



GMP+ C 10

Version EN: 1 January 2022





**GMP+ Feed Certification scheme** 

### History of the document

Revision no. / Date of approval	Amendement	Concerns	Final implementation date
0.0 / 07-2015	This is a new document.	Entire document	01-08-2015
1.0 / 12-2016	Due to the EA Accreditation the term "Approval" is replaced by "Acceptance" "Company" is replaced by "Participant"	Entire document	15-02-2017
	New times frames for the acceptance of new certification bodies.	Article 3.1	
	"Contract" is replaced by "Feed Certification scheme License Agreement"	Article 3.2	
	A deputy GMP+ coordinator may represent the accepted Certification Body. All participation will be registered.	Article 3.3.	
	A GMP+ coordinator may delegate responsibilities to an authorized person.	Article 3.6	
	Acceptation requirements for CB's and auditors for scheme's based on mutual recognition.	Article 3.9	
	Added service scopes, FRA scopes and Country Notes in the application form and in the Qualification requirements.	Annex 1 & 2	
	Added requirements for inspectors.	Annex 2	
	Added exemption possibilities in tables of exemptions.	Annex 2	
	Added requirements for physical harmonization.	Annex 2	
	Clarification of the purpose of examination.	Annex 2	
	Added additional requirements for GMP+ coordinators.	Annex 2b	
	Streamline the validity of the Affreightment examination with short sea shipping and inland waterway transport.	Annex 5	
	Clarification examination fees foreign languages	Annex 5	
2.0 / 11-2017	Editorial changes	Entire docu- ment	01.07.2018
	All relevant documents regarding lead auditors shall be available during the acceptation audit	Paragraph 3.1	
	Additional requirements for the Certification Body/critical location	Paragraph 3.1	
	More extended accreditation requirements	Paragraph 3.3	
	Certification Body is responsible for the competences in accordance with Annex 2, GMP+ coordinator excluded	Paragraph 3.5	



Revision no. / Date of approval	Amendement	Concerns	Final implementation date
	The GMP+ coordinator is responsible for issuing audit time reduction	Paragraph 3.6	
	Use of unique certification agreement/certification agreement template	Paragraph 3.7	
	Additional requirements regarding the application of new certification bodies	Annex 1	
	The 3 acceptance audits must be conducted as an observer Inspector requirements were missing after the integration of the GMP+ C1 into C10 Requirements for the reviewer of GMP+ B4.3 checklists Hours of training per scope is per calendar year GMP+ coordinator must conduct 7 GMP+ audits/inspections per 12 months	Annex 2	
	Applicant auditors of non GMP+ accepted Certification Body can participate in the examination.  Inspector requirements were missing after the integration of the GMP+ C1 into C10 A examination can be declared invalid Not allowed to use Skype, WhatsApp, etc.	Annex 5	
3.0 / 05-2018	Editorial changes related to the definition of GMP+ auditor/inspection and the new GMP+ database	Entire document	01.07.2018
	A Certification Body must have an accredited quality management.	Article 3.3	
	Three new GMP+ standards have been added: GMP+ B11, Protocol for GMP+ registration for laboratories GMP+ BCN VN specific requirements for Vietnam GMP+ MI105 GMO Controlled	Annex 1	
	Competences for auditing GMP+ MI105 GMO controlled have been added	Annex 2	
	Table 1 has been expanded with the new GMP+ standards	Annex 2	
	Table 2 has been expanded with Qqualim, pastus+ and VLOG	Annex 2	
4.0 / 03-2019	Applying for BCN-IP Specific requirements lberian Peninsula is possible	Annex 1	BCN-IP: 15.05.2019
	Competences for assessing GMP+ B10 Laboratory testing and GMP+ B11 Registered laboratory have been added	Annex 2	04.04.2019
	Table of exemptions have been expanded with BCN-IP Specific requirements Iberian Peninsula	Annex 2	BCN-IP: 15.05.2019
4.1 / 09-2019	Clarification scopes MI105 GMO Controlled	Annex 1	17.09.2019



Revision no. / Date of approval	Amendement	Concerns	Final implementation date
4.2/ 02 - 2020	Additional scopes MI105 GMO Controlled	Annex 1 Annex 2	11.05.2020
	The old exam regulations are deleted	Annex 5	11.05.2020
5.0 / 10 - 2021	Editorial changes	Whole docu- ment	01.01.2023
	Responsibilities of GMP+ coordinator: requirements modified	Art. 3.6	01.01.2023
	Country notes BCN-CEE and BCN-IT deleted	Annex 1	01.01.2023



