GMP+ Feed Certification scheme

C

GMP+ C1

Approval requirements and Procedure for Certification Bodies

1

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EN

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Feed for Food

History of the document

Revision no. / Date of approval	Amendement	Concerns	Final implementation date
0.0 / 09-2010	Previous versions can be found in History		01-01-2011
1.0 / 09-2011			01-01-2012
2.0 / 11-2012			01-03-2013
3.0 / 06-2014	Editorial changes: All editorial changes are listed in a fact-sheet Adding the payment for application new certification bodies. Adding requirements for accreditation bodies. Add GMP+ scopes/standards Adding and deleting requirements for GMP+ auditors, GMP+ coordinators, personal involved in certification activities for certification bodies and modification table of exemptions	Entire document Paragraph 3.1 Paragraph 3 Annex 1 Annex 2 (B-C)	01-01-2015
	Some corrections in names	Page 20	
	Modification to Knowledge MI101	Page 13	

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1 Introduction

1.1 General

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

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

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

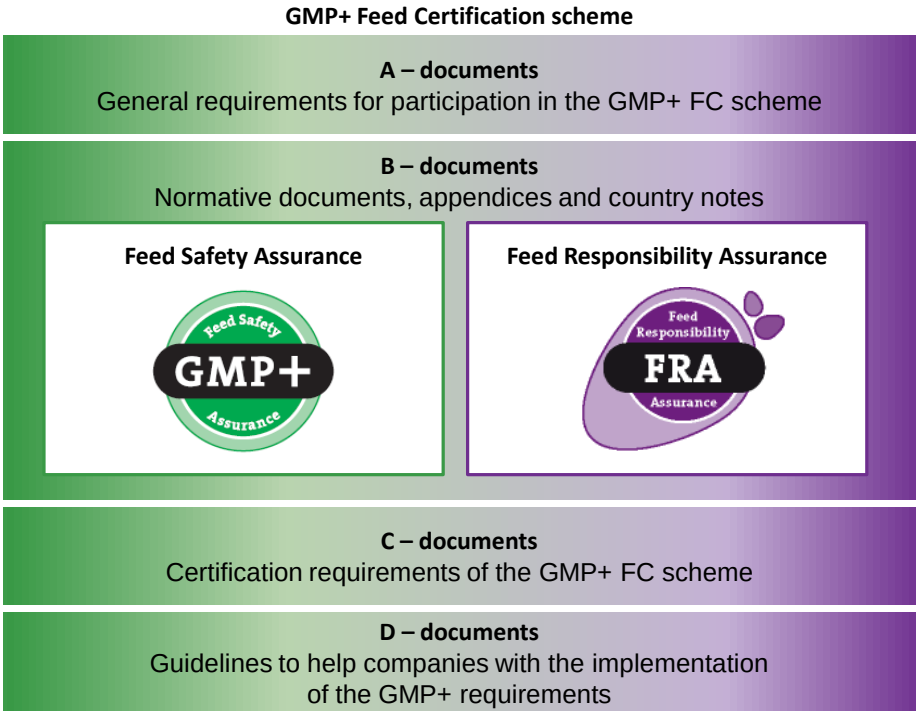
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and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

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

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

1.2 Structure of the GMP+ Feed Certification scheme

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



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

This document is referred to as standard GMP+ C1 *Approval 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 approval 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 approval requirements and procedure are based on section 7.2 of the regulations. These approval 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.

Next to this, also reference to a number of other appendices is made. These appendices 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 which wishes to certify a company under one or more GMP+ standards/ scope(s) should demonstrably comply with the requirements. These are laid down in the following sections.

GMP+ International will approve a certification body as a body which can issue companies with a GMP+ certificate or a temporary approval (see GMP+ C3 *Assessment and Certification Criteria for GMP+ Certification* / GMP+ C6 *Assessment and Certification Criteria for GMP+ Certification / GMP+ C7 Assessment and Certification/Inspection Criteria for GMP+ Certification/inspection*) 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. the requirements specified in this document
c. the approval procedure (annex 3).

GMP+ International determines within the scope of the approval of the certification body which GMP+ standards apply.

