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DE

GMP+ Feed Certification scheme

GMP+ A5 Lizenzvertrag zum *GMP+ Feed Certification scheme*

Fassung: 15. Juli 2017

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Feed for Food

Revisionsinformationen zu diesem Dokument

Revisions-Nr./ Datum der Genehmigung	Änderung	Bezieht sich auf	Implementieru ng spätestens am
0.0 / 02.2015	Neues Dokument	Gesamtes Dokument	10.02.2015
1.0 / 11-2016	Umfassende redaktionelle Verbesse- rungen und Anpassungen an gesetzli- che Anforderungen. Ersetzung des Begriffs "Schema" durch "Annex".	Gesamtes Dokument	15.07.2017
	Aufnahme allgemeiner Erwägungen in die Einführung.	Seite 6	15.07.2017
	Anpassungen, Erweiterung und Ent- fernung von Begriffen (welche in GMP+ A1 genannt werden).	Abschnitt 1 Definitionen	15.07.2017
	Critical location muss akkreditiert sein.	Abschnitt 2.4	15.07.2017
	Übertragung von Tätigkeiten der Zerti- fizierungsstelle.	Abschnitt 2.9	01.10.2017
	Entfernung des Nachunternehmerver- trags.	Abschnitt 2.12 & 2.13 & 2.15 & Übersicht 1.18	15.07.2017
	Entfernung der Anforderungen an die Verwendung des GMP+-Logos, da diesbezüglich auf GMP+ A3 <i>GMP+- Logos und/oder -Markenzeichen</i> ver- wiesen wird.	Kapitel 3	15.07.2017
	Die Zertifizierungsstelle muss bei der <i>Critical location</i> interne Audits durch- führen.	Abschnitt 3.6	01.01.2018
	Die Zertifizierungsstelle muss die ein- schlägige Gesetzgebung des jeweili- gen Landes befolgen.	Abschnitt 3.7	15.07.2017
	Die Zertifizierungsstelle muss die Zer- tifizierungsentscheidung treffen.	Abschnitt 3.8	15.07.2017
	(Non) Critical location, Outsourcing Party darf im Namen der Zertifizie- rungsstelle GMP+-Leistungen anbie- ten.	Abschnitt 4.3	01.10.2017
	Entfernung des Muster- Zertifizierungsvertrags	Ehemaliger Abschnitt 4.3 & Übersicht 1.17	15.07.2017
	Ausschließlich Kontaktangaben der <i>Critical location</i> dürfen im GMP+-Zerti- fikat genannt werden.	Abschnitt 4.4	15.07.2017

Revisions-Nr./ Datum der Genehmigung	Änderung	Bezieht sich auf	Implementieru ng spätestens am
	Vertraulichkeit gilt auch für (non) Criti- cal location and Outsourcing Party.	Abschnitt 5.3	15.07.2017
	Kosten gelten auch für Critical loca- tions.	Abschnitt 6.1	01.01.2018
	Hinzufügung von Anforderungen an Zertifizierungsstellen, die mit <i>Critical and Non-Critical location(s)</i> arbeiten.	Kapitel 9	01.01.2018
	Anforderungen an Zertifizierungsstel- len, die mit einer <i>Outsourcing party</i> ar- beiten.	Kapitel 10	15.07.2017
	Hinzufügung von <i>Critical/Non-critical location</i> und <i>Outsourcing Party</i> zum Haftungsartikel.	Kapitel 12	15.07.2017
	Entfernung der Bestimmungen zum Muster-GMP+-Zertifizierungsvertrag.	Übersicht 1.17	15.07.2017
	Entfernung der Bestimmungen zum Muster-Nachunternehmervertrag.	Übersicht 1.18	15.07.2017
	Aktualisierung der Tabelle mit Stan- dards/Anwendungsbereichen, die vom <i>GMP</i> + <i>Feed Certification scheme</i> (Li- zenz-) Vertrag gedeckt werden.	Anlage 3.1	15.07.2017
	Grafik mit der vertraglichen Kopplung in der gesamten Kette von GMP+ In- ternational bis zum Teilnehmer.	Anlage 1.4	15.07.2017

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1 EINFÜHRUNG

1.1 Allgemeines

Das *GMP*+ *Feed Certification scheme* ist im Jahr 1992 von der niederländischen Futtermittelindustrie als Antwort auf diverse mehr oder weniger schwere Zwischenfälle mit Verunreinigungen in Einzelfuttermitteln initiiert und entwickelt worden. Es war zunächst nur als nationales System konzipiert worden, hat sich jedoch zu einem internationalen System entwickelt, das von GMP+ International in Zusammenarbeit mit diversen internationalen interessierten Parteien verwaltet wird.

