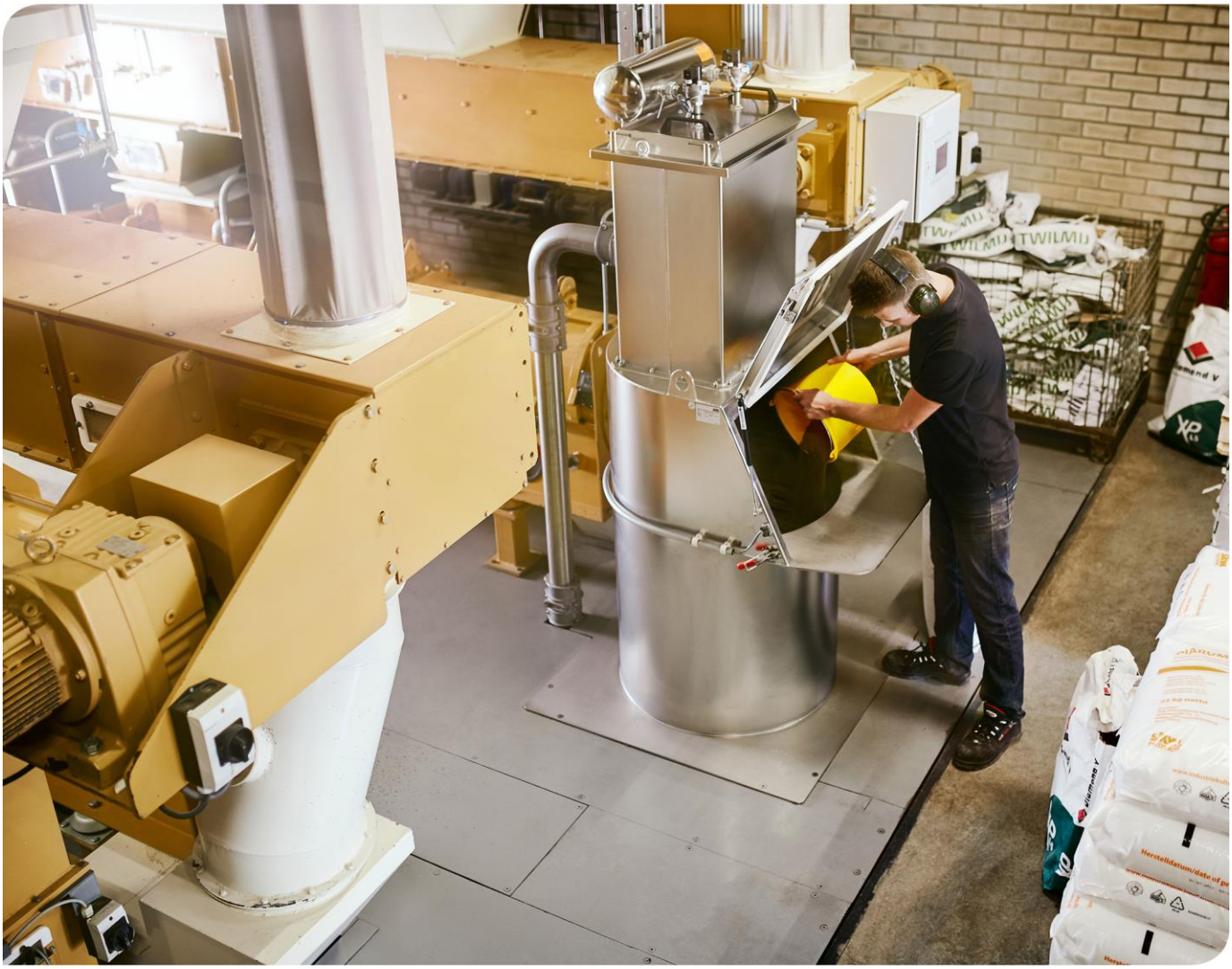
GMP+ International



General Regulation

GMP+ A 1

Version EN: 15 July 2017

GMP+ Feed Certification scheme

Feed Safety Worldwide

gmpplus.org

History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0 / 09-2010	Previous versions can be found in History		01.01.2011
0.1 / 09-2011			01.10.2012
0.2 / 03-2012			01.03.2013
0.3 / 10-2013			01.03.2014
0.4 / 12-2014	Profound editorial and juridical improvements	Entire document	01.01.2015
	New definitions and harmonization definition with ISO 17021 and ISO 22003	2	01.01.2015
	Introducing possibility under certain condition of Subcontractor of a Certification Body	3, 7.7	01.01.2015
	Minimum requirements for agreement between Certification Body and feed Company about certification	3.2	01.01.2015
	Authorization of auditor to verify feed activities certified under other certification scheme	4.1e	01.01.2015
	Basic regulation about the use of the GMP+ FRA logo and adaption of use collective logos due to transfer of product certification towards feed safety management system certification	6	01.01.2016
	Introduction stricter rules for use of GMP+ FSA for GMP+ FRA logo	6.1b	01.01.2016
	Introduction of model – agreement for acceptance of a Certification Body by GMP+ International (GMP+ A5)	7.4	01.01.2015
	Introduction criteria of assessment and decision of Certification Body on objective evidence	7.13	01.01.2015
	Obligation for Participants to update 24/7 emergency phone number and other items in GMP+ Company database	8.3	01.01.2015
	Obligation for Participant to cooperate in case of audits by GMP+ International	8.4	01.01.2015
	Adaption of the basic obligation about an EWS notification	8.7	01.01.2015
	Authorization of competent authority to share inspection results with GMP+ International	8.8	01.01.2015

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
	Improvement of the stipulation about authorizing GMP+ International to inform competent authorities about non-compliance of legal requirements	9.7	01.01.-2015
	Adaptation of the rules for transfer of a certified Company from one to another Certification Body according the international standards of the International Accreditation Forum (IAF)	12	01.01.2015