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

3.1 Application for approval and assessment

The certification body applies 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 including the CVs of at least 2 auditors / inspectors who work in the same field or work have been submitted to GMP+ International.

The application will be considered when the application form has been filled completely, all the requested documents have been sent and the payment for the handling of the application has been made. The handling of the application will take at least 4 and a maximum of 6 weeks. If the application is positively finished within the time frame of 6 weeks, GMP+ International will refund the application fee.

If the handling of the application takes more than 6 weeks up to a maximum of 13 weeks, an additional application fee is applicable. GMP+ International will only refund the additional application fee if the application is positively finished within the time frame of 13 weeks.

The assessment will be carried out as specified in the GMP+ A1 *General Regulation.* After this assessment GMP+ International will carry out an acceptation audit on site at the certification body. The findings of the acceptance audit are part of the assessment of approval of the certification body.

3.2 Contract

If the application is approved then GMP+ International will offer a contract to the certification body as specified in the GMP+ A1 *General Regulation.* GMP+ International will draw up a contract in duplicate and send it to the certification body in question. The certification body will send one of the copies back signed and dated to GMP+ International. The approval is complete following receipt of the signed contract.

GMP+ International will put the approved certification body on a public list with a specification of for which GMP+ FC standards/scopes the approval applies.

3.3 Requirement for certification bodies

A certification body should be accredited (if applicable) for the GMP+ standards/ scopes for which they have applied for approval pursuant to this document, in accordance with the requirements in annex 1, by an accreditation body ~~which is a member of the IAF Multi-Lateral Agreement (MLA)~~, not later than one year after the date of approval by GMP+ International. 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 should allow GMP+ International to inspect reports of audits carried out by an accreditation body which is a member of the IAF Multi-Lateral Agreement (MLA) within the framework of the accreditation for the GMP+ FC scheme.

GMP+ International organises a meeting two times per year on policy coordination and harmonisation. For each meeting there should be at least one person present per certification body (preferably the coordinator).
Each certification body is obliged to supply GMP+ International with at least one case study in good time each year for discussion 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 auditor / inspector or the certification body must demonstrably confirm that there is compliance with the requirements with respect to independence. The certification body and the auditor / inspector may, within a period of two years prior to the audit, not have undertaken any consultancy or training activities at the company to be audited. The quality system and the accounting records of the certification body must show this.

3.5 ~~Requirements for auditors, inspectors, coordinators and technical reviewers~~ Requirements for lead auditors, inspectors, coordinators, personnel involved in certification activities (conducting application review, audit team selection), technical experts and technical reviewers

~~The auditors / inspectors to be used must demonstrably comply with the requirements laid down in annex 2~~.

The lead auditors, coordinators, personnel involved in certification activities (conducting application review, audit team selection), technical experts and technical reviewers to be used must demonstrably comply with the requirements laid down in annex 2.

The certification body will appoint one person as coordinator for the GMP+ certification who will act as contact person to GMP+ International. In addition, a technical reviewer will assess the reports by the auditors / inspectors. The technical reviewer must comply with the requirements specified in annex 2. If the technical reviewer also carries out audits / inspections then it is not possible for him to assess his own reports from these audits / inspections.

The certification body should when applying hand over to GMP+ International the CVs of all qualified auditors / inspectors and of the technical reviewer for approval during the application in accordance with annex 4. This also applies for every new auditor who qualifies and who will be used for GMP+ audits. GMP+ International will maintain a register of approved auditors. If the approval of an auditor / technical reviewer has expired then, if the auditor / technical reviewer wishes to be approved again, then an initial approval procedure should be initiated.

3.6 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 reports will only be issued to the company, GMP+ International and the approval body. The data must be retained for at least six years.
The certification body should record the mandatory issuing of the reports and certification data to GMP+ International in the contract with the company. The auditor / inspector should report the duty of confidentiality to the company. The duty of confidentiality also to applies to the experts in the material who are used. In the transition of a company from one certification body to another, the certification body is obliged to make available all relevant company data to the certification body in question.

3.7 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 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 should begin with checking these immediately after the implementation date.