#### **INDEX**

1	INT	RODUCTION	б
	1.1	GENERAL	ε
	1.2	STRUCTURE OF THE GMP+ FEED CERTIFICATION SCHEME	6
	1.3	SCOPE	7
	1.4	STRUCTURE OF THE DOCUMENT	7
2	GEN	IERAL	8
3		QUIREMENTS WITH RESPECT TO THE IMPLEMENTATION OF STIFICATION FOR THE GMP+ FC SCHEME	g
	3.1	APPLICATION FOR ACCEPTANCE AND ASSESSMENT	9
	3.2	GMP+ FEED CERTIFICATION SCHEME LICENSE AGREEMENT	10
	3.3	REQUIREMENT FOR CERTIFICATION BODIES	10
	3.4	INDEPENDENCE / IMPARTIALITY	11
	3.5	REQUIREMENTS FOR GMP+ AUDITORS, INSPECTORS, COORDINATORS, PERSONNEL	
		INVOLVED IN CERTIFICATION ACTIVITIES, TECHNICAL/MATERIAL EXPERTS AND TECHNI	CAL
		REVIEWERS	11
	3.6	RESPONSIBILITIES	11
	3.7	AVAILABILITY OF AUDIT DATA AND DUTY OF CONFIDENTIALITY	
	3.8	CARRYING OUT THE AUDIT	12
	3.9	ACCEPTANCE OF CERTIFICATION BODY/AUDITOR OF ANOTHER, IN GMP+ ACCEPTED SCHEME	
A	NNEX 1	: APPLICATION FORM	14
A	NNEX 2	2: QUALIFICATION REQUIREMENTS	18
		8: PROCEDURE FOR THE ACCEPTANCE AND ASSESSMENT OF CATION BODIES	27
Α	NNEX 4	I: PERSONAL DETAILS OF COORDINATORS GMP+ FC SCHEME	28



#### 1 Introduction

#### 1.1 General

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

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

<u>GMP+ Feed Safety Assurance</u> 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, to traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

With the development of the <u>GMP+ Feed Responsibility Assurance module</u>, 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 participant can get certified for the GMP+ Feed Responsibility Assurance. GMP+ International facilitates via independent certification the demands from the market.

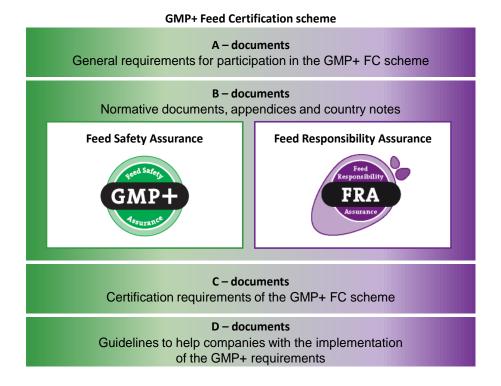
Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

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

#### 1.2 Structure of the GMP+ Feed Certification scheme

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





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

This document is referred to as standard GMP+ C10 Acceptance Requirements and Procedure for Certification Bodies and is part of the GMP+ FC scheme.

#### 1.3 Scope

The establishment of the conditions and procedure for the acceptance of certification bodies with respect to the carrying out of audits as specified in GMP+ A1 *General Regulations* of the GMP+ Feed Certification scheme by GMP+ International. These acceptance requirements and procedure are based on section 7.2 of the regulations. These acceptance requirements are intended for certification bodies which are or will be carrying out GMP+ audits at companies in the feed sector on the basis of the GMP+ scopes as specified in the GMP+ FC scheme.

#### 1.4 Structure of the document

This standard has a structure of its own.

In addition to this, reference to a number of other annexes is made as well. These annexes are only part of this standard, and are attached to it. To indicate them, only the word 'Annex' is used.



#### 2 General

A Certification Body that wishes to certify a participant under one or more GMP+ standards/ scope(s) must demonstrably comply with the requirements. These are laid down in the following sections.

GMP+ International will accept a Certification Body as a body that can issue companies with a GMP+ certificate or a temporary acceptance (see GMP+ C6/C12 Assessment and Certification Criteria for GMP+ Certification) for a particular GMP+ standard/ scope, if it complies with:

- a. that which is determined in GMP+ A1 *General Regulations*, in as far as it is applicable
- b. that which is determined in GMP+ A3 GMP+ Logo, in as far as it is applicable
- c. that which is determined in GMP+ A5 Feed Certification scheme License Agreement.
- d. the requirements specified in this document
- e. the acceptance procedure (Annex 3).

GMP+ International determines which GMP+ standards apply within the scope of the acceptance of the Certification Body.



# 3 Requirements with respect to the implementation of certification for the GMP+ FC scheme

#### 3.1 Application for acceptance and assessment

The Certification Body submits an application using an application form (Annex 1) to GMP+ International. GMP+ International will confirm this application in writing if this has been given the status "complete". This is only possible when all the documents specified in Annex 1 have been submitted to GMP+ International and the Certification Body has two accepted GMP+ auditors. The Certification Body must motivate and document its decision accordantly Annex 2 and must keep all record available for assessment during the acceptation audit.

The application will be considered when the application form has been filled completely and all the requested documents have been received by GMP+ International sent and the payment for the handling of the application has been made.

The first step is a desk assessment of the requested documents, this step will take at least 4 and a maximum of 6 weeks. After a positive result of the desk assessment the second step is for GMP+ International to conduct an acceptation audit. The findings of the acceptation audit are part of the assessment of acceptation of the Certification Body. If the acceptation process is positively finished within 13 weeks, GMP+ International will refund the application fee.

If the handling of the application takes more than 13 weeks up to a maximum of 26 weeks, an additional application fee is applicable. GMP+ International will only refund the additional application fee if the application is positively finished within 26 weeks.

For each additional acceptation audit to finalize the acceptation procedure GMP+International will charge the Certification Body.

