant laboratory education at least at	See applicant
	Bachelor or an equivalent level or	
Knowledge of	experience.  - HACCP (in accordance with ISO/TS22003 latest version), including the Pre-requisite programs (PRPs); and - Food Safety Management Systems principles; and - Feed legislation  In addition FSA:  * For the scope production and/or trade of feed additives demonstrable knowledge of relevant chemical processes.  * For the scopes laboratory testing and registered laboratory knowledge of the	See applicant
	assessment of laboratory analysis.  In addition FRA: - Knowledge and skill with respect to methods and techniques aimed at the assessment of FSMS and, - Mass Balancing and traceability over the production chain.	
Audit skills	Lead assessor or FSSC Lead assessor training (40 hours minimum, IRCA recognized, or demonstrable equivalent). Not applicable for reviewing TS 3.3 <i>Inland waterway transport and short sea shipping of feed</i> .	See applicant
Review/audit experience	- Experience in assessment of a minimum of 10 GMP+ or equivalent (TS 1.2 <i>Purchase</i> ) audit reports/inspection checklists for the relevant scope or, conduct/attend a minimum of 3 GMP+ or equivalent (TS 1.2 <i>Purchase</i> ) audits/inspections for the relevant scope(s)	Conduct/attend at least 5 audits per scope per year for which the GMP+ technical reviewer has been accepted or assess 5 reports/inspection checklists for the relevant scope. Appendix 3.2 is applicable.
Working experience	- Working experience in the feed / food sector in a relevant position (for example quality assurance, production, consultancy on feed safety management systems).	See applicant





Position: GMP+ te	chnical reviewer FSA/FRA	
	Applicant	Accepted
	* For the scopes laboratory testing and registered laboratory at least 2 years of working experiences in the relevant field of work.	
	Exception:  * For the scope Affreightment of animal feed: Demonstrable knowledge of transport. This knowledge to be obtained by demonstrably taking an internal or external course or demonstrable experience in the carrying out of audits or checks at relevant companies.	
Internal harmonization	Each applicant GMP+ technical reviewer must have demonstrably followed an initial training, focussed on the scope(s) in question.	- For each accepted scope the GMP+ technical reviewer must attend in 8 hours of harmonization to a maximum of 24 hours per calendar year organized by a Certification Body.  * Equivalent certification schemes as laid down in TS 1.2 <i>Purchase</i> and/or Appendix 3.2 are applicable.
Examination	Successfully pas the applicable exams. The GMP+ examination regulation and Appendix 3.1 are applicable.	See applicant



## **Appendix 2.4 GMP+ inspector**

Position: GMP+ Inspector	r				
	Applicant	Accepted			
Education	Successfully finished secondary education or at least an equivalent level of experience.	See applicant			
Knowledge of	<ul> <li>HACCP (in accordance with ISO/TS22003 latest version), including the Pre-requisite programs (PRPs); and</li> <li>Food Safety Management Systems principles; and</li> <li>Feed legislation.</li> </ul>	See applicant			
Inspection experience	- Minimum of 3 inspections as an observer.	At least 5 inspections per year  * Equivalent certification schemes as laid down in TS 1.2 <i>Purchase</i> and/or Appendix 3.2 are applicable.  - If the first requirement cannot be met, 1 witness inspection per scope must be performed by Certification Body. The Certification Body must motivate and documents its decision.			
Working experience	Working experience in the feed/ food sector in a relevant position (for example performance of a LCI).	See applicant			
Internal harmonization	Each applicant inspector must have demonstrably followed an initial training program.	Each inspector must attend at least 8 hours of internal harmonization meeting per calendar year organised by the Certification Body.  * Equivalent certification schemes as laid down in TS 1.2 <i>Purchase</i> and/or Appendix 3.2 are applicable.			
Examination	Successfully pas the applicable exams. The GMP+ examination regulation is applicable.	See applicant			



## **Appendix 2.5 GMP+ coordinator**

	Applicant	Accepted		
Education	Bachelor degree or equivalent level of experience as minimum.	See applicant		
Knowledge of	- HACCP (in accordance with ISO/TS22003 latest version), including the Pre-requisite programs (PRPs); and - Food Safety Management Systems principles; and - Feed legislation.	See applicant		
Audit skills	Lead assessor or FSSC Lead assessor training (40 hours minimum, IRCA recognized, or demonstrable equivalent).	See applicant		
Audit experience	7 GMP+ audits or inspections must be carried out and/or attended, equivalent certification schemes as mentioned in TS 1.2 <i>Purchase</i> are applicable.	Per 12 months 7 GMP+ audits or inspections must be carried out and/or attended, equivalent certification schemes as mentioned in TS 1.2 <i>Purchase</i> and/or Appendix 3.2 are applicable.		
Working experience	Working experience in the feed/ food/responsibility sector in a relevant position (for example quality assurance, production, consultancy on feed safety management systems, laboratory).	See applicant		
Internal harmonization	Each coordinator must have demonstrably followed an initial training.	The coordinator must attend at least 8 hours of harmonization to a maximum of 24 hours per calendar year depending on the number of scopes where the Certification Body in question is accepted for. This cannot be delegated.  * Equivalent certification schemes as laid down in TS 1.2 <i>Purchase</i> and/or Appendix 3.2 are applicable.		
Examination	Not applicable	Not applicable		



## Appendix 3: Table of exemptions

In this table the exemptions regarding examination and acceptation are indicated. Each GMP+ scope listed at the top of table is connected to the relevant scope in the left column indicated by X. The table does not apply visa versa.