0.5 / 02-2015	Some editorial corrections	Entire document	10.02.2015
	Addition paragraph	9.8	
	Addition final implementation date	History table	
	Addition address GMP+ International	2	
1.0 /	Use of GMP+ expressions and collective logo is implemented in GMP+ A3	6.1	01.08.2015
1.1 / 11-2016	Profound editorial and juridical improvements	Entire document	15.07.2017
	Expansion of Terminology	Chapter 2	15-07-2017
	Merging chapter 3 & 4	Chapter 3	15.07.2017
	Expansion and merging all requirements for Data/publicly accessible register in one chapter	Chapter 4	15.07.2017
	Transfer of requirements of the GMP+ Logo's/Trademarks	Chapter 5	15.07.2017
	No additional requirements to be determined by CB.	Art. 6.12	15.07.2017
	Requirements of Extraordinary Events for CB's	Art. 6.13	15.07.2017
	Withdrawal of acceptance CB consequences for Participants (adaptation)	Art. 7.4	15.07.2017
	Participants allows GMP+ International to share nonconformities regarding legal requirements related to feed safety	Art. 7.6	15.07.2017
	Requirements of Extraordinary Events for Participants	Art. 7.7	15.07.2017
	Merging the measures and sanction for CB's and Participants in one chapter	Chapter 8	15.07.2017
	Transfer chapter 12 to 9 Liability (transfer from article 9.8)	Chapter 9 Chapter 12	15.07.2017
	Responsibility for GMP+ database	Annex 1	15.07.2017

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1 Introduction

1.1 General

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

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

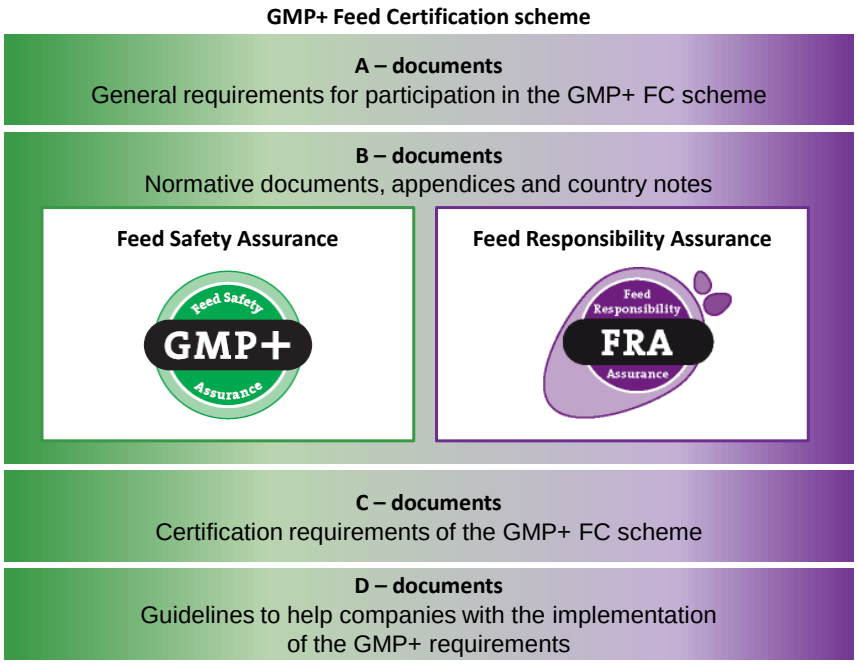
GMP+ Feed Safety Assurance is a complete module with standards for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA module can facilitate this excellently. Based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

With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ Participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a Company can get certified for the GMP+ Feed Responsibility Assurance. GMP+ International facilitates via independent certification the demands from the market.

Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification Bodies are able to carry out GMP+ certification independently.
GMP+ International supports the GMP+ Participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

1.2 Structure of the GMP+ Feed Certification scheme

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



All documents are available on the website of GMP+ International (www.gmp-plus.org).

1.3 Scope and application

This document is referred to as GMP+ A1 General Regulations and is part of the GMP+ FC scheme.
The GMP+ A1 *General Regulations* contain the general regulations regarding certification procedure, public register, and use of collective logo, duties of participants, and other general requirements. The GMP+ A1 *General Regulations* are applicable to all other GMP+ FC standards and forms an integral part of the GMP+ FC scheme and all agreements.

2 Terminology

Unless otherwise defined herein, capitalized terms must have the meanings ascribed to them in the GMP+ FC scheme:

Article	:	An Article of the GMP+ A1 *General Regulations*.
Audit	:	One of the following audits: Initial(Certification) Audit; Surveillance Audit; Recertification Audit; Additional audits. Consisting of but not limited to a planned and documented activity performed by a GMP+ Auditor to determine by investigation, taking samples and laboratory testing, examination, or evaluation of objective evidence, the adequacy and compliance with established procedures, or applicable requirements and the effectiveness of implementation of the requirements of the applicable standard(s) of the GMP+ FC Scheme. Or a compliance audit consisting of but not limited to a planned and documented activity performed by a GMP+ International Auditor to determine by investigation, taking samples and laboratory testing, examination, or evaluation of objective evidence, in order to review comprehensively the Certification Body's or Critical-/Non-Critical and/or Outsourcing Party compliance with the GMP+ FC scheme.
Business Location	:	Any unit of a Participant distinguishable by location or function where activities covered by a scope of the GMP+ FC scheme are carried out.
Certification Criteria	:	Assessment and certification criteria as stipulated in the GMP+ FC scheme.
Chain Oriented Audit (COA)	:	A Compliance Audit at a participant and its certified supplier(s) and / or certified client(s) with a focus on specific requirements of the GMP+ FC scheme.
Company	:	A Company as defined in GMP+ A2 *Definitions and Abbreviations.*
Compliance Assess-ment	:	Assessment of a Certification Body or Critical location to assess compliance with all requirements of the GMP+ FC scheme, which may consist of but is not limited to the following assessment tools: - Desk assessment; - Compliance Audit; - Retrospective analysis; - Overall analysis; - Examination of auditors; - Report assessment.

Compliance Audit	:	An Audit, conducted by a GMP+ International Auditor, at Participants as well as the office(s) of a Certification Body or Critical location in order to review comprehensively the Certification Body's or Critical location compliance with the GMP+ FC scheme, as further set out in GMP+ C11 *Method of and criteria for compliance of Certification Bodies/Critical location,* or A Special Audit, conducted by a GMP+ Auditor at the Participant in order to follow up Major nonconformity(ies), or, An audit conducted by an accepted Certification Body at a Participant.
Contract or Service Level Agreement (SLA)	:	A contract or SLA signed by both parties between the Certification Body and Critical Location or Non-Critical location or Outsourcing Party.
Critical location	:	A location of a Certification Body conducting one or more key activities.
Extraordinary Events	:	In an extraordinary event people are faced with circumstances that go beyond our control, as further described in Article 6.13 and 7.7 of this document. Such circumstances affect normal business environment and thus proper maintenance of accreditation and certification requirements .
GMP+ Accepted Certification Body	:	The legal entity accepted and licensed by GMP+ International for certification of Companies based on the GMP+ FC scheme.
GMP+ Auditor	:	An auditor accepted in accordance with the GMP+ FC Scheme by GMP+ International acting under the responsibility of an accepted Certification Body.
GMP+ International Auditor	:	A qualified auditor acting on behalf of GMP+ International.
GMP+ Certificate	:	A standard format document issued by the Certification Body which states that the feed safety management system, implemented and operated on a particular Business Location of a Company, assures compliance with the GMP+ standard(s). This statement is based on evidence that there is compliance with the requirements in the GMP+ FC scheme.
GMP+ Certification Agreement	:	A written agreement concluded between a Certification Body (Critical/Non-Critical location, Outsourcing Party if applicable) and a(n applicant) Participant in conformity with all requirements as set out in the GMP+ FC scheme can be divided in two categories: 1. A Unique contract signed between Certification Body and individual Companies

