GMP+ Feed Safety Assurance scheme

Approval Requirements and Procedure for Certification Bodies

GMP+ C1

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Feed for Food

History of the document

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0.0 / 09-2010	Transfer of the document from PDV to GMP+ International	Entire document	01-01-2011

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1 Introduction

1.1 General

The GMP+ Feed Safety Assurance scheme (GMP+ FSA) has been developed since 1992. It was managed from 1992 up until 2009 by the Product Board Animal Feed, The Hague, The Netherlands. Since 2010, this scheme is managed by GMP+ International.

It is a scheme for assuring feed safety in all the links in the feed chain. It is also an international scheme, applicable worldwide.

The establishment and development of the scheme was primarily the result of demand from the subsequent links in the animal production chain for better control of feed safety. Another contributory factor was the damage caused by more and less serious contamination incidents.

In the initial phase the demand arose for better differentiation in an increasingly saturated European sales market for animal products. Since 1999, feed & food safety has been a top issue internationally both politically and commercially, because of serious incidents in the feed sector. Because of this, demonstrable assurance of feed safety has become a sales prerequisite.

The basic principle of the GMP+ FSA scheme is that the feed chain is part of the food production chain. Proper assurance of feed safety worldwide is a high priority. Companies must live up to their responsibilities and respond properly and convincingly to the needs of animal production. The GMP+ Feed Safety Assurance scheme is an aid to realise this.

1.2 Structure of the GMP+ Feed Safety Assurance scheme

The documents within the GMP+ FSA scheme are subdivided into a number of series. A description follows of these:

A General (framework) documents	These documents contain the requirements for participation in the certification scheme for companies and certification bodies (framework regulation, the use of logo's, etc.). This series also includes a general list of definitions and abbreviations.

B Normative documents.	These documents contain the international standards and additional country notes for use by companies with respect to the various feed products and production phases including cultivation and industrial production, treatment and processing, collection, trade, means of transport, storage and transhipment.
C Certification requirements	These documents contain the Rules of Certification including those for the approval of certification bodies and auditors, the frequency of audits, minimum audit time, assessment criteria, checklists, etc. There is also an explanation of how the supervision by certification bodies is implemented and of how GMP+ International supervises the certification process..
Document ⇒ Standard	**Code** GMP+ Cxx
	Name e.g. GMP+ C1 *Approval Requirements and Procedure for Certification Bodies*
D Interpretations and accompanying texts	In addition to the above-mentioned normative documents, there are also supporting documents in the D series including a list of frequently-asked questions, manuals and guidances with additional information.

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

The document in the present case is referred to as standard GMP+ C1 *Approval Requirements and Procedure for Certification Bodies* and is part of the GMP+ FSA 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 Safety Assurance scheme by GMP+ International, referred to hereafter as 'GMP+ FSA scheme'. 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+ standards as specified in the GMP+ FSA scheme

1.4 Structure of the document

This standard has a structure of its own.

GMP+ Appendices (GMP+ BAxx), to which there are also references, are separate GMP+ documents within the B segment of the GMP+ FSA scheme. If there is a reference in this standard to such an GMP+ BAxx-appendix, then it applies within the framework of this standard. GMP+ BAxx-appendices are indicated as such.

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 ‘appendix’ is used.

2 General

A certification body which wishes to certify a company under one or more GMP+ standards 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*) for a particular GMP+ standard, 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 (appendix 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+ FSA scheme

3.1 Application for approval and assessment

The certification body applies using an application form (appendix 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 appendix 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.

The assessment will be carried out as specified in the GMP+ A1 *General Regulation.* After this assessment GMP+ International will carry out an approval audit on site at the certification body. The findings of the approval 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+ standards/scopes the approval applies.

3.3 Requirement for certification bodies

A certification body should be accredited (if applicable) for the GMP+ FSA standards for which they have applied for approval pursuant to this document, in accordance with the requirements in appendix 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.

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+ FSA scheme.

GMP+ International organises a meeting three 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

The auditors / inspectors to be used must demonstrably comply with the requirements laid down in appendix 2.
The certifying agency 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 appendix 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 appendix 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 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.

Appendix 1: Application Form

Application for the approval of a certification body for the carrying out of certification in accordance with the GMP+ FSA 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 specified on this form.