## **Appendix 3.1 Table of exemptions Examination and Acceptation**

	Production of compound feed	Production of premixtures	Production of feed additives	Production of feed materials	Trade in feed	Storage and Trans- shipment of feed	Road transport of feed	Affreight- ment	Road transport of feed & Affreightment	Laboratory testing
Production of compound feed - petfood Production of compound feed - GMO controlled	Х									
Production of premixtures - GMO controlled		Х								
Production of feed additives - GMO controlled			Х							
Production of feed materials - petfood Production of feed materials - GMO controlled				Х						
Trade in feed	Х	Х	Х	Х						
Trade in feed - petfood Trade to livestock farms Trade in feed - GMO controlled	Х	Х	х	Х	Х					
Storage and Transshipment of feed	Х	Х	Х	Х						
Storage and Transshipment of feed - GMO controlled	X	X	Х	X		X				
Road transport of feed - GMO controlled							Χ			
Affreightment of short sea shipping Affreightment of inland waterway transport Affreightment of sea transport								Х		

Affreightment of rail transport						]		
Affreightment of road transport						Х		
Antibiotic-free production line(s)	Х	Х	Х	Х				
Antibiotic-free production site	Х	Х	Х	Х				
Dioxin-monitoring in feed for laying hens	Х							
QM-Milch	Х	Х	Х	Х	Х			
RTRS mass balance	Х	Х	Х	Х	Х			
RTRS segregation	Х	Х	Х	Х	Х			
Responsible dairy feed	Х				Х			
Responsible Pig & Poultry feed	Х				Х			
Registered laboratory								Х
Rail transport of feed							Х	

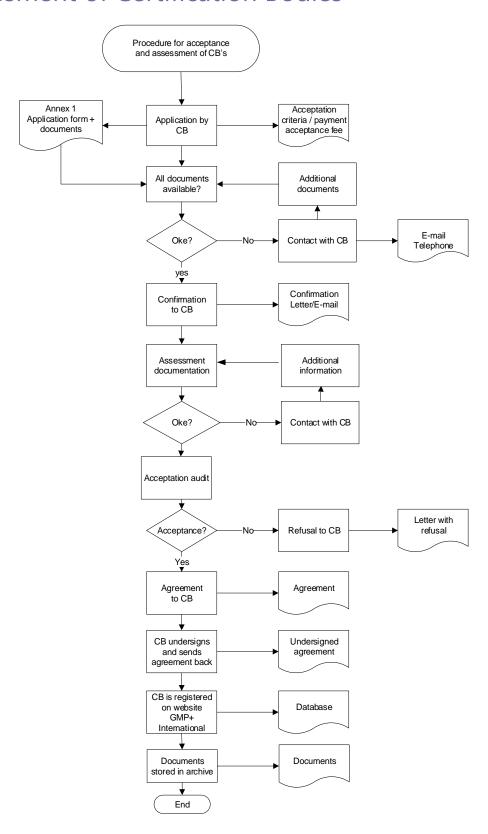
## **Appendix 3.2 Table of exemptions related to audit frequency**

With respect to the retention of acceptance for an auditor/ technical reviewer / inspector insofar the requirement for at least 5 audits per year per scope is concerned, the audits/review/inspection which take place at relevant companies under the accepted certificates as stated in TS 1.2 *Purchase* are applicable in addition the table below may also apply.

An audit for:	Also applies as an audit for:
GMP+ scope:	GMP+ scope:
<ul> <li>Production of compound feed</li> </ul>	<ul> <li>Production of compound feed</li> </ul>
	<ul> <li>Production of premixtures</li> </ul>
	<ul> <li>Production of feed additives</li> </ul>
	<ul> <li>Production of feed materials</li> </ul>
GMP+ scope:	GMP+ scope:
<ul> <li>Production of premixtures</li> </ul>	<ul> <li>Production of compound feed</li> </ul>
·	<ul> <li>Production of premixtures</li> </ul>
	<ul> <li>Production of feed additives</li> </ul>
	<ul> <li>Production of feed materials</li> </ul>
GMP+ scope:	GMP+ scope:
<ul> <li>Production of feed additives</li> </ul>	<ul> <li>Production of compound feed</li> </ul>
	<ul> <li>Production of premixtures</li> </ul>
	<ul> <li>Production of feed additives</li> </ul>
	<ul> <li>Production of feed materials</li> </ul>
Verband Lebensmittel ohne	GMP+ scope:
Gentechnik (VLOG):	<ul> <li>Production of compound feed - GMO Controlled</li> </ul>
	<ul> <li>Production of feed materials - GMO Controlled.</li> </ul>
	<ul> <li>Production of premixtures - GMO Controlled.</li> </ul>
	<ul> <li>Production of feed additives - GMO Controlled.</li> </ul>
	<ul> <li>Trade in feed - GMO Controlled.</li> </ul>
	<ul> <li>Storage and Transshipment of feed -GMO</li> </ul>
	Controlled.
	<ul> <li>Road transport of feed - GMO Controlled.</li> </ul>
Note: the scopes in the left column of	this table apply for the scopes in the right column, but
not vice versa.	



## Appendix 4: Procedure for the Acceptance and **Assessment of Certification Bodies**





## Appendix 5: Application from coordinators GMP+ Feed Certification scheme

To apply use the <u>application form</u> as published on the website of GMP+ International.



## Appendix 6: Assessment criteria

### **Appendix 6.1 Assessment Criteria and Sanctions**

Nonconformities are to be classified on the basis of:

- The general assessment criteria as mention in this Appendix
- The sanctions specified must be imposed as a minimum. GMP+ International is allowed to impose stricter sanctions.

CAR(s) needs to be sent to GMP+ Int. at latest 2 weeks before the deadline. GMP+ International is responsible for making the decision to close the nonconformities.

Classification: Minor nonconformity								
Description Consequences Period to clo								
Certification Bodies     * do not sufficiently describe/implement an element/article	< 5 nonconformities	Comply with the requirements of acceptance	Within max. 6 months (decided by GMP+ Int.)					
of the GMP+ Feed Certification scheme/legislations in the quality management system;  * do not comply with GMP+ International requirements (incidental nature) and the quality of audits is not adversely affected.	≥5 nonconformities	Do not comply with requirements of acceptance	Within 10 weeks					

Classification: Major nonconformity			
Description	Consequences	Period to close	
<ul> <li>* cannot close previous minor nonconformity within the deadline;</li> <li>* structural minor nonconformity and the quality of the audit is not adversely affected;</li> <li>* do not sufficiently describe/implement an element/article of the GMP+ Feed Certification scheme/legislations in the quality management system;</li> <li>* do not comply with comply with GMP+ International requirements (structural nature) and the quality of audits can be adversely affected</li> </ul>	Do not comply with the requirements for acceptance	within 6 weeks	