		2. A standardized contract in the form of a template approved by the Certification Body to be signed by the Certification Body and/or Critical/Non-Critical location, Outsourcing Party and the individual Company.
GMP+ Company Database	:	A database containing relevant information administered by GMP+ International.
GMP+ FC scheme	:	The GMP+ Feed Certification scheme, an international certification scheme covering the whole animal feed chain developed and administered by GMP+ International, consisting of the GMP+ Feed Safety Assurance Module and the GMP+ Feed Responsibility Assurance Module, and set down in the basic documents (A documents), the normative standards (B-documents) and the associated appendices (BA documents) and, if applicable, the Country Notes (BCN documents) as well as the rules of certification containing the requirements for certification and compliance (C documents).
GMP+ Feed Certification scheme License Agreement .	:	A written agreement concluded between GMP+ International and a Certification Body, based on GMP+ A5 *Feed Certification Scheme License Agreement.*
GMP+ International	:	GMP+ International B.V., with offices at Braillelaan 9, 2289CL in Rijswijk, The Netherlands (Chamber of Commerce registration number 27364542).
Initial (Certification) Audit	:	The first audit conducted by the Certification Body at a Company to ascertain that the Company's feed safety management system as well as the application in the daily operations complies with the applicable requirements in the GMP+ FC scheme.
Key-activities	:	Policy formulation, process and/or procedure development, establishing standardized contract, contract review, review, approval and decisions (certification decision excluded) on the result of conformity assessment.
Non key-activities	:	Activities of a Certification Body excluding the key-activities.
Non-Critical location	:	A location of a Certification Body conducting no key-activities.
Objective evidence	:	Any documented information of facts that can be proved through analysis, measures, observations and other such means of research.
Participant	:	A Company holding a valid GMP+ certificate.
Recertification Audit	:	An Audit conducted by a Certification Body at a Participant to ascertain compliance with the GMP+ FC scheme to facilitate the decision on re-certification.

Repeat Audit	:	An additional Audit conducted by a Certification Body at a Participant to ascertain compliance with the GMP+ FC scheme.
Surveillance Audit	:	An Audit conducted by the Certification Body at a Participant to ascertain compliance with the GMP+ FC scheme.
Stricter Supervision	:	Audits conducted by a Certification Body at a Participant, carried out monthly for at least 3 and at most 6 months as stated in the GMP+ FC scheme.
Outsourcing Party	:	A third party, contracted by a Certification Body by means of a contract or Service Level Agreement (SLA) to perform non-key activities, under liability of the Certification Body.

3 Application, certification criteria and procedure

3.1 A Company wishing to participate in the GMP+ FC scheme must submit the application for a GMP+ Certificate to a Certification Body. Upon approval of the application the Certification Body and the Company must conclude a Certification Agreement.

3.2 The Certification Body can only issue a GMP+ Certificate to a Company, if such Company complies with the following criteria:

a. If at a Business Location of a Participant other non-certified companies carry out activities that fall under the scope(s) of the GMP+ FC scheme, each of them must be GMP+ certified, or certified by another scheme which is accepted within the GMP+ FC scheme. See for acceptance of other schemes GMP+ BA10 (chapter 3) *Minimum requirements for purchase*.
b. The result of an Initial Certification Audit must demonstrate, to the satisfaction of the Certification Body that all activities falling under the scope(s) of the GMP+ FC scheme, at all the Business Locations, which are brought under GMP+ certification, are operating in compliance with the GMP+ FC scheme. A Company with more than one Business Locations may decide per Business Location to apply for GMP+ Certification.
c. A Participant with the scope trade and/or storage and/or transport and/or a producer who only trades/stores products from third parties, may per Business Location decide to trade, to store or to transport non-GMP+ certified feed, as long as there is a strict (physical) separation which is demonstrably assured by the Participants feed safety management system and traceability is fully clear.
d. A Participant is not allowed to produce non-GMP+ certified feed on the same Business Location where feed, except pet food, is produced under GMP+ certificate. The entire production must be assured within the GMP+ FC scheme. A Participant may, however, cover parts of this entire production under another scheme that is approved within the GMP+ FC scheme, as long as the entire production is certified. In that case, the Certification Body and GMP+ International have the authority to verify that part of the operations by means of an Audit.
e. All statutory required registrations, approvals, and licenses are in place and evidence of such registrations, approvals, and licenses is provided to the Certification Body. Participant must comply with all applicable legal requirements that are relevant for the GMP+ FC Scheme.
f. An up-to-date group structure of the Company should be available for assessment including ultimate beneficiary ownership and management overview, as well as a statement indicating the Company's, its ultimate beneficiary owner's or its management's involvement in businesses similar to the Company's business, if any.