The undersigned hereby applies for approval as a 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 appendix 4) and list of qualifications for each auditor inspector and CV of the technical reviewer.	

	GMP+ standard / scope	**GMP+ standard**
❑	GMP+ B1 *Production, Trade and Services* /scope: production and/or trade and/or storage of compound feeds	GMP+ B1
❑	GMP+ B1 *Production, Trade and Services* / scope: production and/or trade and/or storage of premixes	GMP+ B1
❑	GMP+ B1 *Production, Trade and Services* / scope: production and/or trade and/or storage of feed materials	GMP+ B1
❑	GMP+ B1 *Production, Trade and Services* / scope: production and/or trade and/or storage of feed additives	GMP+ B1
❑	GMP+ B2 *Quality Control of Feed Materials* / scope: production and/or trade and/or storage of feed materials, trade and/or storage of compound feeds / premixes.	GMP+ B2
❑	GMP+ B2 *Quality Control of Feed Materials* / scope: Trade and/or storage of feed additives	GMP+ B2
❑	GMP+ B2(2010) *Production of Feed Ingrediënts* / scope: production of feed materials	GMP+ B2(2010)
❑	GMP+ B2(2010) *Production of Feed Ingrediënts* / scope: production of feed additives	GMP+ B2(2010)
❑	GMP+ B3 *Trade*	GMP+ B3(2006)
❑	GMP+ B3(2007) *Trade, Collection and Storage & Transhipment* / scope: trade & collection	GMP+ B3(2007)
❑	GMP+ B3(2007) *Trade, Collection and Storage & Transhipment* / scope: storage and transhipment	GMP+ B3(2007)
❑	GMP+ B3(2007) *Trade, Collection and Storage & Transhipment / scope:* transport of own products	GMP+ B3(2007)
❑	GMP+ B3.2 *Trade to Livestock Farms*	GMP+ B3.2
❑	GMP+ B4.1 *Road Transport*	GMP+ B4.1

	GMP+ standard / scope	GMP+ standard
❑	GMP+ B4.2 *Affreightment of Short Sea Shipping and Inland Waterway Transport*	GMP+ B4.2
❑	GMP+ B4.3 *Inland Waterways Transport*	GMP+ B4.3
❑	GMP+ B4.4 *Sea Transport Affreightment*	GMP+ B4.4
❑	GMP+ B4.5 *Rail Transport Affreightment*	GMP+ B4.5
❑	GMP+ B5 *Storage & Transhipment*	GMP+ B5
❑	GMP+ B6 *Feed Materials Cultivation*	GMP+ B6
❑	GMP+ B8 *Production of and Trade in Pet Foods*	GMP+ B8
❑	GMP+ B10 *Laboratory testing*	GMP+ B10

Appendix 2: Requirements for auditors, inspectors and technical reviewers

General	
Training	– Relevant agricultural, foodstuffs, logistics, transport or laboratory training to at least Bachelorlevel (for: GMP+ B4.3 and GMP+ B6: MBO (intermediate vocational education) level) or at least an equivalent level of experience.
Required knowledge	– Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems; – GMP+ standard for feed; – HACCP feed, HACCP foodstuff or ISO 22000; – Feed legislation. Specific (additional): – GMP+ B1 / GMP+ B2(2010) scope: feed additives: Demonstrable knowledge of the relevant chemical processes. – 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.
Audit skills	– Compliance with requirements for auditors EN ISO19011:2002; – Lead assessor training (IRCA certified); – Effective interviews, good depth. N.B. the first two items do not apply for GMP+ B4.3 and GMP+ B6.
Audit experience	– minimum of 3 audits specifically for this standard or equivalent systems as laid down in GMP+ BA10 *Minimum requirements for Purchasing* of the GMP+ FSA 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+ standard, standards with which GMP+ has mutual recognition, HACCP feed / food, ISO 9001/22000.
Work experience	– Extensive experience working in the feed / food sector in a relevant position (for example quality assurance, production, consultancy on quality systems, laboratory). Exceptions to the above are: – GMP+ B4.2 / GMP+ B4.4 / GMP+ B4.5: Demonstrable knowledge of the freight brokerage of inland waterways vessels (GMP+ B4.2), sea-going vessels (GMP+ B4.4), railway wagons (GMP+ B4.5). 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.