If the Certification Body cannot be accepted by GMP+ International B.V. within the timeframe of 26 weeks after the first application GMP+ International will terminate the acceptation procedure. There will be no refund of application fees. The Certification Body is then not allowed to start a new acceptation procedure within a year.

If, during the application procedure, the Certification Body indicates that they operate with critical location(s) the following applies:

- Assessment of the critical location(s) will be part of the acceptation procedure of the Certification Body.
- If an onsite audit of the critical location is applicable GMP+ International will charge the Certification Body.
- The acceptance of the Certification Body can only be finalized if the critical location(s) complies with the requirements as stated in the GMP+ Feed Certification scheme.

The assessment will be carried out as specified in the GMP+ A1 General Regulation.



#### 3.2 GMP+ Feed Certification scheme License Agreement

#### Certification Body:

If the application is accepted then GMP+ International will issue a Feed Certification scheme License Agreement to the Certification Body as specified in the GMP+ A1 General Regulation and the GMP+ A5 GMP+ Feed Certification Scheme License Agreement. GMP+ International will draw up an agreement in duplicate and send it to the Certification Body involved. The Certification Body will send one of the copies back signed and dated to GMP+ International. The acceptance is complete following receipt of the signed 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 GMP+ FC standards/scopes the acceptance applies.

#### 3.3 Requirement for certification bodies

A Certification Body must be accredited for ISO/IEC17065 and/or ISO/IEC17021 and NPR-ISO/TS22003 (if applicable) for the relevant GMP+ standards/ scopes for which they have applied pursuant to this document. This accreditation has to be finalized by an accreditation body not later than one year after the date of acceptance of the Certification Body by GMP+ International. The Certification Body must assure that the critical location(s) have an accreditation within one year.

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 which is a member of the European Accreditation (EA) Multilateral Agreement (MLA) or a member of the International Accreditation Forum Multilateral Agreement (IAF MLA) within the framework of the accreditation for the GMP+ FC scheme.

If the Certification Body cannot be accredited by an accreditation body for the relevant GMP+ scope within a year after acceptance by GMP+ International, the Certification Body must prove that it has an accredited quality management system to ensure the processes of the Certification Body.

GMP+ International organises a meeting two times per year on policy coordination and harmonization. For each meeting the GMP+ coordinator (or authorized person) of the accepted Certification Body must be present. The participation will be registered.

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



#### 3.4 Independence / impartiality

The GMP+ auditor or the Certification Body must demonstrably confirm that there is compliance with the requirements with respect to independence.

The Certification Body and the GMP+ auditor(s) may, within a period of two years prior to the audit, not have undertaken any consultancy or training activities at the participant to be audited. The feed safety management system and the accounting records of the Certification Body must demonstrate this.

# 3.5 Requirements for GMP+ auditors, inspectors, coordinators, personnel involved in certification activities, technical/material experts and technical reviewers

Certification Bodies must ensure that all GMP+ auditors, inspectors, technical/material experts, technical reviewers and personnel involved in certification activities demonstrably comply with the applicable requirements as stated in Annex 2. The Certification Body must motivate and document its decision accordantly Annex 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 inspector may only conduct inspections once the inspector is accepted in the GMP+ database. In addition, a technical reviewer will assess the reports by the GMP+ auditors. The technical reviewer must comply with the requirements specified in annex 2. If the technical reviewer also carries out audits then it is not possible for him to assess (his own) reports from these audits.

The Certification Body will appoint one person as coordinator for the GMP+ certification who will act as contact person to GMP+ International. Application for the acceptance of a GMP+ coordinator must be submitted to GMP+ International by using Annex 4 of this document.

#### 3.6 Responsibilities

#### **Coordinator:**

- a) Contact person to GMP+ International,
- b) Coordination of examination,
- c) Responsible for internal harmonization.
- d) Responsible for ensuring that GMP+ Company Database is up to date,
- e) Responsible for the application review, unless there is another authorized person with these competences (see Annex 2, C),
- f) Acceptance of auditor, inspector and technical reviewer.
- g) Responsible for the selection of the audit team.
- h) Support on making decision on certification (the coordinator shall cannot be member of the audit team) unless there is a committee who carries out this activity at the Certification Body and complies with the competences (see Annex 2, C).
- Responsible for issuing audit time reduction.

It is allowed that the GMP+ coordinator delegate responsibilities to an authorized person.



#### **GMP+ Auditor:**

- a) Responsible for the audit planning activities,
- b) It can be the technical reviewer (see requirements laid down in Annex 2),
- c) Function of technical expert.
- d) Carries out audits,
- e) Conducts the opening and closing meeting for audits,
- f) Prepare and submit the audit report to be reviewed,
- g) Can support on making decision on certification (the GMP+ auditor shall cannot be member of the audit team) unless there is a committee who carries out this activity at the Certification Body and complies with the competences (see Annex 2, C).

#### 3.7 Availability of audit data and duty of confidentiality

The Certification Body has a duty of confidentiality with respect to the dissemination of information obtained during an audit. The audit reports/inspection checklist will be issued to the participant and uploaded into the GMP+ International database. The data must be retained for at least six years.