3.3. The GMP+ Certificate can be valid for a maximum period of three years (and cannot exceed the duration of the GMP+ Certification Agreement), unless GMP+ FC documents indicate differently. The period of validity will be extended by a maximum of three years each time when it expires, except when:

a. The Recertification Audit mentioned in Article 3.4 results in non-conformities as stipulated in Annex 1 of the GMP+ C3/C6/C12,

b. A measure or sanction as specified in Article 8 has been imposed.

c. The GMP+ Certification Agreement ends.

3.4 Prior to the extension of the validity of a GMP+ certificate, the Certification Body has to:

a. Renew or extend the GMP+ Certification Agreement with the Participant, if applicable;

b. Carry out a successful Recertification Audit to ascertain continuing compliance of the Participant with all requirements of the GMP+ FC scheme.

4 Data/Publicly accessible register

4.1 Upon concluding a GMP+ Certification Agreement with a Company, the Certification Body and/or Critical Location must immediately enter the following Company details in the GMP+ Company Database:

a) 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+ C documents,
b) the Business Location where the Company conducts its activities;
c) In case of a multisite certification or a certification for a tractionair which is included in the Participants quality manual, the main office has to be registered in the Company database and connected to the multi-site location/ traction unit.

4.2 After the certification decision of the Certification Body, the Certification Body/Critical location is obliged to keep the certification data up to date.

4.3 The Certification Body and/or Critical location must inform GMP+ International (through the GMP+ Company Database) within two weeks of any change to the information specified in Article 4.1 & 4.1.1.

4.4 The Certification Body and/or Critical location must adjust the GMP+ Company Database within 1 working day to the measure or sanction imposed to a Participant, as set out in Article 8.

4.5 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 one month in advance.

4.6 GMP+ International is authorized to publish including but not limited to the name, logo, address, and registered office of the Certification Body, as well as its Critical location in a public register as well as the scope of acceptance. The Certification Body is responsible for the completeness and correctness of the information provided to be registered in the GMP+ Company Database.

4.7 GMP+ International is entitled to record the information specified in the Articles above in a public register and to make it publicly accessible. See Annex 1.

5 Use of GMP+ FC scheme Logo's/Trademarks

All requirements related to the GMP+ Logo's/Trademarks are described in the GMP+ A3 *GMP+ Logo's/Trademarks.*

6 Certification Bodies and Critical location.

6.1 GMP+ International sets down the procedure and requirements for acceptance of an applicant Certification Body. See GMP+ *C10 Approval Requirements and Procedure for Certification Bodies*.

6.2 An application for acceptance as a Certification Body should be submitted to GMP+ International in writing by using the Annex 1 of GMP+ C10.

6.3 Following submission of a fully-completed application form and all the required documents, GMP+ International will carry out an assessment within a period complied with the requirements specified in the GMP+ C-documents.

6.4 GMP+ International grants an acceptance to an applicant Certification Body by concluding a GMP+ Feed Certification scheme License Agreement which need to be signed mutually.

6.5 Upon acceptance, the Certification Body can grant a GMP+ Certificate to a Company in the animal feed sector, under the requirements specified in the GMP+ FC scheme and in the License Agreement mentioned in Article 6.4.

6.6 An applicant Certification Body as mentioned in Article 6.2 must pay an application fee to GMP+ International as mentioned in the GMP+ C4.

6.7 A Certification Body must pay an annual license fee to GMP+ International, consisting of two main components: a) a (number of) fixed fee(s), and b) a (number of) variable fee(s) depending on the number and kind of activities of the Certification Body of its and Participants. 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 established in article 2.1 of the GMP+ C4.

6.8 GMP+ International will make public the fees as mentioned in Article 6.6 and Article 6.7, at the latest one month before the start of a calendar year. See GMP+ C4 *Tariffs.*

6.9 Regarding the certification process as well as the manner and frequency of performing Audits, the Certification Body must carry it out demonstrably in accordance with the stipulations in the GMP + FC scheme.

6.10 The assessment and decisions of a Certification Body must be demonstrably based on objective evidence of conformity or nonconformity obtained.

6.11 GMP+ International is authorized to carry out a Compliance Assessment at the Certification Body and/or Critical location, Participants or by an external auditor acting on behalf of GMP+ International. See GMP+ C11 *Method of and Criteria for Compliance of Certification Bodies/Critical location.*

6.12 It is for the Certification Body and/or Critical location not allowed to determine and impose additional requirements to the Participant other than specified in the GMP+ FC scheme, unless specified in the internal procedure of the participants.

