



GMP+ C 10

Version EN: 4 April 2019 (corr. 24.04.2019)





**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	



Revision no. / Date of approval	Amendement	Concerns	Final implementation date
	Certification Body is responsible for the competences in accordance with Annex 2, GMP+ coordinator excluded	Paragraph 3.5	
	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 shall 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 shall 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	Annex 5	
3.0 / 05-2018	Not allowed to use Skype, WhatsApp, etc.	Entire	01.07.2019
3.07 05-2016	Editorial changes related to the definition of GMP+ auditor/inspection and the new GMP+ database	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 Iberian 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



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### 1 Introduction

#### 1.1 General

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

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

<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.

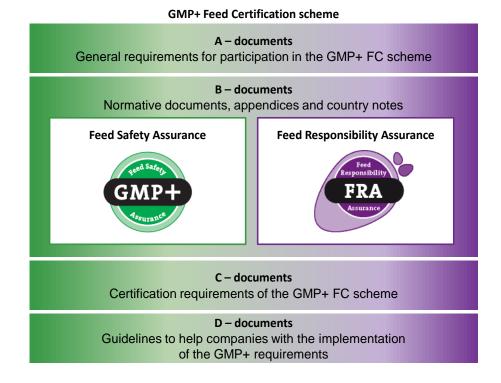
Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

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+ C3/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+ 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+ 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 auditors,
- g) Responsible for the selection of the audit team.
- Support on making decision on certification (the coordinator shall not 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).
- i) 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 not 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

Name of Certification

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

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:



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 Production of Feed Ingredients 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 <i>Trade to Livestock Farms</i> 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
۵	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
	GMP+ BCN-CEE Additional requirements for Central & Eastern Europe Scope: Production of compound feed □ Scope: Production of premixtures □	GMP+ BCN-CEE
	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
	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	GMP+
Scope: Production of compound feed	BCN-IP
Scope: Production of premixtures	2011 11
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 □	
Scope: Road transport of animal feed	
GMP+ MI101 Production and trade of RTRS soy	GMP+
scope: RTRS Mass Balance □	MI101
scope: RTRS Segregation	
GMP+ MI102 Responsible pig & poultry feed	GMP+
Scope: Responsible pig & poultry feed	MI102
GMP+ MI103 Responsible dairy feed	GMP+
Scope: Responsible dairy feed □	MI103
GMP+ MI105 GMO Controlled	GMP+
Scope: GMO Controlled	MI105



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

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

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

module covering the applicable standard / scope.

	the applicable standard / scope.	Feed Safety		Responsi- bility
Element	Requirement	GMP+ FSA module	Country Note <sup>1</sup>	GMP+ FRA module
	Relevant agricultural, foodstuffs, logistics, or transport education er laboratory training to 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.	x		
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+ C3/C6/C12.</li> </ul>	х	х	
Tallowiedge	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+ C3/C6/C12.			x
	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+ FSA module	Country Note <sup>1</sup>	GMP+ FRA 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+ International 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 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:  • The training must contain at least all topics as stated in the FRA training provided by 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	module			
	For auditing GMP+ MI105 GMO Controlled the GMP+ auditor/technical reviewer must have participated 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 certificate 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 Gentechnik".  • The trainer must have a Lead assessor Training of 40 hours (IRCA recognized or equivalent).  • The trainer must have experience of a least 5 FRA audits during the last 12 months.			x	



		FOOD SAIDIV		Responsi- bility	
Element	Requirement	GMP+ FSA module	FSA Note 1	GMP+ FRA module	
	The trainer must have trainer experiences. The duration of the training is 8 hours minimum and must be documented and it must be demonstrable that the auditors participated.				
	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.	x			
	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	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     Effective interviews, good depth.	x	х	х	
	The first item of the box above does not apply for the scope <i>Inland waterways transport</i> .				
Audit	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		
experience	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+ C3/C6//C12.		,		



		Feed Safety		Responsi- bility	
Element	Requirement	GMP+ FSA module	Country Note <sup>1</sup>	GMP+ FRA module	
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	x	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	х	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.  The internal harmonisation must demonstrably be conducted by proof of a participation list/minutes and it must be demonstrable that the auditors participated.	x	x	x	