The Certification Body must record the mandatory issuing of the audit reports/inspection checklists and, if applicable, other audit data and certification data to GMP+ International in the unique certification agreement/certification agreement template with the participant. The GMP+ auditor must report the duty of confidentiality to the participant. The duty of confidentiality also applies for all personnel as stated in Annex 2. In the transition of a participant from one Certification Body to another, the Certification Body is obliged to make available all relevant participant data to the Certification Body in question.

#### 3.8 Carrying out the audit

The Certification Body describes the way in which they carry out the sections which are relevant for GMP+ certification (application through to issuing of the certificate) in procedures and other documents. These documents are part of the quality management system of the Certification Body and will be maintained within the framework of the accreditation (to be obtained) as specified in section 3.3.

In the event of changes in the certification requirements the Certification Body must begin with checking these immediately after the implementation date.

# 3.9 Acceptance of Certification Body/auditor of another, in GMP+ accepted scheme

Additional GMP+ certification for a scope defined in Country Notes or standards in the GMP+ Feed Responsibility Assurance can also be based on certification via another accepted scheme (based on 'mutual recognition'). This original certificate must at least include the relevant scope. Accepted schemes (including the scopes) are mentioned in chapter 3 of GMP+ BA10 *Minimum Requirement for Purchasing*.



In such a situation GMP+ International accepts the acceptance of the Certification Body and/or the auditor, granted by the concerning scheme owner.

GMP+ International does not perform a complete acceptance procedure for the Certification Body (article 3.1 GMP+ C10 *Acceptance Requirements and Procedure for Certification Bodies*). All other stipulations of the GMP+ FC scheme remain in force. The involved Certification Body is obliged to secure that the auditor complies with what is stated in article 3.5 of this document.

Mentioned acceptances, of the certification bodies as well as of the auditors, are only accepted if the Certification Body concerned wants to certify companies for one or more additional scopes (country notes or standards in the GMP+ Feed Responsibility Assurance)

Certification must be in accordance with GMP+ C7 Assessment and Certification/Inspection Criteria for GMP+ Certification/Inspection – additional/specific scopes.



#### **Annex 1: Application Form**

General information

Application for the acceptance of a Certification Body for the carrying out of certification in accordance with the GMP+ FC scheme.

Name of Certification Body (legal registered name)			
Name of the signer			
Name of coordinator			
Location address			
Postal code	I	Place	
Country			
Postal address			
Postal code	ı	Place	
Telephone no.	ı	Fax no.:	
Country			
E-mail address			
standards / scope(s) spec The undersigned hereby a	cified on this forr applies for acce	m. ptance as	es related to the following GMP+ s a Certification Body permitted to ry and to issue GMP+ certificates.
The undersigned is famili	iar with GMP+ C	C10 Acce	ptation Requirements and Proceal and the acceptance procedure

NB: The undersigned must be a legally-entitled representative of the Certification Body.

The following must be enclosed (if applicable):

(NB: Without these enclosures the application will not be considered.)

Signature:

and undertakes to cooperate in the acceptance procedure.



Date:

No	Description	Remarks
1.	Valid accreditation certificate including list of operations (ISO/IEC17065 and/or ISO/IEC17021 and ISO/TS 22003) depending on the application. A valid accreditation for the critical location(s).	
2.	Audit procedure and assessment process	
3.	Other documents used for certification process: - sample quotation/offer unique certification agreement/certification agreement template - sample certificate and temporary acceptance - sample GMP+ report - procedures and forms for internal assessment	
4.	List of at least two accepted GMP+ auditors. The Certification Body must motivate and document its decision accordantly Annex 2 and must keep all records available for assessment during the acceptation audit.	
5.	A copy of the legal business registration by a competent authority (for example Chamber of Commerce, Business Registration, VAT registration).	
6.	Copies of the service level agreement(s) between certification bodies and critical location(s).	

GMP+ standard / scope	GMP+ standard
GMP+ B1/GMP+ 1.2 Production, Trade and Services Scope F: production of compound feed and/or storage and transhipment feed and/or trade in feed	GMP+ B1
GMP+ B1/GMP+ 1.2 Production, Trade and Services Scope L: production of premixtures and/or storage and transshipment feed and/or trade in feed	GMP+ B1
GMP+ B1/GMP 1.2 Production, Trade and Services Scope F: production of feed materials and/or storage and transshipment feed and/or trade in feed	GMP+ B1
GMP+ B1/GMP 1.2 Production, Trade and Services Scope L: production of feed additives and/or storage and transshipment feed and/or trade in feed	GMP+ B1
GMP+ B2 <i>Production of Feed Ingredients</i> Scope F: production of feed materials	GMP+ B2
GMP+ B2-Production of Feed Ingredients Scope L: production of feed additives	GMP+ B2
GMP+ B3 Trade, Collection and Storage & Transshipment Scope H: trade in feed	GMP+ B3