6.13 **Extraordinary Events**

6.13.1 Extraordinary Events or Circumstances affecting Certification Bodies, Critical/Non-Critical locations and Outsourcing Parties.

If the Certification Body and/or Critical location is confronted with an Extraordinary Event, it is obliged to follow the below guidelines based on the IAF Informative Document for Management of extraordinary events or circumstances affecting, Certification Bodies and Participants and which are described as follows:

a) The Participant or Business Location does not exist because it is destroyed by terrorist acts or acts of war; or is taken over by soldiers or rebels and/or pandemic flooding, earthquake, or other man-made and natural disasters . The Certification Bodies, Critical/Non-Critical location and/or Outsourcing Party is informed by the management of the Participant or Business Location or receives the information from another source(s) The Certification Bodies, Critical/Non-Critical location and/or Outsourcing Party is obliged to search for confirmation of the fact from a reliable source. After confirmation, the Certification Body withdraws the GMP+ Certificate and GMP+ International is informed directly in writing, including all the relevant details.

b) The Participant or Business Location is closed by its head office because the region is not safe. The management of the Company or the head office in forms the Certification Bodies, Critical/Non-Critical location and Outsourcing Party. The Certification Body withdraws the GMP+ Certificate and GMP+ International is informed directly in writing, including all the relevant details.

c) The Participant or Business Location cannot be audited because the region is not safe to be visited by auditors from the Certification Bodies, Critical/Non-Critical location and Outsourcing Party. And the Certification Bodies, Critical/Non-Critical location and Outsourcing Party decides that the region is not safe to be visited by an auditor (decision must be based on IAF guidelines) the Certification Bodies, Critical/Non-Critical location and Outsourcing Party must follow d)

d) If the audit frequency as set out in GMP+ C3/C6/C12 cannot be met and assuming that sufficient evidence was collected to provide confidence that the certified management system of the Participant is effective, considerations may be given to postpone the surveillance or recertification audit for a period NOT exceeding 3 months. Otherwise the GMP+ Certificate has to be suspended by the Certification Body. During the period of suspension the surveillance or recertification audit must be carried out, otherwise the certificate has to be withdrawn by the Certification Body.

7 Obligations of Participants

7.1 The Participant is obliged to comply with all requirements and obligations set out in or resulting from the GMP+ FC scheme and the GMP+ Certification Agreement.

7.2 The Participant must cooperate fully with an Audit as specified in the GMP+ FC scheme. Auditing may include taking samples and laboratory testing.

7.3 In the event of amendments of the GMP+ FC scheme, the Participant must comply with the amended requirements within a period as mentioned in the history table of the document, unless GMP+ International determines a shorter period for urgent reasons.

7.4 If the acceptance of the Certification Body, by which the Participant has been certified, has been withdrawn, or when the Certification Body terminates the GMP+ Feed Certification scheme License Agreement with GMP+ International on its own initiative or the Certification Body terminates the GMP+ Certification Agreement with the Participant, the Participant is obliged within three months to enter a Certification Agreement with another Certification Body.

7.5 In case of a perceived non-compliance with a maximum permitted level of a contaminant, the Participant is obliged to notify an EWS report after confirmation of the contamination, to its Certification Body, to the competent authority, and to GMP+ International, as further set out in the GMP+ BA5.

7.6 The Participant allows the competent authority of a national government to inform GMP+ International about noticed nonconformities regarding legal requirements related to feed safety aspects. The Participant allows GMP+ International to inform the competent authority of a national government about noticed nonconformities regarding legal requirements related to feed safety aspects.

7.7 **Extraordinary Events or Circumstances affecting Participants**

7.7.1 In a situation where a Participant is confronted with an Extraordinary Event as set out in Article 6.13, it is obliged to do the following.

a) The Participant does not exist because it is destroyed by terrorist acts or acts of war; or is taken over by soldiers or rebels. The management of the Participant is obliged to inform the Certification Body and Critical/Non-Critical location or Outsourcing Party about the fact.
b) The Participant is closed by its head office because the region is not safe. The management of the Participant or the head office is obliged to inform the Certification Body and Critical/Non-Critical location or Outsourcing Party.

Examples of extraordinary events may exist of:

a) The Participant does not exist because it is destroyed by terrorist acts or acts of war; or is taken over by soldiers or rebels;
b) The Participant is closed by the head office because the region is not safe
c) The Participant cannot be audited because the region is not safe to be visited by GMP+ Auditors from the Certification Body, Critical/Non-Critical location, Outsourcing party (politically unstable areas and war zones and/or pandemic flooding, earthquake, or other man-made and natural disasters).