Additional requirements for technical reviewer	– Minimum 1 years experience in the assessment of audit reports or a minimum of 10 audit (attendances).
Other	
Training and supplementary training, updating and maintaining professional expertise	– Each auditor / technical reviewer / inspector to be used should have demonstrably followed an established initial training programme organised by the certification body. The content of the training programme must be demonstrable. – Each auditor / coordinator / technical reviewer / inspector will attend at least the mandatory number of hours at the professional meetings organised by the certification body. For each approved standard this is 8 hours to a maximum of 32 hours. For the GMP+ B1 / GMP+ B2(2010) standards a distinction is made among the various scopes; 1 scope applies as 1 standard. In addition, equivalent standards / scopes have been formulated for which exemptions are possible. The requirements for these exemptions have been laid down in the following table (see under “number of audits / year”). – Continuous professional development through supplementary work experience, training, study, meetings or other activities.
Examinations	– After the training programme the auditor / technical reviewer / inspector must successfully take an initial examination for each GMP+ standard. 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 appendix 5 (Examination Regulation) of this standard. 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”)

Number of audits per year

- In order to retain approval each auditor / technical reviewer / inspector should carry out at least five 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 GMP+ audits then the internal attendances at relevant GMP+ audits may be counted. The following exemptions apply:

An audit / examination / professional meeting / approval for:	**Also applies audit / examination / professional meeting / approval for:**
GMP+ B1 any scope	GMP+ B3(2006), GMP+ B2, GMP+ B2(2010) scope: production of feed materials, GMP+ B5, GMP+ B6, GMP+ B3(2007) scopes trade and storage, GMP+ B3.2
GMP+ B1 scope compound feed	GMP+ B8(2005) and GMP+ B8(2008)
GMP+ B1 scope feed additives	GMP+ B2(2010) scope: production of feed additives
GMP+ B1 scope feed materials	GMP+ B2(2010) scope: production of feed materials
GMP+ B2	GMP+ B3(2007) scopes trade and storage, GMP+ B3.2, GMP+ B5
GMP+ B3(2006)	GMP+ B3(2007) scope trade
GMP+ B3(2006) + GMP+ B5	GMP+ B3.2
GMP+ B3(2007) scopes trade + storage	GMP+ B3.2
GMP+ B3(2007)	GMP+ B5
GMP+ B1+ GMP+ B4.1	GMP+ B3(2007) all scopes
GMP+ B2+ GMP+ B4.1	GMP+ B3(2007) all scopes
GMP+ B3(2006) + GMP+ B4.1 + GMP+ B5	GMP+ B3(2007) all scopes
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