	GMP+ standard / scope	GMP+ standard
	GMP+ B3 Trade, Collection and Storage & Transshipment Scope J: storage and transshipment feed	GMP+ B3
	GMP+ B3.2 Trade to Livestock Farms Scope H: Trade in feed	GMP+ B3.2
	GMP+ B4 <i>Transport</i> Scope J: road transport □ Scope J: rail transport □ Scope J: affreightment □	GMP+ B4
	GMP+ B4.3 Inland Waterways Transport Scope J: Inland waterways feed	GMP+ B4.3
	GMP+ B8 Production of and Trade in Pet Foods Scope F: production of pet foods and/or trade in pet foods	GMP+ B8
	GMP+ B10 Laboratory testing scope: laboratory testing	GMP+ B10
	GMP+ B11 Protocol for GMP+ registration for laboratories scope: registered laboratory	GMP+ B11
	GMP+ BCN-CN1 Supplier assurance for China Scope: assuring suppliers of feed ingredients and services for China	GMP+ BCN-CN1
	GMP+ BCN-NL1 Antibiotics free feed Scope: Antibiotics-free feed produced at an antibiotics-free production site or Antibiotics-free feed produced on antibiotics-free production line(s)	GMP+ BCN-NL1
	GMP+ BCN-NL2 <i>Dioxin monitoring in laying hens (rearing) feeds</i> Scope: Dioxin-monitoring in laying hens (rearing) feeds	GMP+ BCN-NL2
	GMP+ BCN-DE1 QM-Milch	GMP+ BCN-DE1
<del>-</del>	GMP+ BCN-CEE Additional requirements for Central & Eastern Europe Scope: Production of compound feed □ Scope: Production of premixtures □	GMP+ BCN-CEE
<del>-</del>	GMP+ BCN-IT Specific requirements for Italy Scope: Production of compound feed □ Scope: Production of premixtures □ Scope: Production of feed material □ Scope: Trade in compound feed □ Scope: Trade in premixtures □ Scope: Trade in feed materials □ Scope: Road transport of animal feed □	GMP+ BCN-IT
0	GMP+ BCN-VN Specific requirements for Vietnam Scope: Production of compound feed □ Scope: Production of premixtures □ Scope: Production of feed material □ Scope: Trade in compound feed □ Scope: Trade in premixtures □ Scope: Trade in feed materials □	GMP+ BCN-VN



GMP+ standard / scope	GMP+ standard
GMP+ BCN-IP Specific requirements for Iberian Peninsula Scope: Production of compound feed  Scope: Production of premixtures  Scope: Production of feed additives  Scope: Production of feed material  Scope: Trade in compound feed  Scope: Trade in premixtures  Scope: Trade in feed additives  Scope: Trade in feed materials	GMP+ BCN-IP
Scope: Road transport of animal feed  GMP+ MI101 Production and trade of RTRS soy scope: RTRS Mass Balance  scope: RTRS Segregation  GMP+ MI102 Responsible pig & poultry feed Scope: Responsible pig & poultry feed  Scope: Responsible pig & poultry feed	GMP+ MI101 GMP+ MI102
GMP+ MI103 Responsible dairy feed Scope: Responsible dairy feed □	GMP+ MI103
GMP+ MI105 GMO Controlled  Scope: Production of compound feed GMO Controlled  Scope: Production of feed materials GMO Controlled  Scope: Production of premixtures GMO Controlled  Scope: Production of feed additives GMO Controlled  Scope: Trade in feed GMO Controlled  Scope: Storage & transshipment of feed GMO Controlled  Scope: Transport of feed, road transport GMO Controlled	GMP+ MI105



#### **Annex 2: Qualification Requirements**

# A. Qualification Requirements for GMP+ auditors, coordinators, technical/material experts, inspectors and technical reviewers

The Certification Body must have personnel with sufficient competence for managing the process for certification of GMP+ FSA

module covering the applicable standard / scope.

module coverii			Feed Safety	
Element	Requirement	GMP+ FSA module	Country Note <sup>1</sup>	GMP+ FRA module
	Relevant agricultural, foodstuffs, logistics, or transport education at least Bachelor level or at least an equivalent level of experience.	Х	х	x
Education	For the scopes <i>Inland waterways transport</i> of GMP+ FSA module intermediate vocational education level or at least an equivalent level of experience.	х		
	For the scopes laboratory testing and registered laboratory a relevant laboratory education at least at Bachelor or an equivalent level or experience.	х		
Knowledge	<ul> <li>Knowledge and skills with respect to methods and techniques aimed at the assessment of feed safety management systems;</li> <li>HACCP (in accordance with ISO/TS22003 latest version), including the Pre-requisite programs (PRPs); and</li> <li>Food Safety Management Systems principles; and GMP+ FC scheme; and</li> <li>Feed legislation,</li> <li>As mentioned in Annex 2 of at the GMP+ C6/C12.</li> </ul>	х	х	
Knowledge	Knowledge and skills with respect to methods and techniques aimed at the assessment of feed safety management systems; As mentioned in Annex 2 of at the GMP+ C6/C12.			х
	Knowledge of and experience with mass balancing and traceability over the production chain.			х
	Knowledge: GMP+ MI101: RTRS endorsed auditor training			Х

<sup>&</sup>lt;sup>1</sup> Applicable for CB's who use the country note beside an accepted scheme/standard/scope according to GMP+ BA10 *Minimum Requirements for Purchasing* 