		Feed Safety		Responsi- bility
Element	Requirement	GMP+ FSA	Country Note <sup>1</sup>	GMP+ FRA module
	Continuous professional development through supplementary work experience, training, study, meetings or other activities.	module		
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.	х	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		
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>	x	
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> .		x	
Working experience in the feed / food / responsibility sector in a rele- vant 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	
Ongoing training in  - HACCP related to certification processes; and - Food Safety Management Systems principles; and - and GMP+ FSA module;		x	
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 supplementary training, updating and maintaining professional 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 list/minutes and it must be demonstrable that personnel involved participated.  Continuous professional development through supplementary work experience, training, study, meetings or other activities.	X
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 shall 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

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: 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 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 feed additives	scope production of feed additives – BCN-IP, scope of trade BCN-IP
Scope: Production of feed materials	scope production of/and trade in feed material (pet food)
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 responsible diary feed, scope RTRS mass balance system, scope RTRS segregated system, scope trade BCN-VN, GMO Controlled, scope of trade BCN-IP
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: 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 which take place at relevant companies under the following equivalent standards may also apply:

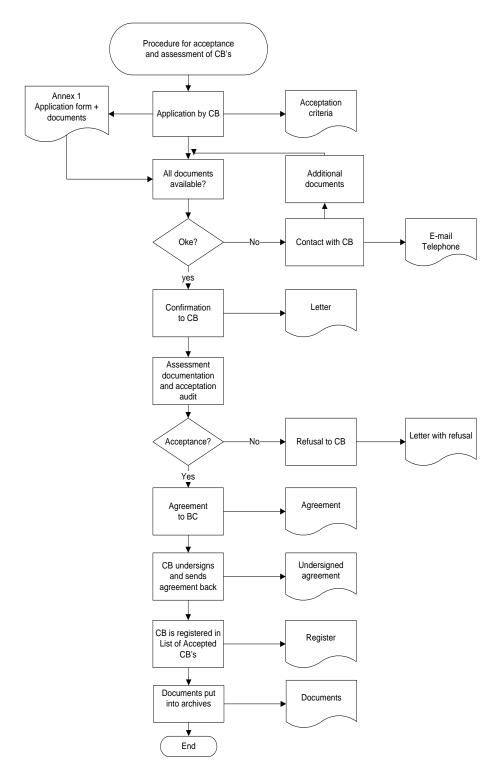
Table 2

An audit for:	Also applies as an audit for:				
FAMI-QS scope:	GMP+ scope:				
Specialty Feed Ingredients: - Feed additives	Production of feed additives				
Specialty Feed Ingredients: - Functional Feed Ingredients	Production of feed materials				
Mixtures: - Premixtures	<ul> <li>Production of premixtures</li> </ul>				
Mixtures:  - Specialty Complementary Feed  - Specialty Complementary Dietetic Feeds	<ul> <li>Production of compound feed.</li> </ul>				
GMP-OVOCOM/Feed Chain Alli- ance-OVOCOM	GMP+ for the relevant scope				
QS	GMP+ for the relevant scope				
Qualimat	GMP+ scope:  - Road transport of feed				
EFISC	GMP+ scope:  - Production of feed material				
FEMAS	GMP+ scope:  - Production of feed material				
<u>UFAS</u>	GMP+ scope:  - Production of compound feed,  - Production of premixtures				
Oqualim scope:  - Production of compound feed  - Production of premixtures  Pastus+	GMP+ scope:  - Production of compound feed  - Production of premixtures				
<ul> <li>Production of compound feed</li> </ul>	Production of compound feed				
Production of feed materials	Production of feed materials				
- Trade	- Trade				
Storage & transshipment  Read transport of food	Storage & transshipment  Read transport of food				
Road transport of feed  CMB: coepe:	Road transport of feed  CMR: cooper				
GMP+ scope:  - Production of compound feed	GMP+ scope:  - Production of compound feed  - Production of premixtures  - Production of feed additives  - Production of feed materials				
GMP+ scope:  - Production of premixtures	GMP+ scope:  - Production of compound feed - Production of premixtures - Production of feed additives - Production of feed materials				