3.8 Acceptance of certification body/auditor of another, in GMP+ accepted scheme

Additional GMP+ certification for a scope defined in a Country Note or a Feed Responsibility Assurance standard, can also be based on certification via another, in the GMP+ FC scheme, accepted scheme (based on ‘mutual recognition’). This original certificate should 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 approval of the certification body and/or the auditor, granted by the concerning scheme owner.

GMP+ International does not perform a complete approval procedure for both CB and/or auditor (cf. articles 3.1 and 3.5 of GMP+ C1 *Approval Requirements and Procedure for Certification Bodies*). All other stipulations of the GMP+ FC scheme remain in force.

Mentioned approvals, 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 (in country notes or standards in the GMP+ Feed Responsibility Assurance)

Certification should be in accordance with GMP+ C7 *Assessment and Certification/Inspection Criteria for GMP+ Certification/Inspection - additional scopes,*

The certification body can contact GMP+ International for more information.

Annex 1: Application Form

Application for the approval of a certification body for the carrying out of certification in accordance with the GMP+ FC scheme.

General information

Name of certification body			
Name of the signer			
Name of coordinator			
Location address			
Postal code		Place	
Country			
Postal address			
Postal code		Place	
Telephone no.		Fax no.:	
Country			
E-mail address			

This application relates to the issuing of certificates related to the following GMP+ standards / scope(s) specified on this form.

The undersigned hereby applies for approval as a certification body permitted to carry out GMP+ audits and audits in the feed industry and to issue GMP+ certificates.

The undersigned is acquainted with GMP+ C1 *Approval Requirements and Procedure for Certification Bodies* of GMP+ International and the approval procedure and undertakes to cooperate in the approval procedure.

Date: Signature:

NB: The undersigned must be a legally-entitled representative of the certification body .

The following must be enclosed:
(NB: Without these enclosures the application will not be considered.)

No	Description	Remarks
1.	Valid accreditation certificate including list of operations ~~(EN 45011)~~ depending on the application	
2.	Audit procedure and assessment process	
3.	Other documents used during certification - sample contract - sample certificate and temporary approval - procedure and forms for internal assessment for GMP+ audits	
4.	List of qualified auditors / inspectors / technical reviewers including CV (drawn up in accordance with the sample in annex 4) and list of qualifications for each auditor inspector and CV of the technical reviewer.	

	GMP+ standard / scope	**GMP+ standard**
❑	GMP+ B1/GMP+ B1.2 *Production, Trade and Services* scope: production of compound feed and/or storage and transshipment feed and/or trade in feed	GMP+ B1/ GMP+ B1.2
❑	GMP+ B1/GMP+ B1.2 *Production, Trade and Services* scope: production of premixtures and/or storage and transshipment feed and/or trade in feed	GMP+ B1/ GMP+ B1.2
❑	GMP+ B1/GMP+ B1.2 *Production, Trade and Services* scope: production of feed materials and/or storage and transshipment feed and/or trade in feed	GMP+ B1/ GMP+ B1.2
❑	GMP+ B1/GMP+ B1.2 *Production, Trade and Services* scope: production of feed additives and/or storage and transshipment feed and/or trade in feed	GMP+ B1/ GMP+ B1.2
❑	GMP+ B2~~(2010)~~ *Production of Feed Ingredients* scope: production of feed materials	GMP+ B2~~(2010)~~
❑	GMP+ B2~~(2010)~~ *Production of Feed Ingredients* scope: production of feed additives	GMP+ B2~~(2010)~~
❑	GMP+ B3~~(2007)~~ *Trade, Collection and Storage & Transshipment* scope: trade in feed	GMP+ B3~~(2007)~~
❑	GMP+ B3~~(2007)~~ *Trade, Collection and Storage & Transshipment* scope: storage and transshipment feed	GMP+ B3~~(2007)~~