Obwohl das *GMP*+ *Feed Certification scheme* aus der Perspektive der Unbedenklichkeit von Futtermitteln entstanden ist, wurde im Jahr 2013 der erste Standard für Futtermittelnachhaltigkeit veröffentlicht. Zu diesem Zweck sind zwei Module entwickelt worden: *GMP*+ *Feed Safety Assurance* (das sich auf die Futtermittelsicherheit konzentriert) und *GMP*+ *Feed Responsibility Assurance* (das auf nachhaltige Futtermittel abzielt).

<u>GMP+ Feed Safety Assurance</u> ist ein vollständiges Modul mit Normen zur Gewährleistung unbedenklicher Futtermittel auf allen Stufen der Futtermittelkette. Die nachweisliche Gewährleistung der Futtermittelsicherheit ist in vielen Ländern und Märkten eine unabdingliche Voraussetzung für den Verkauf in der Futtermittelbranche, und die Teilnahme am GMP+ FSA Modul kann dafür als ausgezeichnetes Instrument dienen. Auf der Grundlage der Bedürfnisse aus der Praxis sind diverse Komponenten in den GMP+-FSA-Normen integriert worden, etwa die Anforderungen an ein "feed safety management system" (Sicherheitsmanagementsystem für Futtermittel) und an die Anwendung von HACCP-Prinzipien sowie Elemente wie die Rückverfolgbarkeit, die Überwachung, das Programm mit Grundbedingungen, der Kettenansatz und das Early Warning System.

Mit der Entwicklung des <u>"GMP+ Feed Responsibility Assurance</u>"-Moduls entspricht GMP+ International den Bedürfnissen der GMP+-Teilnehmer. Von der Futtermittelwirtschaft wird gefordert, dass sie auf verantwortungsvolle Art und Weise arbeitet. Dies betrifft beispielsweise die Beschaffung von Erzeugnissen wie Soja und Fischmehl, die mit Respekt gegenüber Menschen, Tieren und der Umwelt hergestellt und vertrieben werden sollen. Zum Nachweis eines nachhaltigen Herstellungsprozesses und Handels kann ein Unternehmen eine Zertifizierung für die *GMP*+ *Feed Responsibility Assurance* beantragen. GMP+ International wird dem Bedürfnis aus dem Markt mit Hilfe einer unabhängigen Zertifizierung gerecht.

Gemeinsam mit den GMP+-Partnern definiert GMP+ International auf transparente Art und Weise Anforderungen im *Feed Certification scheme*. Zertifizierungsstellen sind in der Lage, die GMP+-Zertifizierung auf unabhängige Art und Weise durchzuführen.

GMP+ International unterstützt die GMP+-Teilnehmer mit praktischen und nützlichen Informationen. Dies erfolgt mit Hilfe einer Reihe von Leitfäden sowie mit Hilfe von Datenbanken, Rundschreiben, Fragen- und Antwortenkatalogen und Seminaren.

1.2 Aufbau des GMP+ Feed Certification scheme

Die Dokumente innerhalb des *GMP*+ *Feed Certification scheme* gliedern sich in eine Reihe Serien. Die nächste Seite enthält eine schematische Wiedergabe des Inhalts des *GMP*+ *Feed Certification scheme*:



Alle diese Dokumente sind auf der Internetseite von GMP+ International (www.gmpplus.org) zu finden.

Das vorliegende Dokument wird als GMP+ A5 *Lizenzvertrag zum GMP*+ *Feed Certification scheme* bezeichnet.

1.3 Anwendungsbereich und Anwendung dieses Standards

Dieser Standard enthält den Mustervertrag zur Lizenzierung, der von GMP+ International verwendet wird, um die einzelnen Lizenzverträge zum *GMP*+ *Feed Certification scheme* für jede Zertifizierungsstelle gemäß Artikel 3.2 von GMP+ A1 Allge*meines Reglement* zu definieren.

1.4 Allgemeine Erwägungen und Hintergrund

Dieses Dokument hat den Zweck, allen Parteien, die am *GMP*+ *FC scheme* beteiligt sind (gemäß der Visualisierung in Anlage 4), einen juristischen Rahmen zu bieten. Zur Gewährleistung der Transparenz und Deutlichkeit in Richtung aller beteiligten Parteien wurden folgende Ziele festgelegt:

- Verwirklichung einer vertraglichen Kopplung ab GMP+ International bis zum Teilnehmer.
- Ein *Compliance assessment* kann ausschließlich von Auditoren mit einer GMP+-Zulassung durchgeführt werden.