Classification: Critical nonconformity			
Description	Consequences	Period	
* cannot close previous major nonconformity within the deadline;  * attractive to previous major nonconformity within the deadline;	level.1 GMP+ acceptance can be continued only if the NCR is closed		
at the contract of the contrac	level.2 GMP+ acceptance will be suspended: maximum 3 months		
* do not sufficiently describe/implement an element/article of the GMP+ Feed Certification scheme/legislations in the quality management system and quality of the audit is adversely affected.	level.3 GMP+ acceptance will be terminated	Within 1 week	
Certification Bodies     * it is reasonable to assume that there is case of gross negligence,	level.1 GMP+ acceptance will be suspended: maximum 3 months		
fraudulent actions or economic malpractice;  * do not cooperate in (planning/conducting) compliance audit by GMP+ International.	level.2 GMP+ acceptance will be terminated		

## **Appendix 6.2 - Reference document for description of NCR's for GMP+ accepted Certification Bodies**

Ref.	NCR's Compliance assessment				
	CENTERAL				
1.0	GENERAL  Assessment of ENIC files (if applicable)				
1.0	Assessment of EWS files (if applicable)				
1.1	Assessment of the contract/SLA with critical/non-Critical Locations and/or outsourcing party				
1.2	Non-compliance regarding internal procedures of the CB.				
1.3	Documents / QM-system documentation is not up-to-date.				
1.4	Non-compliance with the accreditation requirement(s)				
	CERTIFICATION AGREEMENT				
2.0	No agreement between the CB and GMP+ Certified Company				
2.1	The agreement is not secured with the right legal entity				
2.2	Non-compliance with the minimum obliged audit time.				
2.3	Non-compliance because of re-calculation				
2.4	The GMP+ requirements as stated in the GMP+ Feed Certification scheme are not secured in the agreement.				
2.5	Non-compliance tender to the companies				
2.6	Non-compliance impartiality				
2.7	Non-compliance regarding key activities				
2.8	Non-compliance in the criteria for calculation of the minimum obliged audit time				
	PLANNING, GMP+ COMPANY DATABASE, ROTATION AUDITORS				
3.0	The GMP+ Company Database is not up to date				
3.1	Non-compliance auditor acceptation documentation				
3.2	Noncompliance with the rotation requirements				
3.3	Non-compliance with the audit frequency.				
3.4	Non-compliance with the minimum obliged internal harmonization hours.				
3.5	Non-compliance with audit planning				
3.6	Non-compliance with audit time reductions				
3.7	Noncompliance auditor acceptation				



Ref.	NCR's Compliance assessment
no.	
	CERTIFICATION, REVIEW
4.0	Incorrect classification of non-conformity.
4.1	Incorrect certification process
4.2	Non-compliance in the review process
4.3	Non-compliance conformity assessment
	GMP+ CERTIFICATES/TEMPORARY ACCEPTANCE
5.0	GMP+ CERTIFICATES/TEMPORARY ACCEPTANCE  Non-compliance in issued certificates/temporary acceptance
5.0	1
5.0	1
5.0 6.0	Non-compliance in issued certificates/temporary acceptance
	Non-compliance in issued certificates/temporary acceptance  ASSESSMENT AND REPORTING

Ref. no.	NCR's Parallel audits / Witness audits / Retrospective analysis			
	CERTIFICATION CRITERIA AND -PROCEDURE			
8.0	Incorrect certification process (CR2.0 and CR3.0)			
	ASSESSMENT AND REPORTING			
9.0	Insufficient assessment and/or reporting of the GMP+ FC requirements (CR 2.0 and CR 3.0)			





## Appendix 6.3 - Reference document for the description of findings at GMP+ Certified Companies established during parallel audits.

Ref.	Findings during parallel audits			
no.	i manigo daring paraner addito			
10.0	Noncompliance with related legal requirements.			
10.1	Noncompliance with certification requirements.			
10.1	Noncompliance with certification requirements.			
	Possible topics:			
	- GMP/ non GMP production;			
	- Proper certified scopes for the site;			
	- Public accessible data requirements.			
10.2	Noncompliance with feed safety management system requirements.			
10.2	reoncompliance with recu surety management system requirements.			
	Possible topics:			
	- Quality policy;			
	- Quality manual;			
	- Document control;			
	- Responsibilities.			
10.3	Noncompliance with personnel requirements.			
10.4	Noncompliance with infrastructure requirements.			
	Possible topics:			
	Prerequisites of the infrastructure.			
10.5	Noncompliance with Recall/ EWS requirements.			
10.6	Noncompliance with HACCP requirements.			
	Possible topics:			
	- HACCP team			
	- Product description			
	- Process description			
	- Control measures			
	- Validation			
10.7	Noncompliance with internal audit requirements.			
10.8	Noncompliance with management review requirements.			
10.9	Noncompliance with complaints requirements.			
10.11	Noncompliance with sale and contract requirements.			
10.11	roncomphance with sale and contract requirements.			
10.13	Nancompliance with elegating requirements			
10.12	Noncompliance with cleaning requirements.			
10.13	Noncompliance with inspection load compartments			



## CR1.0 - Acceptation requirements

Ref.	Findings during parallel audits
no.	
10.14	Noncompliance with maintenance requirements.
10.15	Noncompliance with identification and traceability requirements.
10.16	Noncompliance with purchase requirements.
10.17	Noncompliance with verification of received products requirements.
10.18	Noncompliance with storage requirements.
10.19	Noncompliance with production requirements.
10.20	Noncompliance with delivery/ labelling requirements.
10.21	Noncompliance with transport requirements.
10.22	Noncompliance with monitoring and measuring



## Appendix 7: Responsibility for processing data into the GMP+ database and/or entitlement to publish

Responsible for:	Article	GMP+ Int.	CB/Critical Location
Publication of CB/Critical Location		X	-
Publication of a suspended CB/Critical		X	-
Location			
Publication of the termination of the GMP+		X	-
Feed Certification scheme			
License Agreement			
Publication that GMP+ International will not		X	-
renew the GMP+ Feed Certification scheme			
License Agreement			
Publication that another CB takes over the		X	-
obligations when the original CB is			
suspended			
Inform involved GMP+ Certified Companies		X	-
when the acceptance of a CB is			
withdrawn/not renewed.			
Publication of a suspended Company		Х	-
Publication of the withdrawal of a GMP+		Х	-
Certificate of a Company due to			
noncompliance			