	GMP+ standard / scope	GMP+ standard
❑	~~GMP+ B3(2007) *Trade, Collection and Storage & Transshipment* / scope: transport of own products~~	GMP+ B3~~(2007)~~
❑	GMP+ B3.2 *Trade to Livestock Farms* scope: Trade in feed	GMP+ B3.2
❑	GMP+ B4 *Transport* scope: road transport ❑ scope: rail transport ❑ scope: affreightment ❑	GMP+ B4
❑	GMP+ B4.3 *Inland Waterways Transport* scope: Inland waterways feed	GMP+ B4.3
❑	GMP+ B6 *Feed Materials Cultivation* scope: feed materials cultivation	GMP+ B6
❑	GMP+ B8 *Production of and Trade in Pet Foods* scope: production of pet foods and/or trade in pet foods	GMP+ B8
❑	GMP+ B10 *Laboratory testing* scope: laboratory testing	GMP+ B10
❑	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 *Dioxin monitoring in laying hens (rearing) feeds* 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+ B101 *Production & Trade of responsible soy*~~ ~~scope: RTRS mass balance system ❑~~ ~~scope: RTRS Segregated system ❑~~	~~GMP+ B101~~
❑	GMP+ MI101 Production and trade of RTRS soy scope: RTRS Mass Balance ❑ scope: RTRS Segregation ❑	GMP+ MI101
❑	GMP+ MI102 Responsible pig & poultry feed Scope: Responsible pig & poultry feed ❑	GMP+ MI102
❑	GMP+ MI103 Responsible dairy feed Scope: Responsible dairy feed ❑	GMP+ MI103

Annex 2: Requirements for (lead-)auditors, inspectors and technical reviewers

Element	Requirement	Feed safety			Responsibility
		GMP+ FSA module	Country Note [1]	~~ISO22000 PAS 222~~	GMP+ FRA module
Education	Relevant agricultural, foodstuffs, logistics, transport or laboratory training to at least Bachelor level or at least an equivalent level of experience.	x	x	~~x~~	x
	For the scopes *Inland waterways transport* and scope *Cultivation feed materials* of GMP+ FSA module intermediate vocational education level or at least an equivalent level of experience.	x		~~x~~	
Required knowledge	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems; – HACCP feed, HACCP foodstuff or ISO 22000;	x	x	~~x~~	x
	– GMP+ FC scheme – Feed legislation	x	x	~~x~~	
	Knowledge of and experience with mass balancing and traceability over the production chain.				x
	~~Lead assessors that want to be accepted for the scopes RTRS Mass Balance System and/or RTRS Segregated system within the GMP+ B101 Production and trade of responsible soy, must have successfully completed the RTRS endorsed training.~~ Knowledge: GMP+ MI101: RTRS endorsed auditor training / GMP+ FRA auditor training GMP+ MI102: GMP+ FRA auditor training GMP+ MI103: GMP+ FRA auditor training If an auditor has successfully complete the RTRS endorsed training the auditor does not have to follow the GMP+ FRA auditor (an exemption for GMP+ MI102 and GMP+ MI103).				~~x~~ x x x

[1] Applicable for CB's who use the country note beside an accepted scheme/standard/scope according to GMP+ BA10 *Minimum Requirements for Purchasing*

Element	Requirement	Feed safety			Responsibility
		GMP+ FSA module	Country Note [1]	~~ISO22000 PAS 222~~	GMP+ FRA module
	Additional: for the scope *Production and/or trade of feed additives* of the GMP+ FSA ~~scheme~~ module: Demonstrable knowledge of the relevant chemical processes.	x			
	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	x	~~x~~	x
Audit skills	– Compliance with requirements for auditors EN ISO19011~~:2002~~ – Lead assessor (40 hours) training (IRCA certified, or demonstrable equivalent); – Effective interviews, good depth. The first two items of the box above do not apply for the scope *Inland waterways transport* and *Cultivation feed materials*	x	x	~~x~~	x
Audit experience	Minimum of 3 audits specifically for this scope or equivalent systems as laid down in GMP+ BA10 *Minimum requirements for Purchasing* of the GMP+ FC scheme (accompanied by an experienced GMP+ auditor; and also a minimum of 5 independently carried out audits in relevant fields of work (for example another GMP+ scope(s)/standard with which GMP+ has mutual recognition, HACCP feed / food, ISO 9001/22000, BRC, IFS and FSSC 22000.	x	x	~~x~~	
Work experience	Working experience in the feed / food sector in a relevant position (for example quality assurance, production, consultancy on quality systems, laboratory). Exceptions to the above are: Scope affreightment of animal feed: demonstrable knowledge of the freight brokerage of inland waterways vessels, sea-going vessels, railway wagons or road transport. This knowledge to be obtained by demonstrably taking an internal or external course of demonstrable in the carrying out of audits or checks at relevant companies.	x	x		x
Additional requirements for technical	Minimum 1 year experience in the assessment of audit reports or a minimum of 10 audits (attendances).	x	x	~~x~~	x