		Feed Safety		Responsi- bility	
Element	Requirement	GMP+	Country	GMP+ FRA	
		FSA	Note 1	module	
		module			
	If an auditor has successfully completed the RTRS endorsed training the auditor receives an				
	exemption for MI102 and MI103 or the auditor will be trained by a trainer who must comply with the following requirements:				
	The trainer must have a certificate of the FRA training provided by GMP+ Interna-				
	tional in the past and/or the trainer succeeded for the RTRS endorsed training.				
	The trainer must have a Lead assessor Training of 40 hours (IRCA recognized or				
	equivalent).				
	The trainer must have experience of performed at least 5 FRA audits during the last 12 months.				
	The trainer must have trainer experiences.				
	And the training has to consist at least off:				
	<ul> <li>The training must contain at least all topics as stated in the FRA training provided by</li> </ul>				
	GMP+ International:				
	- GMP+ FRA certification				
	- GMP+ B100 Feed Responsibility Management System				
	- GMP+ MI documents				
	- Certification in practice & cases				
	The duration of the training is 4 hours minimum				
	For auditing GMP+ MI105 GMO Controlled the GMP+ auditor/technical reviewer must have par-			х	
	ticipated in a VLOG approved training program for the VLOG "Ohne Gentechnik" standard and				
	must be in possession of a valid training certificate. When the validity period of the training cer-				
	tificate is expired no further "Ohne Gentechnik" audit/review may be performed unless the GMP+				
	auditor/technical reviewer has completed a next training session and is in possession of a valid				
	training certificate, or the auditor/technical reviewer will be trained by a trainer who must comply				
	with the following requirements:				
	The trainer must always be in possession of a valid certificate VLOG "Ohne Gentech-				
	nik".				
	<ul> <li>The trainer must have a Lead assessor Training of 40 hours (IRCA recognized or</li> </ul>				
	equivalent).				



		Feed Safety	Responsi- bility	
Element	Requirement	GMP+ FSA module	Country Note <sup>1</sup>	GMP+ FRA module
	<ul> <li>The trainer must have experience of a least 5 FRA audits during the last 12 months.</li> <li>The trainer must have trainer experiences.</li> <li>The duration of the training is 8 hours minimum and must be documented and it must be demonstrable that the auditors participated.</li> </ul>			
	And the training has to consist at least of:  • Equivalent topics as address in the VLOG "Ohne Gentechnik" training.			
	Additional: for the scope <i>Production and/or trade of feed additives</i> of the GMP+ FSA module: Demonstrable knowledge of the relevant chemical processes.	х		
	Additional: for the scopes laboratory testing and registered laboratory knowledge of the assessment of laboratory analysis.	х		
	<u>Technical expert</u> : A GMP+ auditor is a technical expert (the GMP+ auditor has a satisfactory level of expertise within the audit team after the GMP+ examination is succeeded).	х	х	
	Material expert: A Certification Body must ensure that there is a satisfactory level of expertise within the audit team. If an auditor does not have a satisfactory level of expertise in a specific material then the Certification Body must add an expert in the material to the audit team.			x
Audit skills	<ol> <li>Lead assessor (40 hours) training latest version (IRCA certified, or demonstrable equivalent) or FSSC Lead assessor (40 hours minimum) training latest version (IRCA certified, or demonstrable equivalent) based on compliance with requirements for auditors given in ISO 17021; and</li> <li>Effective interviews, good depth.</li> </ol>	х	х	х
	The first item of the box above does not apply for the scope <i>Inland waterways transport</i> .			
Audit experience	Minimum of 3 audits/inspections as an observer specifically for the relevant GMP+ scope(s) see table of exemption, table 1 or equivalent certification schemes as laid down in GMP+ BA10 <i>Minimum requirements for Purchasing</i> of the GMP+ FSA scheme accompanied by an experienced GMP+ auditor/inspector;	x	x	



		Feed Safety		Responsi- bility
Element	Requirement		Country Note <sup>1</sup>	GMP+ FRA module
	and also a minimum of 5 independently carried out audits as lead auditor in relevant fields of work as laid down in GMP+ BA10 <i>Minimum requirements for Purchasing</i> or schemes as mentioned in Annex 2 of the GMP+ C6//C12.			
Work experience	Working experience in the feed / food sector in a relevant position (for example quality assurance, production, consultancy on feed safety management systems, laboratory).  Exceptions to the above are:  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.  For the scopes laboratory testing and registered laboratory at least 2 years of working experiences in the relevant field of work.	x	х	х
Additional requirements for technical reviewer	Experience in the assessment of audit reports (minimum 3 for the relevant scope) or conduct/attend a minimum of 10 audits for the relevant scope.  Experience in the assessment of GMP+ B4.3 checklist (minimum 3 in total per calendar year) or conduct/attend a minimum of 10 inspection.	x	x	х
Other				
Training and supplementary training, updating and maintaining professional expertise	Each GMP+ auditor, technical/material expert, technical reviewer, inspector must have demonstrably followed an established initial training programme. The content of the training programme must be demonstrable focussed on the scope.  Each GMP+ auditor, technical/material expert, technical reviewer, inspector must have a training related to the GMP+ Feed Certification scheme when there are changes.  Each GMP+ auditor, technical/material expert, technical reviewer, inspector will attend at least the mandatory number of hours at the internal harmonization meetings organised by the Certification Body. For each accepted scope this is 8 hours to a maximum of 32 hours per calendar year. In addition, equivalent scopes have been formulated for which exemptions are possible. The requirements for these exemptions are stated in the tables of exemptions.  Physical internal harmonization is mandatory with a minimum of once per 2 years.  The GMP+ coordinator or authorized person is responsible for the internal harmonization and must participate.	X	x	X