Responsible for:	Article	GMP+ Int.	CB/Critical Location
Processing data of GMP+ Certified Company (visiting address) to be published on			
the public part of the GMP+ portal			
Name of GMP+ Certified Company	4.3.7.1	-	X
Street	4.3.7.1	-	X
Number	4.3.7.1	-	X
Zip code	4.3.7.1	-	X
City	4.3.7.1	-	X
Country	4.3.7.1	-	X
Business legal registration number / number	4.3.7.1	-	Х
Chamber of Commerce			
Phone number	4.3.7.1	-	Х
Fax number	4.3.7.1	-	X
E-mail address	4.3.7.1	-	X
Website	4.3.7.1	-	X
Ship name	4.3.7.1	-	X
EU number	4.3.7.1	-	Х
Processing data of GMP+ Certified Company	y (postal add	ress) to be pub	olished on the
public part of the GMP+ portal	-	_	
PO Box number		-	Х
Zip code		-	X
City		-	Х
Country		-	X



Certification data of GMP+ Certified Company to be partly published on the public part of the GMP+ portal			
GMP+ standard(s)		-	Х
Scope(s)		-	Х
Certified since		-	Х
Start date of certificate		-	Х
End date		-	X
Date suspension (if applicable)		-	X
Date withdrawal (if applicable)		-	X
Reason of suspension (if applicable)		-	X
Date suspension lifted			X
Reason of withdrawal (if applicable)		-	X
Certification status		-	X

Responsible for:	Article	GMP+ Int.	CB/Critical Location	
Certification data of GMP+ Certified Company to be partly published on the public				
part of the GMP+ portal				
Linking/Unlinking of a multisite		X	-	
location/traction unit to head office/principal				
Contact person at GMP+ Certified Company		-	X	
Emergency telephone number (24/7 number)		-	Х	

# Appendix 8: GMP+ Feed Certification scheme License Agreement

This Appendix contains the model of the license agreement which will be used by GMP+ International to define the individual GMP+ Feed Certification scheme License Agreement for each Certification Body as mentioned in article 4 of F 0.1 Rights and Obligations.

The goal of this document is to provide legal framework for all parties involved in the GMP+ Feed Certification scheme, visualized in Appendix 8.4 of this document. Enabling transparency for all parties involved the following main objectives were determined:

- establish a contractual link, starting from GMP+ International up to and including to the GMP+ certified company;
- Compliance assessment toward Certification Bodies can be carried out only by GMP+ International auditors

To establish this, the criteria laid down in this document are based as much as possible on international standards and including the GMP+ requirements.





## **Appendix 8.1: Model agreement**

The following text must be used for the GMP+ Feed Certification scheme License agreement between GMP+ International and an accepted Certification Body.

Beginning (model) agreement:

#### The undersigned:

1. The Dutch law limited liability company GMP+ International BV, with its registered office at the Braillelaan 9 in (2289 CL) Rijswijk (The Netherlands), registered at the Trade Register of the Dutch Chamber of Commerce under number 27364542,

(hereinafter: "GMP+ International"),

and

 [Name of the certification body], with its registered office at the [address, including country], registered at the [official name of local trade register where the entity is registered] under number [],

(hereinafter: "Certification Body"),

(hereinafter collectively referred to as "the Parties")

#### Whereas:

- GMP+ International is the holder of rights to the GMP+ Feed Certification scheme, an international
  certification scheme covering the whole animal feed chain, consisting of the GMP+ Feed Safety
  Assurance Module for the assurance of feed safety and the GMP+ Feed Responsibility Assurance
  Module for the assurance of feed responsibility.
- 2. The GMP+ Feed Safety Assurance Module integrates a variety of feed safety requirements into one module, such as requirements for the feed safety management system, HACCP, product standards, traceability, monitoring, prerequisites programs, chain approach and the Early Warning System. The GMP+ Feed Responsibility Assurance Module incorporates requirements for production, trade, storage & transshipment, affreightment and transport of animal feed products with respect for humans, animals and the environment;
- 3. GMP+ International holds rights to the Licensed IP, (definitions are described in Article 1 below);
- 4. The certification of the GMP+ Feed Certification scheme is not performed by GMP+ International but by licensed Certification Bodies. Companies wishing to obtain GMP+ Feed Certification scheme certification directly approach such a licensed certification body;



- 5. The Certification Body is involved in the certification and is interested in obtaining a License Agreement to perform certification according GMP+ Feed Certification scheme and using the Trademarks, Logos and Documentation;
- 6. GMP+ International is interested in granting the Certification Body a License Agreement, with the aim to allow the Certification Body to certify companies complying with the scope(s) and standard(s) of the GMP+ Feed Certification scheme.

#### Now it is agreed between the Parties as follows:

#### 1. Definitions

For the purpose of this Agreement, the definitions in the GMP+ Feed Certification scheme are applicable. See GMP+ A1 *General Regulations*, GMP+ A2 *Definitions and Abbreviations*, and the applicable GMP+ B and GMP+ C standards.

In addition or notwithstanding, the following terms and definitions shall have the meaning within the framework of this Agreement as set forth below:

- 1.1 **Appendix(es)**: the Appendixes attached to this agreement which form an integral part of this agreement and have been separately initialed by the Parties and in which the agreements between the Parties have been detailed.
- 1.2 **Annual (License) Fee**: an annual (license) fee, consisting of two components: a) a fixed fee, and b) a variable fee depending on the number and kind of activities of the Certification Body, of its Critical Location and the Participants certified by the Certification Body.
- 1.3 Approved Accreditation Body: an accreditation body which is a member of the IAF Multi-Lateral Agreement (MLA) and which has agreed a Standard Accreditation Protocol with GMP+ International.
- 1.4 Critical location: a location of Certification Body conducting one or more key activities (for definition key activities see Chapter 2 of GMP+ A1 General Regulations)
- 1.5 **Database**: a publicly accessible database administered by GMP+ International and actualized by GMP+ International, Certification Bodies and/or Critical Location containing details of the Certification Bodies, Critical Locations and Participants.(See Appendix 1 of the A1)
- 1.6 **Documentation**: any documentation provided to the Certification Body by GMP+ International during the term of the License Agreement, including but not limited to the documents of the GMP+ Feed Certification scheme.
- 1.7 **Licensed IP**: Trademarks, Logos and the Documentation.