Element	Requirement	Feed safety			Responsibility
		GMP+ FSA module	Country Note [1]	~~ISO22000~~ ~~PAS 222~~	GMP+ FRA module
reviewer					
Other					
Training and supplementary training, updating and maintaining professional expertise	Each auditor / technical reviewer / inspector should have demonstrably followed an established initial training programme The content of the training programme must be demonstrable focused on the scope. Each auditor / coordinator / technical reviewer / inspector will attend at least the mandatory number of hours at the internal harmonization ~~professional meetings~~ organized by the certification body. For each approved scope this is 8 hours to a maximum of 32 hours In addition, equivalent scopes have been formulated for which exemptions are possible. The internal harmonization must demonstrably been conducted by proof of a presentation/minutes. The requirements for these exemptions have been laid down in the following table (see table exemptions). Continuous professional development through supplementary work experience, training, study, meetings or other activities. If chapter 3.8 of this document is applicable auditors must be harmonized by the certification body. For each approved Country Note this is 8 hours. In addition, equivalent scopes have been formulated for which exemptions are possible (see table exemptions).	x	x	~~x~~	x
Examinations	After the training program the auditor / technical reviewer / inspector must successfully take an initial examination for each standard/ scope. For retention of approval every auditor / technical reviewer / inspector should pass the periodic examination. This checks expertise in the field of animal feed. These examinations are taken by GMP+ International on behalf of the IEC. 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 following table (see under “number of audits / year”)	x		~~x~~	x

Element	Requirement	Feed safety			Responsibility
		GMP+ FSA module	Country Note [1]	~~ISO22000 PAS 222~~	GMP+ FRA module
Number of audits per year	In order to retain approval each auditor / technical reviewer / inspector should carry out at least 5 audits per year per standard / scope for which the auditor / technical reviewer / inspector in question has been approved. The audits will take place at the appropriate companies. If the technical reviewer does not carry out independent audits then the internal attendances at relevant audits may be counted. The exemptions for GMP+ auditors in table 1 and 2 may apply.	x	x	~~x~~	x

B. Qualification Requirements for coordinators and personnel involved in certification activities (conducting application review, audit team selection)

Element	**Requirements for coordinators**	**GMP+ FSA module**
Education	Bachelor degree or equivalent level of experience as minimum.	x
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	x
Audit skills	– Lead assessor training (40 hours IRCA certified, or demonstrable equivalent); and – Effective interviews, good depth	x
Audit experience	It is not mandatory to have or to maintain audit experience.	x
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).	x
Element	**Requirements for personnel involved in certification activities (conducting application review, audit team selection)**	**GMP+ FSA module**
Education	Secondary education or equivalent level of experience as minimum.	x
Knowledge	Ongoing training in – HACCP related to certification processes; and – Food Safety Management Systems principles; and – and GMP+ FSA module;	x
Audit skills	Not applicable	x
Audit experience	It is not mandatory to have or to maintain audit experience.	x
Work experience	Not applicable	x

Other		
Training and supplementary training, updating and maintaining professional expertise	Each coordinator / personnel involved in certification activities should 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 should have a training related to the GMP+ scheme documents (A and C documents) when there are changes in these documents. Each coordinator will attend at least the mandatory number of hours at the professional meetings organised by the certification body. For each approved scope this is 8 hours to a maximum of 32 hours In addition, equivalent scopes have been formulated for which exemptions are possible. The requirements for these exemptions have been laid down in the following table (see table exemptions). Continuous professional development through supplementary work experience, training, study, meetings or other activities.	x
Examinations	Not applicable	x
Number of audits per year	Not applicable	x

C. Table of competences criteria: For the determination of competence criteria, competencies shall be defined according to the ISO 17065:2012.