Element		Feed Safety		Responsi- bility
	Requirement	GMP+ FSA module	Country Note <sup>1</sup>	GMP+ FRA module
	The internal harmonisation must demonstrably be conducted by proof of a participation list/minutes and it must be demonstrable that the auditors participated.  Continuous professional development through supplementary work experience, training, study, meetings or other activities.			
Examinations	After the training program the GMP+ auditor / technical reviewer / inspector must successfully take an initial examination for each standard/ scope. For retention of acceptance every GMP+ auditor / technical reviewer / inspector must pass the periodic examination. The examination is a check if the assessing auditor / technical reviewer / inspector has enough knowledge of the normative standards and rules of certification, including the classification of nonconformities as well as the characteristics of the production processes and services activities in the feed chain. These examinations are provided by GMP+ International on behalf of the International Expert Committee.  Refer also to Annex 5 (Examination Regulation) of this document. It is possible to obtain exemption for some examinations. The requirements for these exemptions have been laid down in the table of exemptions, table 1.	X		
Number of audits per year	In order to retain acceptance, each GMP+ auditor / technical reviewer / inspector must carry out at least 5 audits/inspections per year per standard / scope for which the GMP+ auditor / technical reviewer / inspector in question has been accepted. If the technical reviewer does not carry out independent audits/inspections then the internal attendances at relevant audits may be counted. The exemptions for GMP+ lead auditors and technical reviewers are stated in table of exemptions, table 2.	x	х	х



### B. Qualification Requirements for coordinators and personnel involved in certification activities

Element	Requirements for coordinators	GMP+ FSA module
Education	Bachelor degree or equivalent level of experience as minimum.	х
Knowledge	Successfully completed training in  - HACCP, including the Pre requisite programs (PRPs); and  - Food Safety Management Systems principles; and  - and GMP+ FSA module; and  - Feed legislation	х
Audit skills	<ol> <li>Lead assessor (40 hours) training (IRCA certified, or demonstrable equivalent) or FSSC Lead assessor training (40 hours, minimum) IRCA certified, or demonstrable equivalent) based on compliance with requirements for auditors given in and ISO 17065 and/or 17021; and</li> <li>Effective interviews, good depth</li> </ol>	х
Audit experience	At least 7 GMP+ audits/inspections must be carried out and/or attended per 12 months and/or conduct/attend audits/inspections in relevant fields of work as laid down in GMP+ BA10 <i>Minimum requirements for Purchasing</i> .	х
Work 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).	х
Element	Requirements for personnel involved in certification activities	GMP+FSA module
Education	Secondary education or equivalent level of experience as minimum.	х
Knowledge	Ongoing training in  - HACCP related to certification processes; and  - Food Safety Management Systems principles; and  - and GMP+ FSA module;	х
Audit skills	Not applicable	
Audit experience	It is not mandatory to have or to maintain audit experience.	
Work experience	Not applicable	



Other	Requirements for coordinators	GMP+ FSA module
Training and supple- mentary training, updat- ing and maintaining pro- fessional expertise	Each coordinator / personnel involved in certification activities must have demonstrably followed an established initial training programme. The content of the training programme must be demonstrable focussed on the scope.  Each coordinator / personnel involved in certification activities must have a training related to the GMP+ Feed Certification scheme and when there are changes in these documents.  Each coordinator will attend at least the mandatory number of hours at the internal harmonization meetings organised by the Certification Body. For each accepted scope this is 8 hours to a maximum of 32 hours per calendar year. In addition, equivalent scopes have been formulated for which exemptions are possible. The requirements for these exemptions have been laid down in the tables of exemptions.  The GMP+ coordinator or authorized person is responsible for the training and must participate. The training must demonstrably be conducted by proof of a participation	X
	list/minutes and it must be demonstrable that personnel involved participated.  Continuous professional development through supplementary work experience, training, study, meetings or other activities.	
Examinations	Not applicable	
Number of audits per year	Seven per 12 months (conducting and/or attending).	

C. <u>Table of competences criteria</u>: For the determination of competence criteria, competencies must be defined according to the ISO 17021:latest version, Annex A table A.1 and ISO/TS 22003: latest version, Annex C table C.1.