- 1.8 Logos: any logo of GMP+ International that is protected or not by a trademark in the countries of activity of the Certification Body, Critical/Non- Critical Location, Outsourcing Party and Participant.
- 1.9 **Measure(s):** has the meaning as defined in Article 8 of GMP+ A1 *General regulations* of the GMP+ Feed Certification scheme.
- 1.10 **Non-Critical location**; a location of a Certification Body conducting no key-activities.
- 1.11 **Outsourcing Party** (conditions): A third party, contracted by a Certification Body by means of a contract or Service Level Agreement (SLA) to preform non-key activities, under liability of the Certification Body.
- 1.12 **Participant Emergency Telephone Number**: a telephone number of the Participant which can be reached 24/7 and 365 days of the year in case of emergencies.
- 1.13 **Sanction(s):** has the meaning defined in Article 8 of GMP+ A1 *General regulations* of the GMP+ Feed Certification scheme.
- 1.14 **Suspension**: the Certification Body is temporarily suspended with a maximum period of 3 months, if GMP+ International rules that the Certification Body's is in breach of this License Agreement and therefore denied the rights arising from this License Agreement. All remaining requirements and obligations are stated in Article 8 of GMP+ A1 *General regulations* of the GMP+ Feed Certification scheme.
- 1.15 **Termination**: To terminate the License Agreement under the conditions as set out in GMP+ Feed Certification scheme.
- 1.16 **Trademarks**: the trademarks licensed to GMP+ International, listed in Appendix 1.7.
- 1.17 **Website**: GMP+ International's website <u>www.gmpplus.org</u>.



#### 2. The GMP+ Feed Certification scheme

- 2.1 Upon signing of this License Agreement, the Certification Body guarantees that it implements and complies with all applicable requirements in the GMP+ Feed Certification scheme. Parties agree that the most recent version of the GMP+ Feed Certification scheme is integral part of this License Agreement.
- The most recent version of the GMP+ Feed Certification scheme is publicly accessible at the Website <a href="www.gmpplus.org">www.gmpplus.org</a> of GMP+ International. Upon request of the Certification Body, GMP+ International shall promptly provide the Certification Body with a free copy of the most recent version of the GMP+ Feed Certification scheme, electronically or otherwise. By signing this License Agreement, the Certification Body expressly agrees to the above ways to take note of the GMP+ Feed Certification scheme and declares that prior to signing this License Agreement it has read and understood these documents.
- 2.3 GMP+ International may at any time amend the GMP+ Feed Certification scheme. GMP+ International shall promptly, electronically or otherwise, notify the Certification Body of amendments to the GMP+ Feed Certification scheme. The certification body must comply with the amendments requirements within a period, as mentioned in the history table of the involved document, unless GMP+ International determines a shorter period for urgent reasons.
- 2.4 In the event that upon signing of this License Agreement the Certification Body does not have the required accreditation from an Approved Accreditation Body, the Certification Body shall ensure that it obtains such accreditation for the relevant GMP+ scopes ultimately within one year from the signing date of this License Agreement and provides GMP+ International with a copy of this accreditation.
  - The Certification Body must ensure that the Critical location has a valid accreditation.
- 2.5 The Certification Body must provide full cooperation to GMP+ International in the accurate implementation of the GMP+ Feed Certification scheme.
- 2.6 GMP+ International is allowed to conduct Compliance Assessments and/or Compliance Audits at the premises of the Certification Body and its, Critical Location(s) as well as at the Participants. The Certification Body and its Critical Location(s) must lend its full cooperation to such Compliance Assessments.
- 2.7 GMP+ International shall, as far as reasonably possible, enable the Certification Body to give advice with respect to proposed changes to the GMP+ Feed Certification scheme via its public consultation procedure.
- 2.8 The Certification Body has right to nominate candidates to represent all Certification Bodies for membership of the GMP+ Subcommittee Certification & Compliance.



- 2.9 The Certification Body can only transfer key activities to Critical Location(s) and non-key activities to Non-Critical location(s) and Outsourcing Parties by means of a Contract or a Service Level Agreement (SLA).
- 2.10 The Certification Body shall keep proper records of Contracts and/or SLA established between the Critical/Non-Critical location(s) and Outsourcing Parties, and shall have these records readily available for assessment by GMP+ International during a Compliance Assessment.
- 2.11 The Certification Body must inform GMP+ International immediately in case a Critical/Non-Critical location, Outsourcing Party is in breach of the Contract and/or SLA.

#### 3. Grant of license

- 3.1 Subject to the terms and conditions of the License Agreement, GMP+ International grants and the Certification Body accepts, a non-exclusive license to certify companies complying with the scope(s) and standard(s) of the GMP+ Feed Certification scheme.
- 3.2 Subject to the terms of the License Agreement, GMP+ International allows the Certification Body to use the GMP+ Logo/Trademarks as further set out in GMP+ A3 GMP+ Logo's and/or Trademarks. The right to use the GMP+ Logo/Trademarks can exclusively be granted by GMP+ International. The right to use the GMP+ Logo/Trademark can be withdrawn if the Certification Body does not comply with the requirements as set out in the GMP+ Feed Certification scheme and fails to remedy the same within the determined timeframe.
- 3.3 The Documentation shall not be published nor modified in any way by the Certification Body.

  The Certification Body has the right to reproduce the Documentation for its own use or, subject to the conditions of the License Agreement, to make it available to the Participants.
- 3.4 The Certification Body has the duty to immediately report to GMP+ International any infringement of the Licensed IP which comes to the notice of the Certification Body.
- 3.5 GMP+ International shall always have the right to sue in respect of infringement of the Licensed IP without the Certification Body, at its own expense and under its sole liability, and to earn exclusively the results of the proceedings.
- 3.6 The Certification Body will perform and document its internal audits (at the Critical location) to be conducted every 12 months.
- 3.7 The Certification Body is responsible to comply with the applicable country legislation were the Certification Body is located.
- 3.8 The Certification Body is responsible for the certification decision.



### 4. Certification and auditing of Companies

- 4.1 The Certification Body shall conclude a unique Certification Agreement with a Company before conducting an Initial (Certification) Audit. During the validity of a GMP+ certificate, the Certification Body must conduct audits at the Participant in accordance with the GMP+ Feed Certification scheme.
- 4.2 After the decision of the Certification Body, the Certification Body/Critical location shall have the right to issue Certificates to Companies for the standards or scopes specified in Appendix 4.1. As a holder of the Certificate the Participant can use the Trademarks, the Logos and the Documentation in accordance with the GMP+ Feed Certification scheme.
- 4.3 The Critical/Non-Critical locations and/or Outsourcing Party may offer GMP+ International's activities to the local market only on behalf of the Certification Body.