An audit for:	Also applies as an audit for:			
GMP+ scope:	GMP+ scope:			
<ul> <li>Production of feed additives</li> </ul>	<ul> <li>Production of compound feed</li> </ul>			
	<ul> <li>Production of premixtures</li> </ul>			
	<ul> <li>Production of feed additives</li> </ul>			
	<ul> <li>Production of feed materials</li> </ul>			
Verband Lebensmittel ohne Gen-	GMP+ scope:			
technik (VLOG):	<ul> <li>GMP+ GMO Controlled</li> </ul>			
<ul> <li>Ohne Gentechnik</li> </ul>				
Note: the scopes in the left column o	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	ation Body							
Address	3							
Place of	residence							
	Consultanton	1						
	f coordinator							
	residence							
E-mail a	address							
Fducation	on (after secondary	school)						
	onal institution	Year	(Graduatio	n) subi	ects		Diploma	
	ona monaci.	100.	(Oracaaaa	11/ 00~,	00.0		Diploma .	
			1					
Relevan	nt courses and train	ing						
Name o	f course / training	Year	Educational institution   Diploma/Certificat			ma/Certificate		
descript	ion							
	perience (starting v							
	nd location of em-	Period	Function		Desc	riptior	of activities	
ployer								
Audit av	perience (relevant	audits in th	a last three	veare i	nel ni	ımhar	of audits car-	
ried out)	•	auuits iii ti	ie iasi ii ii ec	y <del>c</del> ais i	HOI. HIC	IIIIDEI	UI audits cai	
Date	Participant name	Activities	/ sector of	ector of Norm ch		ced	(Lead)Audi-	
					and scopes		tor/Observer	
					<b>I</b>			
				1				

Add: Relevant diplomas and certificates



### Annex 5: GMP+ International Examination Regulation

#### General

Examinations will be set to validate the knowledge of GMP+ auditors, technical reviewers and inspectors and to accept new applicants. The acceptance of a GMP+ auditor/inspectors for a particular period to be able to carry out audits/inspections at companies and the review of report by a technical reviewer, will be effective by way of success in an examination for a particular GMP+ scope. This acceptance is only completed for new GMP+ auditors, inspectors and technical reviewers after a positive document assessment by the Certification Body as specified in article 3.5, Annex 2 of the GMP+ C10 *Acceptance Requirements and Procedure for Certification Bodies* and processed in the GMP+ database.

Costs will be charged for examinations. The Certification Body will be invoiced for the examination fees each year. If the applicant auditor(s) of a non GMP+ accepted Certification Body wants to participate in the GMP+ examination the following applies:

- The applicant Certification Body must have submitted Annex 1 with all relevant documents and must have paid the application fee for certification bodies.
- The examination fees for the applicant auditor(s) must be paid at the latest two
  week before the examination takes place. If the examination fees are not paid
  the applicant auditor(s) cannot participate in the examination.

GMP+ International may refuse participation in examinations on the grounds of nonfulfilment of financial obligations, suspension or withdrawal of acceptance or for other valid reasons.

The dates for examinations are notified in the list of GMP+ examinations in the login section of GMP+ International website.

### **Application**

Application for participation in the examination is done using the application form which is to be found in the log-in section of the website. This application will determine the examination fees which will be charged to the Certification Body each year. Only application forms received from coordinators will be considered by GMP+ International. Application forms received after the closing date of the application period (two weeks before the relevant examination date) will no longer be considered. GMP+ International will only provide the examinations specified in the application forms

#### Cancellation

Cancellation of examinations by candidates for which the certification bodies have submitted an application must be done at the latest 1 week before the examinations in question. Cancellations (except in the case of force majeure) which are submitted to GMP+ International within 1 week of the examination will not be considered. The examination fees will then be charged to the Certification Body.

#### **Examination**

Participants in the examination must, if requested, be able to provide identification for the examination. This identification is done by handing over one of the following valid documents:

- a. Passport
- b. Driving licence,
- c. ID card.



Examinations for a particular GMP+ scope will consist of a number of relevant questions. These may be open questions or multiple choice questions or a combination of the two types.

The maximum examination time depends on the number of examinations made by the candidate. If a candidate decides to not make one of the exams for which they applied for the candidate has to inform the surveillance team immediately. The surveillance team will deduct the applicable examination time from the total examination time. If the candidate does not inform the surveillance team upfront and exceed the applicable examination time for the examination(s) made, the examination(s) made can be declared invalid.

If a candidate does not show up for the examination then GMP+ International will charge the fees for the examinations which the candidate had registered.

During the examination the candidates may make use of a calculator, a laptop, the standards documents on the Internet or the standards documents and other relevant sources in hard copy form. The correct use of the Internet is the responsibility of the candidate and must be ensured before the start of the examination.

Candidates may not make use of E-mail or telephones (mobile phones must be switched off) and must answer the questions completely independently without consulting colleagues. It is also not permitted to send or receive any kind of external communication with another person by email, messaging program (for example Skype, Whatsapp, Microsoft Lync, etc.) during the time you are in the examination room.