8 Measures and sanctions

8.1 **Certification Bodies**:

If GMP+ International determines that a Certification Body does not comply with the requirements and obligations of the GMP+ FC 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 by means of and official letter.

a) Stating a period of time when the Certification Body/Critical location must comply with the requirements of the GMP+ FC scheme. The Certification Body will be asked to provide a corrective action report within this 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 three months which automatically results in the Critical location and 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.

8.1.2 During a suspension as mentioned in Article 8.1 under c the Certification Body must arrange that all its obligations under the GMP+ FC scheme are taken over by another Certification Body.

8.1.3 As a consequence of not renewing/termination as mentioned in Article 8.1 b and d, the concerned Certification Body will be excluded for a period of at least one year from participation in the GMP+ FC scheme. GMP+ International will inform the involved Participants.

8.1.4 GMP+ International has the authority to give a Certification Body a binding instruction with regard to:

The implementation of measures and sanctions for the whole GMP+ FC scheme towards a Participant in accordance with the GMP+ C documents related to Assessment and Certification Criteria.

The Certification Body is obliged to comply with the binding instruction within 2 working days. Deviation is only possible after consultation with GMP+ International giving substantial reasoning.

8.2 **Participants:**

If the Certification Body determines that a Participant does not comply with the requirements of the GMP+ FC scheme or the GMP+ Certification Agreement, it must impose measures or sanctions to the Participant in accordance with the stipulations in the GMP+ FC scheme regarding assessment and certification criteria. nonconformities must be classified according these criteria.

A Certification Body is allowed to impose stricter measures, but not to deviate from them by less strict measures.

8.2.1 The measures or sanctions mentioned in Article 8.2 are one of the measures or sanctions under a) up to and including e):

a) A compliance audit at the Participant. The cost for this audit is at the expenses of the Participant.

b) A stricter supervision audit at the Participant. The cost for this audit are at the expenses of the Participant.

c) Suspension of the GMP+ Certificate for of maximum of three months;

d) Withdrawal of the GMP+ Certificate for a minimum period of at least one year;

e) Publication by GMP+ International of the suspension and the withdrawal as set out in 8.2.1. c) and d).

8.2.3 When a sanction in Article 8.2.1 d) is applied, the Company will be excluded for at least twelve months from reapplying for participation in the GMP+ FC scheme. A former Participant can be excluded for a longer period of time if previous nonconformities show that the former Participant is not quality-minded.

8.2.4 If a Certification Body has determined a critical nonconformity at the Participant during an audit, it is not allowed for the Participant to withdraw the GMP+ Certificate on own request. The GMP+ Company Database must be adapted by the Certification Body to status: “withdrawn” reason: “does not meet the requirements”.

8.2.5 Where it is justified in the judgment of GMP+ International, the exclusion set out in the previous Articles may also be applied to any other business over which decisive control is obtained or exercised in any way, whether directly or otherwise, by:

a. The excluded Company,

b. A legal entity exercising decisive control in any way, whether directly or otherwise, on the excluded business, currently or has done so during the period of certification, or

c. A natural person exercising decisive control in any way, whether directly or otherwise, on the excluded business, currently or during the period of certification.

8.2.6 GMP+ International is entitled to report findings about breach of statutory requirements on the basis of Audits and EWS notifications to the concerned Certification Body as well as to competent authorities.

9 Transfer to another Certification Body

During the validity of a GMP+ certificate, a Participant is entitled to transfer its supervision to another Certification Body. Such transfer is subject to the following conditions:

9.1 Pre-transfer review

The accepting Certification Body/Critical location must carry out a review of the GMP+ certification of the prospective Participant. This review must cover the following aspect and its findings must be documented:

a) Confirmation that the activities of the Participant fall within the accepted scope of the Certification Body and/or Critical Location.
b) Reason for transfer.
c) Verification of compliance with the criteria of Article 3.2 & Article 8.2.4
d) An evaluation of the last (re)-certification reports and any unclosed nonconformity that may arise from them. This evaluation can include other relevant documentation, regarding the (re)-certification process i.e. notes, checklists, etc.
e) Confirmation that the Participant has no unfulfilled contractual obligations with the departing Certification Body.

9.2 Certification

This Article is applicable for Participant who have a GMP+ Certificate(s) that is still valid during the transfer to another Certification Body and must comply with the following conditions:

a) The accepting Certification Body, Critical/Non-Critical location, Outsourcing Party has to conclude a GMP+ Certification Agreement with the Participant.
b) The certification cycle between the accepting Certification Body/Critical/Non-Critical location, Outsourcing and the Participant has always to start with an Initial (Certification) Audit (stage 1 & stage 2). It is not allowed to transfer a GMP+ Certificate from the departing Certification Body to the accepting Certification Body without the Initial (Certification) Audit.
c) Open nonconformities should be closed before transfer, otherwise the nonconformities must be closed by the accepting Certification Body/Critical location during the Initial (Certification) Audit (stage 1 & stage 2).
d) A Certification Body is not allowed to accept transfer of a Company which GMP+ Certificate has been or should be suspended or withdrawn. Except for withdrawal on “own request”.