  The reports issued to the Participants shall contain the name and address of the GMP+ International accepted Certification Body without the logo of the Critical and/or Non-Critical location, Outsourcing Party. However the report may make reference to the contact details of the Critical and/or Non-Critical location, Outsourcing Party issuing the report in question.
- 4.4 The certificate issued to the Participant shall contain the name and address of the Certification Body without the logo of the Critical Location. However the certificate may make reference to the contact details of the Critical location issuing the certificate in question. The certificate issued shall not create any confusion as to the Certification body.
- 4.5 The Certification Body, Critical/Non-Critical Location and/or Outsourcing Party is obliged to keep proper records of unique- and/or standardized Certification Agreement in the form of a template approved by the Certification Body, and results and reports of the Audits at Participants and is obliged to have these records readily available for Compliance assessment by GMP+ International. In case GMP+ International wants to receive (copies of) records, the Certification Body, Critical/Non-Critical Location and/or Outsourcing Party is obliged making the requested information available to GMP+ International accordingly.
- 4.6 The Certification Body must inform GMP+ International immediately in case a Participant is in breach of the Certification Agreement with respect to conditions and obligations arising from the GMP+ Feed Certification scheme.
- 4.7 The Certification Body must conduct a Recertification Audit prior to the expiration of a GMP+ certificate.
- 4.8 GMP+ International has the right, at any time, to conduct a Compliance Audit of the Participant. or to participate as witness during an Audit. The cost of these audits is at the expense of GMP+ International.



### 5. Confidentiality

- 5.1 The Certification Body must not disclose to third parties any Documentation, or use it for any purpose other than as described herein, unless GMP+ International agrees otherwise prior to disclosure in writing.
- 5.2 Non-disclosure obligations arising from Article 5.1 shall not apply to Documentation the contents of which have become generally known or easily accessible or which have been lawfully revealed by a third party. In case to comply with law and/or legal regulation and/or by orders of a court, governmental agency or accreditation body but always with prior notice to GMP+ International.
- 5.3 The Certification Body must procure that all of its employees and Critical/Non-Critical location and Outsourcing Party and their employees, if any, adhere to the obligations arising out of Article 5.1.
- 5.4 With exception of the cases of authorization mentioned in the GMP+ Feed Certification scheme, GMP+ International shall not disclose to third parties any information of the Certification Body and will not use it for any purpose other than as described herein, unless the Certification Body agrees otherwise prior to disclosure in writing.

#### 6. Fees

- 6.1 Every year, the Certification Body must pay to GMP+ International the Annual (License) Fee. The amounts hereof are specified in the GMP+ C4 document of the GMP+ Feed Certification scheme. The amounts specified therein are agreed net. If VAT is applicable, this shall be borne by the Certification Body. Any local and/or other taxes, governmental fees or dues, if applicable, shall also be borne by the Certification Body.
  - Every year, the Critical Location must pay to GMP+ International a fixed fee as establish in article 2.1 of the GMP+ C4.
- The Annual (License) Fee is determined by GMP+ International. GMP+ International reserves the right to unilaterally adjust the amounts in the GMP+ C4 document of the GMP+ Feed Certification scheme.
- 6.3 The Certification Body/Critical location must keep the GMP+ Company Database up to date as mentioned in Appendix 1 of GMP+ A1 *General Regulations* in order to enable GMP+ International to extract the necessary information required to calculated the Annual License Fee.
- In addition to the Annual (License) Fee, the Certification Body hereby agrees to pay GMP+ International a fee for the examination by GMP+ International of its auditors. The amounts hereof are specified in the GMP+ C4 document of the GMP+ Feed Certification scheme.



The amounts specified therein are agreed net. If VAT is applicable, this shall be borne by the Certification Body. Any local and/or other taxes, governmental fees or dues, if applicable, shall also be borne by the Certification Body.

#### 7. GMP+ Company Database

7.1 The Certification Body must comply with the (applicable) requirements and obligations as stated in Chapter 4 of the GMP+ A1 *General Regulations* which is an integral part of this agreement.

#### 8. Default

8.1 In the event the Certification Body, Critical/Non-Critical location, Outsourcing Party is not or not fully performing one or more of the obligations arising from this Agreement, including but not limited to obligations arising from the GMP+ Feed Certification scheme measures and sanctions as stated in Article 8 of the GMP A1 *General Regulations*, which is an integral part of this agreement, will be imposed.

## 9. Conditions for the GMP+ accepted Certification Body operating with Critical and Non-Critical Location(s).

- 9.1 The Certification Body and its Critical and Non-Critical location must operate under the same management and the same global quality management system.
- 9.2 The Certification Body shall have the means to substantially influence and control the activities of the sites. The Certification Body shall be able to demonstrate that such influence and control is in place and properly working.
- 9.3 The Critical and Non-Critical locations shall offer GMP+ International services to the local market not under their own name and logo, there must always be name and logo of the Certification Body.
- 9.4 The Certification Body maintains the final responsibility for the GMP+ International activities performed by the Critical, Non-Critical location.
- 9.5 Where the Critical location(s) carry out key activities then the GMP+ International accepted Certification Body shall in its contract and/or SLA clearly identify the address of these sites.
- 9.6 The use of Critical and/or Non-Critical locations is only allowed for locations within the same organization and where the Certification Body maintains the legal responsibility for the activities performed and certificates/reports issued by the Critical and/or Non-Critical locations.



The legal responsibility must be demonstrated on the basis of contract/SLA or equivalent legal relationships between the Certification Body and the Critical and/or Non-Critical locations and internal regulations in the organization that further specify these relationships in terms of management and legal responsibilities.

- 9.7 Using Critical and/or Non-Critical locations is possible for all types of local sites such as subsidiaries, branches, agencies, offices, etc. regardless of their legal personality, as long as they carry out clearly defined and relevant activities within the scope(s) of the GMP+ Feed Certification scheme.
- 9.8 Holding the final responsibility as mentioned in article 9.4 for activities performed by the Critical and/or Non-Critical location, implies that the Certification body takes the operational, financial and legal responsibility/liability for activities performed by these locations, and this operational, financial and legal responsibility/liability must be stated in the GMP+ certification agreement with its customers.
- 9.9 In the standardized certification agreement in the form of a template approved by the Certification Body, between the Critical/Non-Critical location and the Company a legal or contractual link to the Certification Body and legal entity name must be included, stating the financial-, operational- and legal matter related to activities performed by the Critical/Non-Critical location are under the liability of the Certification Body.