#### **Tables of exemptions**

Table 1

l able 1	
An audit / examination /	Also applies audit / examination / acceptation for:
acceptation for:	
Scope: Production	scope trade, scope storage & transshipment, scope trade to live- stock farms, scope antibiotics free feed, scope QM-Milch, scope production of feed material BCN-IT, scope trade BCN-IT, Scope RTRS mass balance system, scope RTRS segregated system, scope production of feed material – BCN-VN, scope trade BCN- VN, GMO Controlled, scope production of feed material BCN- IP, scope of trade BCN-IP, scope trade in feed GMO Controlled, scope storage & transshipment of feed GMO Controlled.
Scope: Production compound feed	scope production of/and trade in compound feed (pet food), scope supplier assurance for China, scope dioxin monitoring in laying hens (rearing) feeds, scope: production compound feed – CEE, scope production of compound feed BCN-IT, scope trade BCN-IT, scope responsible pig & poultry feed, scope responsible dairy feed, scope production of compound feed BCN-VN, scope trade BCN-VN, scope production of compound feed BCN-IP, scope of trade BCN-IP, production of/and trade compound feed (pet food), scope production of compound feed GMO Controlled
Scope: Production of Premixtures	scope: Production of premixtures – CEE, scope supplier assurance for China, scope production of premixtures – BCN-IT, scope trade BCN-IT, scope production of premixtures – BCN-VN, scope trade BCN-VN, scope production of premixtures BCN-IP, scope of trade BCN-IP, scope production of premixtures GMO Controlled.
Scope: Production of feed additives	scope production of feed additives – BCN-IP, scope of trade BCN-IP, scope production of feed additives GMO Controlled.
Scope: Production of feed materials	scope production of/and trade in feed material (pet food), scope production of feed materials GMO Controlled
Scope: Trade	scope trade in pet food, scope trade to livestock farms, scope QM-Milch, scope trade BCN-IT, Scope responsible pig & poultry feed, scope rresponsible diary feed, scope RTRS mass balance system, scope RTRS segregated system, scope trade BCN-VN, GMO Controlled, scope of trade BCN-IP, scope trade in feed GMO Controlled
Scope: Road transport	scope affreightment of road transport, scope transport of feed road transport BCN-IT, scope transport of feed road transport BCN-IP, scope transport of feed, road transport GMO Controlled.
Scope: Affreightment	scope affreightment of short sea shipping and inland waterways transport, scope affreightment of rail transport, scope affreightment of sea transport.
Scope: Road transport & Affreightment	scope rail transport
Scope Laboratory testing	Scope Registered Laboratory

Because these standards / scopes are not equivalent, the left column of this table applies for the scopes in the right column, but not vice versa.



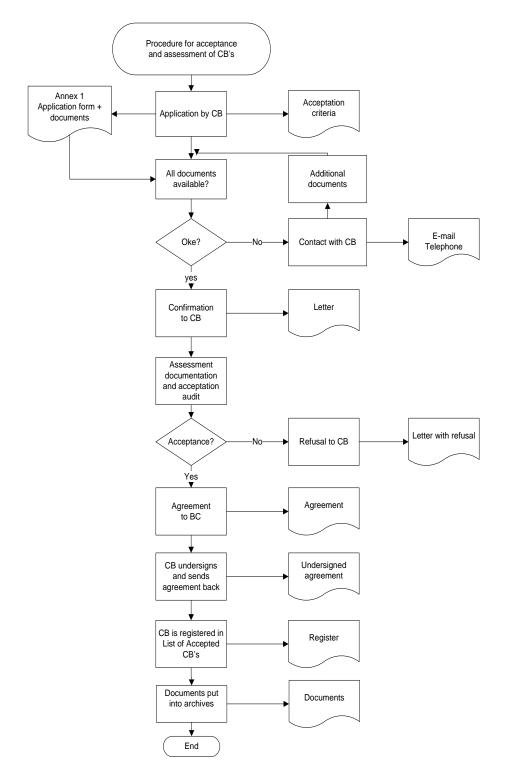
With respect to the retention of acceptance for an auditor/ technical reviewer / inspector insofar the requirement for at least 5 audits per year per standard / scope is concerned, the audits/review/inspection which take place at relevant companies under the accepted certificates as stated in chapter 3 of the GMP+ BA10 Minimum Requirements for Purchasing are applicable in addition the table below may also apply.

Table 2

Table 2					
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>				
	Production of feed materials				
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>				
	Production of feed materials				
Verband Lebensmittel ohne Gen-	GMP+ scope:				
technik (VLOG):	<ul> <li>Production of compound feed GMO Controlled</li> </ul>				
<ul> <li>Ohne Gentechnik</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 &amp; transshipment GMO Controlled.</li> </ul>				
	<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.					



# Annex 3: Procedure for the acceptance and assessment of certification bodies





#### Annex 4: Personal details of coordinators GMP+ FC scheme

Certifica	tion Body							
Address								
Place of	residence							
Name of	f coordinator							
	residence							
E-mail a	ddress							
	on (after secondary	school)						
Education	onal institution	Year	(Graduation	า) subj	ects		Diploma	
Relevan	t courses and train	ina						
Name of course / training description		Year	Educational institution Diploma/Certifica			oma/Certificate		
Work ex	perience (starting v	vith the mo	ost recent)					
Name and location of employer		Period	,		n of activities			
Audit ex ried out)	perience (relevant	audits in th	e last three	years i	ncl. nu	mber	of audits car-	
Date	Participant name	Activities	/ sector of	ector of Norm		ed	(Lead)Audi-	
	participant		and scopes			tor/Observer		
					•			

Add: Relevant diplomas and certificates





#### **GMP+ International**

Braillelaan 9 2289 CL Rijswijk

The Netherlands

- t. +31 (0)70 307 41 20 (Office) +31 (0)70 - 307 41 44 (Help Desk)
- e. info@gmpplus.org

#### 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

#### © GMP+ International B.V.

All rights reserved. The information in this publication may be consulted on the screen, downloaded and printed as long as this is done for your own, non-commercial use. For other desired uses, prior written permission should be obtained from the GMP+ International B.V.