Certification functions knowledge and skills	**Conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit time**	**Reviewing audit reports and making certification decisions**	**Leading the audit team**
Knowledge of business management practices			X
Knowledge of audit principles, practices and techniques		X	X+
Knowledge of specific requirements of the normative documents GMP+ FSA module per applicable standard / scope	X	X	X+
Knowledge of certification body's processes	X	X	X
Knowledge of client business sector	X	X	X+
Knowledge of clients products, processes and organization	X		X+

Note:
X means that the certification body shall define the criteria, together with the depth of knowledge and skills.
X+ indicates a need for deeper knowledge and skills.
GMP+ International has not considered auditors in the audit team because all GMP+ accepted auditors are lead auditors (all GMP+ accepted lead auditors must comply with a number of minimum 3 audits, specifically for this scope or equivalent systems as laid down in GMP+ BA10 *Minimum requirements for Purchasing* of the GMP+ FSA module (accompanied by an experienced GMP+ lead auditor (see Annex 2- A).

Tables of exemptions

Table 1

An audit / examination / acceptation for:	Also applies audit / examination / acceptation for:
~~GMP+ B1 any scope~~ Scope: Production	~~GMP+ B2(2010) scope: production of feed materials, GMP+ B6, GMP+ B3(2007) scopes trade and storage, GMP+ B3.2~~ scope trade, scope storage & transshipment, scope trade to livestock farms, scope feed material cultivation, scope antibiotics free feed, scope QM-Milch. Scope RTRS mass balance system, scope RTRS segregated system
~~Scope: Production (and the training Feed Responsibility Management system)~~	~~scope responsible pig & poultry feed, scope responsible diary feed.~~
~~GMP+ B1 scope compound feed~~ Scope: Production compound feed	~~GMP+ B8(2008), GMP+ BCN-CN1 Suppliers assurance for China, GMP+ BCN-NL1 Antibiotics free feed, GMP+ BCN-NL2 Dioxin monitoring~~ scope production of/and trade in pet food, scope supplier assurance for China, scope dioxin monitoring in laying hens (rearing) feeds, scope: production compound feed – CEE, dcope responsible pig & poultry feed, scope responsible dairy feed
Scope: Production of Premixtures	scope: Production of premixtures – CEE scope supplier assurance for China
~~GMP+ B1 scope feed materials~~ ~~Scope: Production compound feed (and successfully completed the RTRS endorsed training).~~	~~GMP+ B2(2010) scope: production of feed materials, GMP+ B101 production and trade responsible soy~~ ~~scope: RTRS mass balance system~~ ~~scope: RTRS Segregated system~~
~~GMP+ B2(2010)~~	~~GMP+ B3(2007) scopes trade and storage, GMP+ B3.2~~
~~GMP+ B3(2007) scopes trade + storage~~	~~GMP+ B3.2~~
~~GMP+ B3(2007) scope trade~~ Scope: Trade	~~GMP+ B101 production and trade responsible soy~~ ~~Scope trade of responsible soy~~ scope trade in petfood, scope trade to livestock farms, scope QM-Milch, scope responsible pig & poultry feed, scope responsible diary feed, scope RTRS mass balance system, scope RTRS segregated system.
~~GMP+ B1 & GMP+ B4.1/GMP+ B4 scope road transport~~	~~GMP+ B3(2007) all scopes~~
~~GMP+ B2 & GMP+ B4.1/GMP+ B4 scope road transport~~	~~GMP+ B3(2007) all scopes~~
~~GMP+ B4 scope road transport~~ Scope: Road transport	~~GMP+ B4.1; GMP+ B3(2007) transport of own products~~ scope affreightment of road transport, scope transport of own products
~~GMP+ B4 scope affreightment~~ Scope: Affreightment	~~GMP+ B4.2; GMP+ B4.4 & GMP+ B4.5~~ scope affreightment of short sea shipping and inland waterways transport, scope affreightment of rail transport, scope affreightment of sea transport.
~~GMP+ B4.2~~	~~GMP+ B4.4 and GMP+ B4.5~~
~~GMP+ B4.4~~	~~GMP+ B4.2 and GMP+ B4.5~~
~~GMP+ B4.5~~	~~GMP+ B4.2 and GMP+ B4.4~~
Scope: Road transport & Affreightment	scope rail transport