## 10. Conditions for the GMP+ accepted Certification Body operating with Outsourcing Party

- 10.1 The Certification Body must have a process in which it describes the conditions under which outsourcing (which is sub-contracting to another organization to provide non-key activities on behalf of the Certification Body) may take place.
  - The Certification Body shall have a legally enforceable contract/SLA covering the arrangements, including confidentiality and conflict of interests, with each organization that provides outsourced non-key activities. This can include outsourcing to other non-accepted Certification Bodies.
- 10.1.1 Decisions for granting, maintaining, renewing, extending, suspending or withdrawing certification shall never be outsourced.
- 10.3 The Certification Body shall:
  - a. take responsibility for all non-key activities outsourced to an Outsourcing Party.
  - b. ensure that the Outsourcing Party and the individuals that it uses comply with the requirements of the GMP+ Feed Certification scheme, including competence, impartiality and confidentiality.



- c. ensure that the Outsourced Party and the individuals that it uses, is not involved either directly or through any other employer with an organization to be audited, in such a way that impartiality could be compromised.
- 10.4 The Certification Body must have documented procedures for the qualification and monitoring of all Outsourcing Parties that provide non-key activities for certification and must ensure that records of the competences of auditors and technical reviewers are maintained.
- 10.5 The Certification Body must require external auditors and external technical reviewers to have a written agreement by which they commit themselves to comply with applicable policies and procedures as defined by the Certification Body and the requirements of the GMP+ Feed Certification scheme. The agreement must address aspects relating to confidentiality and to independence from commercial and other interest and must require external auditors and external technical reviewers to notify the Certification Body of any existing or prior association with any organization they may be assigned to audit. The involved external auditors and external technical reviewers must be accepted by GMP+ International.
- 10.6 In the standardized certification agreement in the form of a template approved by the Certification Body, between the Outsourcing Party location and the Company a legal or contractual link to the Certification Body and legal entity name must be included, stating the financial-, operational- and legal matter related to activities performed by the Outsourcing Part are under the liability of the Certification Body.

#### 11. Duration and termination

- 11.1 This Agreement will enter into force on the date of signature by the Parties and will remain in force until 31 December 20XX.
- 11.2 GMP+ International is entitled to terminate this Agreement with immediate effect by written notice to the Certification Body if:
  - a) the Certification Body does not comply with the binding instructions issued by GMP+ International as stated in Chapter 8 of the GMP+ A1 *General Regulations*.
  - b) the Certification Body is not accredited by an Approved Accreditation Body within one year from the signing date of this Agreement;
  - c) the Certification Body does not or not fully perform one or more of the essential of its obligations arising from the GMP+ Feed Certification scheme.
- 11.3 Either Party may terminate this Agreement with immediate effect or not to renew by written notice to the other Party if:
  - either Party commits any breach of any of the provisions of this Agreement and, in the case of a breach capable of remedy, fails to remedy the same within a determined timeframe after receipt of an official letter giving full particulars of the breach and require corrective actions;
  - an encumbrance takes possession or a receiver is appointed over any of the property or assets of that other Party or is declared bankrupt;



- c) that other Party makes any voluntary arrangement with its creditors or becomes subject to an administration order;
- d) that other Party goes into liquidation;
- e) anything which, under the law of any jurisdiction, is analogous to any of the acts or events specified in clauses 11.3 a)-d) of this Agreement; or
- f) that other Party ceases, or threatens to cease, to carry on business.
- 11.4 In the event that a Certification Body terminates or not to renew the License Agreement they are obliged to inform all parties concerned three months in advance to enable all Participants to transfer to another Certification Body.

#### 12. Liability

- 12.1 The Certification Body shall reimburse GMP+ International for the principal amount of a claim for compensation or damages by a Participant and/or a Company directed at GMP+ International insofar as GMP+ International's liability towards the Participant and/or the Company is related to the performance of the Certification Agreement by the Certification Body and subsequently its Critical/Non-Critical location and/or its Outsourcing Party and on the condition that such liability has been established by a final court judgment or final arbitral award.
- 12.2 The indemnity as set out in Article 12.1 does not apply if:
  - 1. A claim directed at GMP+ International is based on acts of GMP+ International itself (including but not limited to use of the binding instruction, a violation by GMP+ International of the GMP+ scheme or external communication by GMP+ International)
  - 2. Or the claim is based on such facts or circumstances as the Certification Body and subsequently its Critical/Non-Critical location and/or its Outsourcing Party did not know or could not have been expected to know and taken into account at the time of the performance of the Certification Agreement.
- 12.3 The indemnity as set out in Article 12.1 applies nonetheless if an act of GMP+ International as set out in Article 12.2 is due to GMP+ International having based its conduct on incorrect information provided by the Certification Body and/or Critical/Non-Critical location and/or its Outsourcing Party (and the Certification Body and/or Critical/Non-Critical location and/or its Outsourcing Party knew or have known that it was incorrect).
- 12.4 In case of a claim within the scope of this Article 12, GMP+ International shall forthwith fully inform the Certification Body and not enter into an amicable settlement with claimant without prior written consent of the Certification Body, on penalty of forfeiture of the rights under this Article 12.
- 12.5 The Certification Body shall at all times be fully liable towards GMP+ International for all acts and omissions by its Critical/Non-Critical location and/or its Outsourcing Party.



12.6 The liability of parties towards each other in connection with performance of this Agreement and this Article 12 is at all times limited to € 250,000 per claim with a maximum of € 1,000,000 per calendar year.

#### 13. Miscellaneous

- 13.1 This Agreement constitutes the complete and full agreement between the Parties.
- 13.2 Any invalidity of individual provisions of this Agreement shall not affect the validity of the remaining provisions of this Agreement. The remaining provisions of this Agreement shall remain in full force and effect and enforceable to the fullest extent permitted by law. Any provisions found to be invalid or unenforceable shall be substituted by such other provisions coming, in a legally permissible way, as close as possible to the economic meaning and intention of such invalid provision.
- 13.3 The Certification Body is not allowed to assign this Agreement in whole or in part or any benefit or interest therein.

#### 14. Applicable law and disputes

- 14.1 This Agreement shall be governed by and construed in accordance with the laws of The Netherlands.
- 14.2 All disputes arising in connection with the Agreement, or further contracts resulting therefrom, shall be heard by the District Court of Rotterdam, having exclusive jurisdiction.