Um dies zu verwirklichen, wurden die in diesem Dokument enthaltenen Anforderungen möglichst weitgehend auf der Grundlage internationaler Standards erstellt, wobei jedoch auch immer darauf geachtet wurde, diese weitestgehend den GMP+-Anforderungen entsprechen zu lassen.

2 Mustervertrag

2.1 GMP+ Feed Certification Scheme License Agreement

Der nachstehende Text wird für den Lizenzvertrag zum *GMP*+ *Feed Certification Scheme* zwischen GMP+ International und einer zugelassenen Zertifizierungsstelle verwendet.

Anfang des (Muster-) Vertrags:

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

2. [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:

- 1. 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);
- 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+ FC 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 **Annex(es)**: the annexes 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 Annex 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+ FC 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+ FC Scheme.

- 1.10 **Non-Critical location**; a location of a Certification Body conducting no keyactivities.
- 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+ FC 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+ FC scheme.
- 1.15 **Termination**: To terminate the License Agreement under the conditions as set out in GMP+ FC scheme.
- 1.16 **Trademarks**: the trademarks licensed to GMP+ International, listed in Annex 1.7.
- 1.17 **Website**: GMP+ International's website www.gmpplus.org.

2. The GMP+ FC 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+ FC scheme. Parties agree that the most recent version of the GMP+ FC scheme is integral part of this License Agreement.
- 2.2 The most recent version of the GMP+ FC scheme is publicly accessible at the Website www.gmpplus.org 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+ FC scheme, electronically or otherwise. By signing this License Agreement, the Certification Body expressly agrees to the above ways to take note of the GMP+ FC 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+ FC scheme. GMP+ International shall promptly, electronically or otherwise, notify the Certification Body of amendments to the GMP+ FC 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+ FC 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+ FC 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+ FC 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+ FC 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 Annex 4.1. As a holder of the Certificate the Participant can use the Trademarks, the Logos and the Documentation in accordance with the GMP+ FC 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 guestion.
- 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+ FC 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+ FC 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+ FC 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.

- 6.2 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+ FC scheme.
- 6.3 The Certification Body/Critical location must keep the GMP+ company database up to date as mentioned in annex 1 of GMP+ A1 *General Regulations* in order to enable GMP+ International to extract the necessary information required to calculated the Annual License Fee.
- 6.4 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+ FC 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+ FC 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+ FC 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.

- 10.2 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+ FC 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+ FC 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+ FC scheme.
- 11.3 Either Party may terminate this Agreement with immediate effect or not to renew by written notice to the other Party if:
 - a) 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;
 - b) 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 should 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 \in 250,000 per claim with a maximum of \in 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.

Drawn up and signed in duplicate,

GMP+ International BV

Johan den Hartog Managing Director [Name Certification Body]

[Name of legal representative] (Title of legal representative)

.....

.....

Place: Rijswijk

(Signature)

Date:....

Place:....

.....

Date:....

Übersicht 1.7: Handelsmarken / Logos

Die Markenzeichen und das/die gültige/n Logo(s) werden in einem separaten Vertrag bzw. separaten Verträgen hinzugefügt.

- 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" Eintragung wird durchgeführt;
- Benelux Trademark "GMP+ Feed Responsibility Assurance" *Eintragung wird durchgeführt*;

Anlage 3.1: Standards/Anwendungsbereiche, die dem GMP+ Feed Certification scheme (Lizenz) Agreement unterliegen

Dieses Dokument ist Bestandteil des **GMP+ Feed Certification scheme License Agreement**, das am <Tag><Monat><Jahr> in Kraft getreten ist und bis zum <Tag><Monat><Jahr> zwischen GMP+ International und der nachstehenden Zertifizierungsstelle gilt.

:

:

:

Name der Zertifizierungsstelle Adresse Standort

Der Lizenzvertrag bezieht sich auf die folgenden Standards und Anwendungsbereiche des *GMP*+ *FC scheme* ab dem nachstehend angegebenen Datum:

GMP+ activity ¹	Accepted /
	Not accepted
Scope: Production of compound feed	
GMP+ B1 Production, trade and services / GMP+ B1.2	
Scope: Production of premixtures	
GMP+ B1 Production, trade and services / GMP+ B1.2	
Scope: Production of feed material	
GMP+ B1 Production, trade and services/ GMP+ B1.2	
GMP+ B2 Production of Feed Ingredients	
Scope: Production of feed additives	
GMP+ B1 Production, trade and services/ GMP+ B1.2	
GMP+ B2 Production of Feed Ingredients	
Scope: Trade in animal feed	
CMD, D2 Trade collection and starses & transphinment	
GMP+ B3 Trade, collection and storage & transshipment GMP+ B3.2 Trade to livestock farm	
Scope: Storage & transshipment	
GMP+ B3 Trade, collection and storage & transshipment	
Scope: transport of own products	
GMP+ B3 Trade, collection and storage & transshipment	
Scope: Transport of animal feed, road transport	
CMD. D4 Transport score read transport	
GMP+ B4 Transport, scope road transport Scope: Transport of animal feed, rail transport	
GMP+ B4 Transport, scope rail transport	
Scope: Transport of animal feed, short sea shipping and inland water-	
way Transport	
GMP+ B4.3 Short Sea Shipping and Inland Waterways Transport	