If the surveillance team establishes during the examination that the examination regulations are not being complied with or if the surveillance team has a serious suspicion that the work is not being done independently then the surveillance team may decide to declare all examinations taken on the day in question by the candidate to be invalid. The examination fees will still be charged to the Certification Body.

### **Assessment**

Answers to the questions will be assessed in their correctness by GMP+ International and each correct answer will be included in the calculation of the final result. Open questions may be answered partially correctly and in those cases points will be allocated accordingly. Certification bodies can request the examination results of GMP+ auditors in their employment or who carry out services for them. After the examination moment in June it is possible to receive a copy of the examination results on request. This will involve extra costs which will be charged to the Certification Body.

The validity of the examinations is as followed:

- a Score 0% 59%: validity not effective and/or not extended.
- b Score 60% 69%: validity effective and/or extended for 1 year.
- c Score 70 % 79%: validity effective and/or extended for 2 years.
- d Score 80 % 100%: validity effective and/or extended for 3 years.

An exception to this is the successful taking of the examination relating to the scope Short Sea Shipping and Inland Waterway Transport and Affreightment (all types of Affreightment, Affreightment of Road Transport excluded).

- a Score 0% 59%: validity not effective and/or not extended.
- b Score 60% 79%: validity effective and/or extended for 2 years.
- c Score 80% 100%: validity effective and/or extended for 4 years.



#### Re-examination

GMP+ International organises examination sessions spread across the calendar year. GMP+ auditors may take a maximum of two examinations per year per scope. If GMP+ auditors fail one or more examinations in a calendar year then they can do one resist of those examinations which they failed. This re-examination can be taken during one of the examination sessions in the current calendar year.

#### **Exemptions**

Because there are common areas among the various GMP+ standards it is not always necessary to take an examination for each GMP+ standard in order to become accepted or to continue to be accepted as a GMP+ auditor. The provision of exemptions is done in accordance with the table of exemptions, table 1 of Annex 2 of this document on the same conditions.

If a GMP+ auditor does decide to take part in an examination which is not mandatory then the result of the examination is binding. An exemption is then not possible anymore.

GMP+ Int. is responsible to process the exemption in the GMP+ database. The Certification Body must also be accepted for the GMP+ standard for which the exemption is granted. If the validity for one GMP+ standard / scope expires then the (possibility of) exemption for the related standards / scopes will also expire automatically.

### Compensation of examination results.

The examination results continue to determine the duration of the acceptance period for GMP+ auditors. In some cases the results of examinations may be rounded to the next higher value. In this way GMP+ International wants to offer GMP+ auditors the possibility to compensate for lower examination results so that they do not have to come back each year.

In order to qualify for the compensation of the examination results, the coordinator of the Certification Body must file a motivated request with GMP+ International. This will be checked against the following criteria:

- a. The examination result for which the Certification Body files a request, must be at least 60%.
- b. The GMP+ auditor concerned must have examinations that have been taken with a better result in the same and/or previous year and the exam results must still be valid.
- c. The coordinator of a Certification Body may submit such a request for a maximum of two standards / scopes per GMP+ auditor during a calendar year.

The acceptance period can be extended due to the averaging by a maximum of 1 year.



### <u>Guidance:</u>

Example averaging:

scope compound feed	90
scope feed additives	95
scope feed materials	67
scope road transport	65

In this example, the average is 79. The lowest two results (67 and 65) will be replaced with the average 79. This means that for these results the acceptation is prolonged from 1 year to 2 years for feed materials and road transport.

#### Communication

The coordinator of the Certification Body of the examination candidate will be informed of the assessment of the examinations taken by way of the GMP+ database.

If desired, the Certification Body may request certificates relating to the acceptance of each individual GMP+ auditor working with the Certification Body. This will involve extra costs which will be charged to the Certification Body.

### **Translation fees of exams**

The following conditions for translation fees regarding exams are applicable:

- In principle, the exams will be taken in 3 languages: Dutch, German or English. In all situations no translation fees are applicable for these languages.
- The Certification Body may request the exams in an additional language. If
  this is one of the languages as mentioned on the website of GMP+ International, the exams of the additional language are free of charge. However, if
  a GMP+ auditor chooses to answer the exams questions in one of the languages as mentioned on the website, GMP+ International will pass the
  translation fees of the answers to the involved Certification Body (Dutch,
  German and English excluded).
- A Certification Body may request an exam in another languages as mentioned on the website of GMP+ Int. In this case all translation fees (questions and/or the answers) will be passed to the involved Certification Body.

GMP+ International BV shall not be responsible for incorrect translation of the exams into any language other than Dutch, German and English.





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