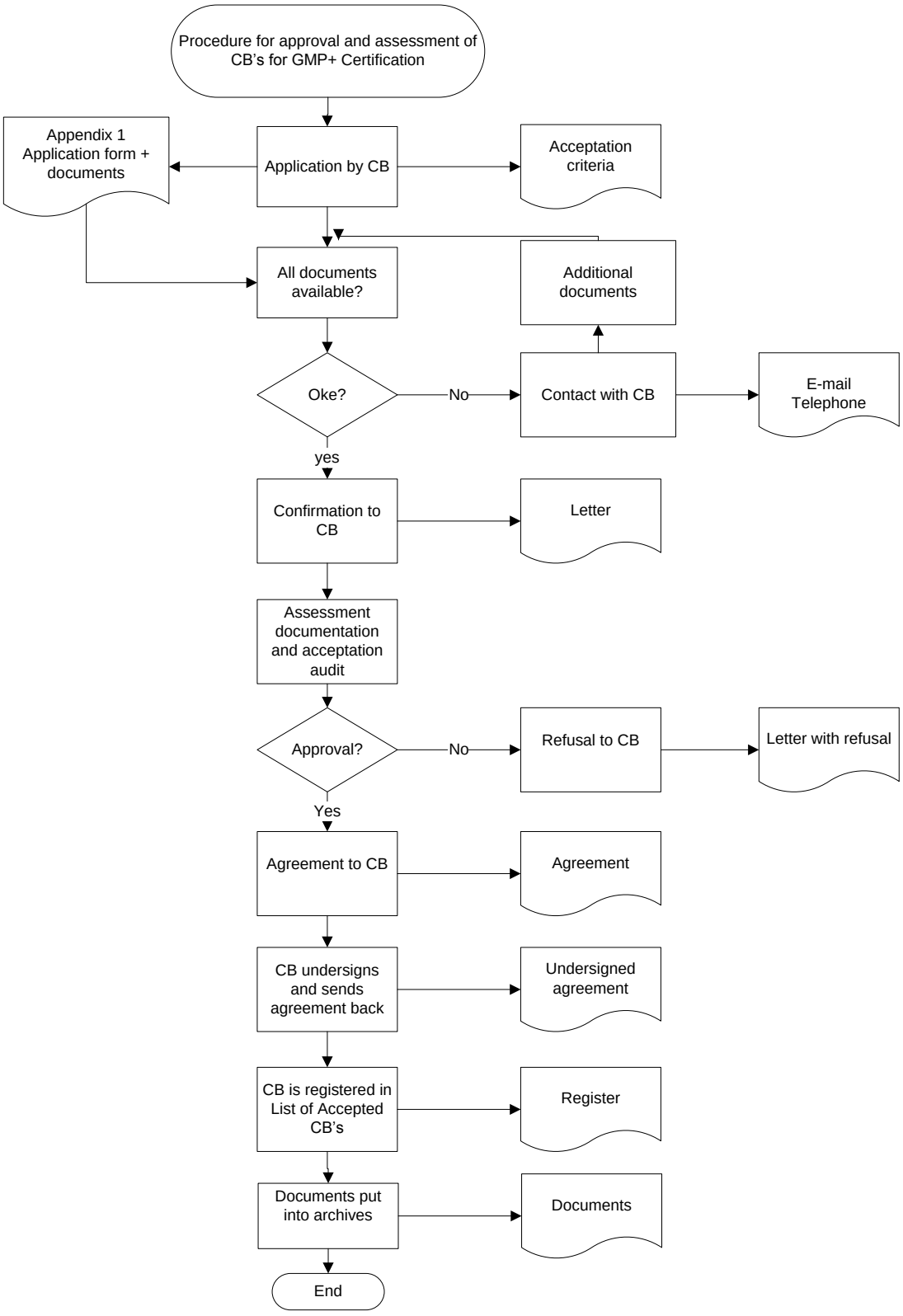
Because these standards / scopes are not equivalent, the exemption does not apply the opposite way.