10 Dispute Resolution

10.1 Any dispute between a Participant and a Certification Body as well as between a Participant and GMP+ International arising out or in connection with the GMP+ FC scheme must be settled in accordance with GMP+ A4 *Disputes Procedure*.

11 Temporary provisions

11.1 GMP+ International is entitled, in exceptional situations or in the event of an emergency situation related to those subjects which are regulated in the GMP+ FC scheme, to draw up short-term additional provisions for Certification Bodies/Critical/Non-Critical locations/Outsourcing Party and/or Participants by way of an executive decree.

11.2 The Certification Body/Critical/Non-Critical location/Outsourcing Party and/or the Participants are obliged to comply with and/or implement the temporary additional provisions referred to in Article 11.1.

11.3 GMP+ International is entitled to:

a. In a case which is eligible, provide full or partial exemption to what is determined in the GMP+ FC scheme and associates such an exemption with requirements or conditions whereby in the event of non-compliance, not in due time compliance the exemption in question will be considered to have been retracted,

b. Withdraw an exemption which has been given to Certification Body/Critical location and/or Participant.

12 Liability

12.1 GMP+ International shall only be liable for damages incurred by a Company and/or Participant and/or Certification Body in the event such damages are a direct result of neglect, intent and/or a violation by GMP+ International of its obligations under the GMP+ FC Scheme, provided that such violation by GMP+ International was not due to insufficient or incorrect information provided to GMP+ International by the Company and/or Participant and/or Certification Body. In any case the liability of GMP+ International shall be limited to EUR 250,000 per claim with a maximum of EUR 1,000,000 per calendar year.

Annex 1. Responsibilities for processing data into the GMP+ database and/or entitlement to publish.

This table indicates the responsibilities for processing data into the GMP+ database and/or entitlement to publish, based on the requirements as mentioned in the GMP+ A1 *General Regulations.*

Responsible for:	Article	GMP+ Int.	CB/Critical location
Publication of CB/Critical location	4.5	X	-
Publication of a suspended CB/Critical location	8.1.c	X	-
Publication of the termination of the GMP+ Feed Certification scheme License Agreement	8.1.d	X	-
Publication that GMP+ International will not renew the GMP+ Feed Certification scheme License Agreement	8.1.b	X	-
Publication that another CB takes over the obligations when the original CB is suspended	8.1.2	X	-
Inform involved Participants when the acceptance of a CB is withdrawn/not renewed.	8.1.3	X	-
Publication of a suspended Company	8.2.1.e	X	-
Publication of the withdrawal of a GMP+ Certificate of a Company	8.2.1.e	X	-

Responsible for:	Article	GMP+ Int.	CB/Critical location
Processing data of Participant (visiting address) to be published on the public part of the GMP+ portal			
Name of Participant	4.1	-	X
Street	4.1	-	X
Number	4.1	-	X
Zip code	4.1	-	X
City	4.1	-	X
Country	4.1	-	X
Business legal registration number / number Chamber of Commerce	4.1	-	X
Phone number	4.1	-	X
Fax number	4.1	-	X
E-mail address	4.1	-	X
Website	4.1	-	X
Ship name	4.1	-	X
EU number	4.1	-	X
Processing data of Participant (postal address) to be published on the public part of the GMP+ portal			
PO Box number	4.1	-	X
Zip code	4.1	-	X
City	4.1	-	X
Country	4.1	-	X
Certification data of Participant to be partly published on the public part of the GMP+ portal			
GMP+ standard(s)	4.1.1	-	X
Scope(s)	4.1.1	-	X
Certified since	4.1.1	-	X
Start date of certificate	4.1.1	-	X
End date	4.1.1	-	X
Date suspension (if applicable)	4.1.1	-	X
Date withdrawal (if applicable)	4.1.1	-	X
Reason of suspension (if applicable)	4.1.1	-	X
Reason of withdrawal (if applicable	4.1.1	-	X
Status	4.1.1	-	X

Responsible for:	Article	GMP+ Int.	CB/Critical location
Certification data of Participant to be partly published on the pu-blic part of the GMP+ portal			
Linking of a multisite location/traction unit to head office/principal	4.1	X	-
Contact person at Participant	4.1	-	X
Emergency telephone number (24/7 number)	4.1	-	X

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