**GMP+ International BV** [Name Certification Body] Roland van der Post [Name of legal representative] Managing Director (Title of legal representative) ..... ..... (Signature) (Signature) Place: Rijswijk Place: ...... ..... Date: Date: ..... .....



Drawn up and signed in duplicate,

## **Appendix 8.2: Trademarks and Logo's**

Trademarks and applicable logo(s) will be added in individual Agreement(s)

- Community Trademark "GMP+ Feed Safety Assurance" No 009547795;
- International Trademark "GMP+ Feed Safety Assurance" No 1037745;
- Benelux Trademark "GMP+ Feed Safety Assurance" No 0876782.
- Community Trademark "GMP+ Feed Responsibility Assurance" No 013946199;
- International Trademark "GMP+ Feed Responsibility Assurance" registration in progress;
- Benelux Trademark "GMP+ Feed Responsibility Assurance" registration in progress.



## **Appendix 8.3: Scopes covered by the GMP+ Feed Certification scheme (License) Agreement**

This document is part of the GMP+ Feed Certification scheme License Agreement which has been entered into force <date><month><year> for the period until <date><month><year> between GMP+ International and

Name of the Certification Body Address Location

The GMP+ Feed Certification License Agreement will relate to the following scopes of the GMP+ Feed Certification scheme with effect from the date specified below:

GMP+ scopes	Accepted / Not accepted
Production of compound feed	,
Production of compound feed	
Production of compound feed – petfood	
Production of compound feed – CN	
Production of compound feed – VN	
Production of compound feed - IP	
Production of premixtures	
Production of premixtures	
Production of premixtures – CN	
Production of premixtures – VN	
Production of premixtures – IP	
Production of feed additives	
Production of feed additives	
Production of feed additives – IP	
Production of feed materials	
Production of feed materials	
Production of feed materials – petfood	
Production of feed materials – VN	



GMP+ scopes	Accepted / Not accepted
Production of feed materials – IP	
Trade	
Trade in feed	
Trade in feed – petfood	
Trade in feed – VN	
Trade in feed – IP	
Trade to livestock farms	
Storage and Transshipment	
Storage and Transshipment of feed	
Transport	
Road transport of feed	
Road transport of feed – IP	
Rail transport of feed	
Inland waterway transport and short sea shipping of feed	
Affreightment	
Affreightment of short sea shipping	
Affreightment of inland waterway transport	
Affreightment of sea transport	
Affreightment of rail transport	
Affreightment of road transport	
Laboratories	
Laboratory testing	
Registered laboratory	
Additional scopes	•
Antibiotics-free production line(s)	
Antibiotics-free production site	



GMP+ scopes	Accepted / Not accepted
Dioxin-monitoring in feed for laying hens	
QM-Milch	
FRA scopes	
RTRS mass balance	
RTRS segregation	
Responsible dairy feed	
Responsible Pig & Poultry feed	
Production of compound feed – GMO controlled	
Production of premixtures – GMO controlled	
Production of feed additives – GMO controlled	
Production of feed materials – GMO controlled	
Trade in feed – GMO controlled	
Storage and Transshipment of feed – GMO controlled	
Road transport of feed – GMO controlled	



## CR1.0 - Acceptation requirements

Valid until: <date><month><year:< th=""><th>&gt;</th></year:<></month></date>	>
GMP+ International B.V.	
Roland van der Post	
Managing Director	
[Name Certification Body]	
[Name of legal representative]	
Managing Director	
(Signature)	



Date:....

## **Appendix 8.4: Contractual links**

#### **GMP+International**

GMP+ Feed Certification Scheme License Agreement



#### GMP+ accepted CB:

- Responsible for accreditation of head office and critical location
- Auditor acceptation, maintenance of qualification, training etc.
- Internal audits
- Responsible for implementation of GMP+ requirements
- Coordinator
- Responsible to comply with country legislation
- Clear governing procedures including delegation of responsibilities.
- Certificate decision

Publishing in the database, in which countries they are active.

Unique Certification Agreement/ Template



Company

Contract or SLA including GMP+ accepted CB tasks and legal responsibilities and tasks and responsibilities of the Critical location as well as functions and competences needed signed by both parties



CB tasks and legal responsibilities and tasks and responsibilities of the Non-Critical location as well as functions and competences needed signed by both parties.

Contract or SLA including GMP+ accepted CB tasks and legal responsibilities and tasks and responsibilities of the Outsourcing Party as well as functions and competences needed signed by both parties.

## **Critical location** (according to ISO17011 article 7.5.7):

Performing one or more of the following key activities

- Policy formulation
- Process and/or procedure development
- Contract review
- Review
- Approval and decision on the results of conformity assessments(certification decision excluded)

Must be audited by GMP+ Int. at least once per 2 years

Should be linked with the accepted CB in the GMP+ database and visible on the public part of the GMP+ database.

#### Non-Critical location

Performing activities excluded the key activities

Does not need to be audited by GMP+
Int

Not linked to the accepted CB in the database and also not visible on the public part of the GMP+ database

Outsourcing Party (as stated in ISO 17021 art. 7.5)

Performing activities excluded the key activities

Does not need to be audited by GMP+ Int.

Not linked to the accepted CB in the database and also not visible on the public part of the GMP+ database.

## Certification agreement template

(including legal and/or contractual link to GMP+ accepted CB and legal entity name. Stating that financial, operational, an legal matters related to activities performed by the Critical location are under the legal responsibility/liability of the CB.)



Certification agreement template (including legal and/or contractual link to GMP+ accepted CB and legal entity name. Stating that financial, operational, an legal matters related to activities performed by the Non-Critical location are under the legal responsibility/liability of the CB.)

Certification agreement template (including contractual link to GMP+ accepted CB and legal entity name. Stating that financial, operational, an legal matters related to activities performed by the Outsourcing Party are under the legal responsibil-

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ity/liability of the CB.)

#### Company





At GMP+ International, we believe everybody, no matter who they are or where they live, should have access to safe food.

#### **GMP+ International**

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The Netherlands

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#### Disclaimer

This publication was established for the purpose of providing information to interested parties with respect to GMP+-standards. The publication will be updated regularly. GMP+ International B.V. is not liable for any inaccuracies in this publication.

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