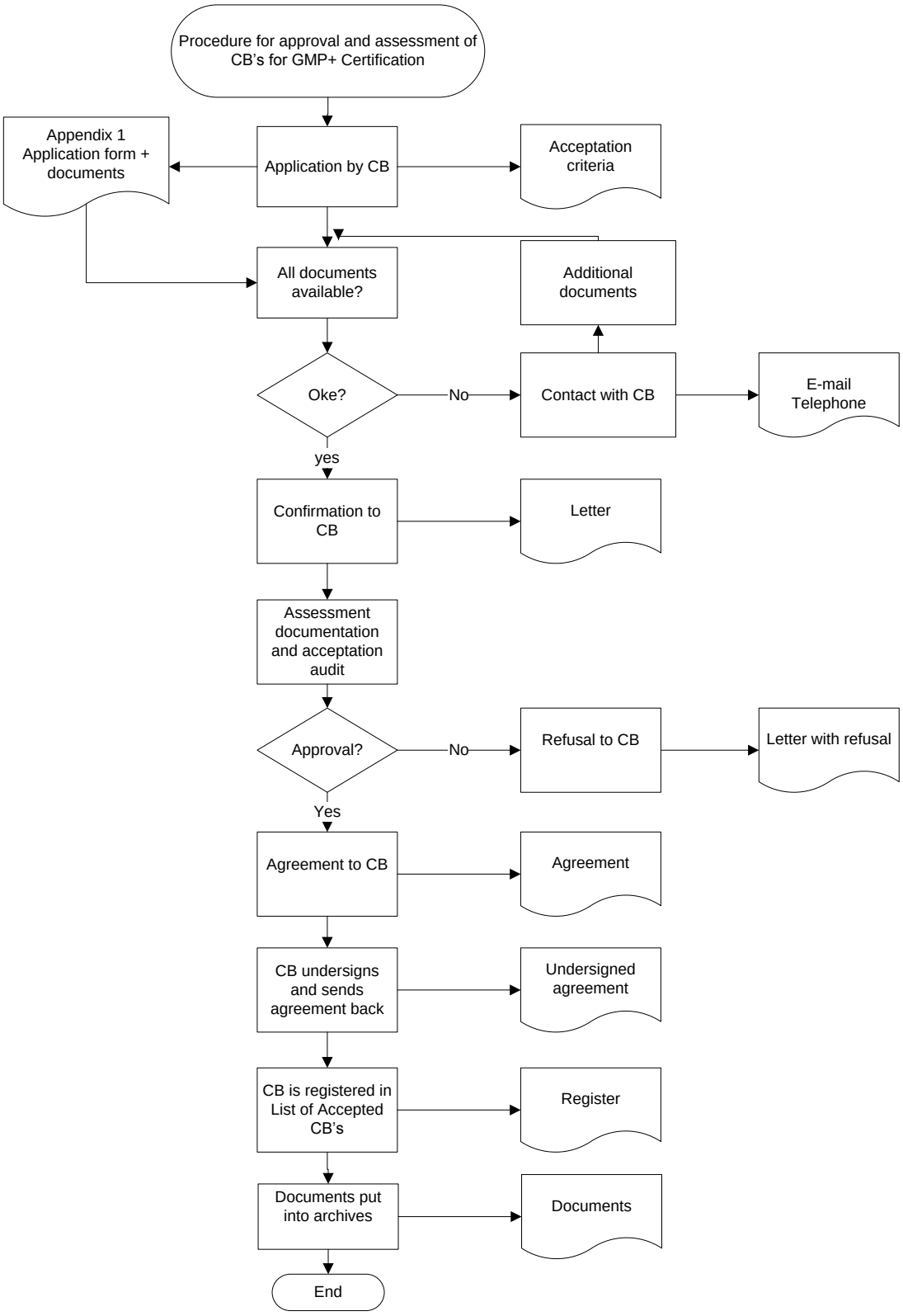
Because these standards / scopes are not equivalent, the exemption does not apply the opposite way.

N.B. The above table also applies for any exemptions from examinations and time spent at the professional meetings and approval of auditor / inspector..

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:

An audit for:	**Also applies as an audit for:**
FAMI-QS	GMP+ B1 / GMP+ B2(2010); with the scope: production of feed additives
GMP-Ovocom	GMP+ for the relevant standard / scope
IFIS	GMP+ B1 / GMP+ B2 / GMP+ B2(2010) with the scope: production of feed materials

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



Appendix 4: Personal details of the auditors / inspectors and coordinators / technical reviewers GMP+ FSA 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 employer	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

Appendix 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+ standard / scope. This approval is only effective for new auditors after a positive document assessment by GMP+ International as specified in appendix 2 of the GMP+ C1 *Approval Requirements and Procedure for Certifcation 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+ standard /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 GMP+ B4.3 *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 standard/scope. If auditors fail one or more examinations in a calendar year then they can do one resit 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 on page 11, appendix 2 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 an exemption is requested on the basis of a combination then the lowest percentage in the combination is binding for the period of exemption.
The exemption will always be linked to the last successful examination. If the approval for one GMP+ standard / scope expires then the (possibility of) exemption for the related standards / scopes will also expire automatically.

Averaging 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 rounded off upwards. This can only be done if other examinations have been passed with a better result.
To be eligible for the averaging of examinations results, the certification body must submit a reasoned request to GMP+ International. The coordinator of a certification body may submit such a request for a maximum of two standards / scopes per auditor during a calendar year. A request such as this may not be submitted if the examination result is less than 60%.
GMP+ International wishes to avoid the situation where auditors who attain good examination results for, for example, one examination have to come back the next year.

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

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.