With respect to the retention of an approval for an auditor/ technical reviewer / inspector as far as the requirement for at least five 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	with the scope: – production of feed additives and / or – production of feed premixtures
GMP-OVOCOM	GMP+ for the relevant scope
QS	GMP+ for the relevant scope

Annex 3: Procedure for the approval and assessment of certification bodies



Annex 4: Personal details of the auditors / inspectors and coordinators / technical reviewers GMP+ FC scheme

Certification body	
Address	
Place of residence	

Name of auditor / inspector	
Address	
Place of residence	
E-mail address	
Date of birth	

Education (after secondary school)			
Educational institution	Year	(Graduation) subjects	Diploma

Relevant courses and training			
Name of course / training description	Year	Educational institution	Diploma/Certificate

Work experience (starting with the most recent)			
Name and location of em-ployer	Period	Function	Description of activities

Audit / inspection experience (relevant audits in the last three years incl. number of audits carried out)				
Date	Company name	Activities / sector of company	Norm checked	(Lead)Auditor/ Observer

Add: Relevant diplomas and certificates

Annex 5: GMP+ International Examination Regulation

General
Examinations will be set to validate the approval of GMP+ auditors and to approve new candidates. The approval of an auditor for a particular period to be able to carry out audits at companies will be effective by way of success in an examination for a particular GMP+ scope. This approval is only effective for new auditors after a positive document assessment by GMP+ International as specified in annex 2 of the GMP+ C1 *Approval Requirements and Procedure for Certification Bodies* document.

Costs will be charged for examinations. The certification body will be invoiced for the examination fees each year.

GMP+ International may refuse participation in examinations on the grounds of non-fulfilment of financial obligations, suspension or withdrawal of approval or for other valid reasons.

The dates for examinations are notified in the list of GMP+ examinations in the log-in 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 for the examination session in question will no longer be considered. GMP+ International will only take the examinations specified in the application forms.

Cancellation
Cancellation of examinations by candidates for which the certification bodies have submitted an application should be done at least 1 week before the examinations in question. Cancellations (except in the case of force majeur) 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 for which the candidate has registered.

If a candidate does not turn 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 use of the Internet is at one's own expense and good operation should 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 should answer the questions completely independently without consulting colleagues.
If a GMP+ International staff member establishes during the examination that the examination regulation is not being complied with or if he or she has a serious suspicion that the work is not being done independently then he or she 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 n their correctness by GMP+ International's employees and each correct answer will be include in the calculation of the final result. Open questions may be answered partially correctly and in that cases points will be allocated accordingly. Certification bodies can request the examination results of auditors in their employment or who carry out services for them. 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 approval of an auditor will be effective or not depending on the result of the examinations:
Score 0% – 59%: approval not effective and/or not extended.
Score 60% – 69%: approval effective and/or extended for 1 year.
Score 70 % – 79%: approval effective and/or extended for 2 years.
Score 80 % – 100%: approval 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 Waterways Transport
a. Score 0% – 59%: approval not effective and/or not extended.
b. Score 60% – 79%: approval effective and/or extended for 2 years.
c. Score 80% – 100%: approval effective and/or extended for 4 years.

Re-examination
GMP+ International organises examination sessions spread across the calendar year. Auditors may take a maximum of two examinations per year per scope. If 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 approved or to continue to be approved as an auditor. The provision of exemptions is done in accordance with the table 1 of annex 2 (table of exemptions) of this document on the same conditions.

If an auditor does decide to take part in an examination which is not mandatory then the result of the examination is binding.
The issuing of an exemption will only be done at the request of the coordinator of the certification body. The certification body should also be approved for the GMP+ standard for which the exemption has been requested. If the approval 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 approval period for auditors. In some cases the results of examinations may be compensated. In this way GMP+ International wants to offer 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 auditor concerned must have examinations that have been taken with a better result
c. The coordinator of a certification body may submit such a request for a maximum of two standards / scopes per auditor during a calendar year.

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

Guidance:

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 web application.

If desired, the certification body may request written certificates relating to the approval of each individual auditor working with the certification body. This will involve extra costs which will be charged to the certification body.