¹ Can be modified in case of deleted or new standards / scopes

GMP+ activity ¹	Accepted /
Occurrent Affrecials (and of internal under an and the second second	Not accepted
Scope: Affreightment of inland waterways transport	
GMP+ B4 Transport, scope affreightment	
Scope: Affreightment of short sea shipping	
GMP+ B4 Transport, scope affreightment Scope: Affreightment of Sea transport	
GMP+ B4 Transport, scope affreightment	
Scope: Affreightment of Rail transport	
CMD: D4 Transport scope offreightment	
GMP+ B4 Transport, scope affreightment Scope: Affreightment of Road transport	
GMP+ B4 Transport, scope affreightment	
Scope: Feed material cultivation	
GMP+ B6 Feed materials cultivation	
Scope: Production of and trade in pet food	
GMP+ B8 Production of and trade in pet food	
Scope: Laboratory testing	
GMP+ B10 Laboratory testing	
Scope: Antibiotics free feed	
CMD, DON NILA Antibiotics from food	
GMP+ BCN-NL1 Antibiotics free feed Scope: Dioxin-monitoring in laying hens (rearing) feeds	
Scope. Dioxin-monitoring in laying hens (rearing) leeus	
GMP+ BCN-NL 2 dioxin-monitoring in laying hens (rearing) feeds	
Scope: Supplier assurance for China	
GMP+ CN-1 Supplier assurance for China	
Scope: Scope: Production of compound feed	
GMP+ BCN-CEE Additional requirements for Central & Eastern Europe	
Scope: Scope: Production of premixtures	
GMP+ BCN-CEE Additional requirements for Central & Eastern Europe	
GMP+ BCN-DE1 QM Milch	
Cooper Dreduction of compound for d	
Scope: Production of compound feed	
GMP+ BCN-IT specific requirements for Italy	
Scope: Production of premixtures	
CMD, BCN IT aposition requirements for Italy	
GMP+ BCN-IT specific requirements for Italy Scope: Production of feed materials	
GMP+ BCN-IT specific requirements for Italy	

GMP+ activity ¹	Accepted / Not accepted
Scope: Trade in compound feed	
Trade in premixtures	
Trade in feed materials	
GMP+ BCN-IT specific requirements for Italy	
Scope: Road transport of animal feed	
GMP+ BCN-IT specific requirements for Italy	
Scope: RTRS Mass Balance	
GMP+ MI101 Production and trade of RTRS soy	
Scope: RTRS Segregation	
GMP+ MI101 Production and trade of RTRS soy	
Scope: Responsible pig & poultry feed	
GMP+ MI102 Responsible pig & poultry feed	
Scope: Responsible dairy feed	
GMP+ MI103 Responsible dairy feed	
Date of implementation: <date><month><year></year></month></date>	

Valid until: <date><month><year>

GMP+ International B.V.

Johan den Hartog Managing Director

[Name Certification Body]

[Name of legal representative] Managing Director

..... (Signature)

.....

Date :

GMP+ A5 *Lizenzvertrag zum GMP*+ *Feed Certification scheme* Fassung: 15. Juli 2017

Anlage 4



GMP+ Feed Certification Scheme License Agreement

Contract or SLA

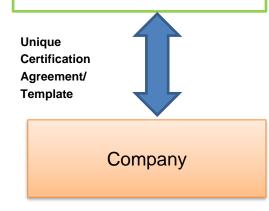
including GMP+ accepted CB tasks and legal responsibilities and tasks and responsibilities of the Critical location as well as functions and competences needed signed by both parties



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.



Contract or SLA including GMP+ accepted 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

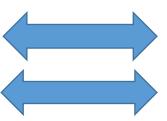
Performing activities excluded the key activities <u>Does not need to be audited by GMP+</u> <u>Int.</u> <u>Not linked to the accepted CB in the da-</u> <u>tabase and also not visible on the public</u> <u>part of the GMP+ database</u>

Outsourcing Party (as stated in ISO 17021 art. 7.5) Performing activities excluded the key activities

> Does not need to be audited by <u>GMP+ Int.</u> 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 responsibility/liability of the CB.) Company