



Protocol for GMP+ registration for laboratories

GMP+ B 11

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GMP+ Feed Certification scheme



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History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0 / 01-2018	New document	-	01-07-2019
1.0 / 03-2019	New requirement in case of outsourcing has been added.	Part 3 -art. 3.1.g	06-06-2019

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 (focused on feed safety) and GMP+ Feed Responsibility Assurance (focused 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 programs, chain approach and the Early Warning System.

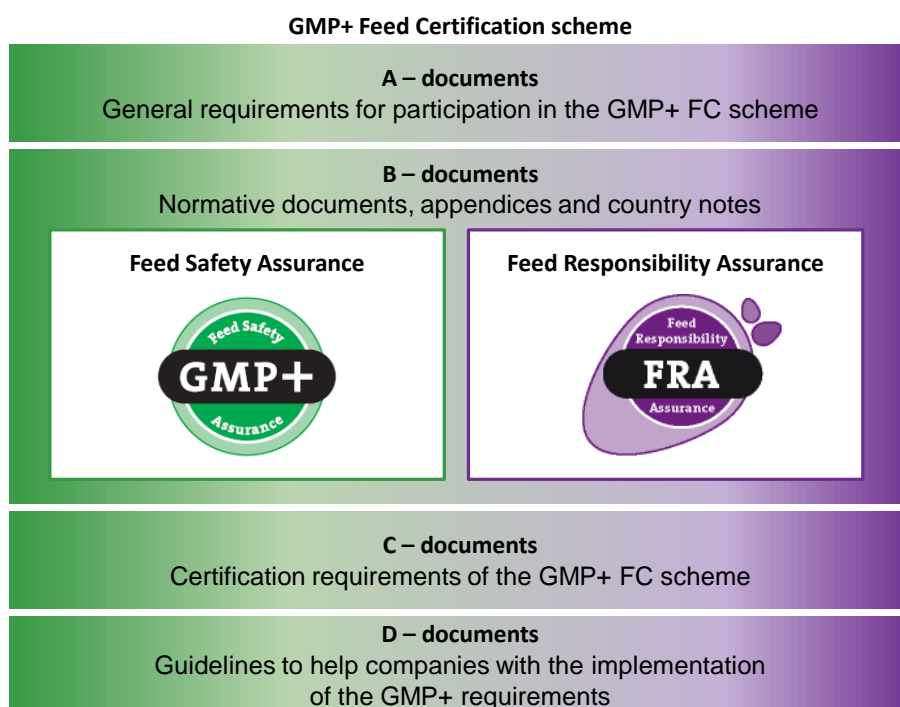
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and 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 GMP+ B11 *Protocol for GMP+ registration for laboratories* and is part of the GMP+ FSA module.

1.3. Scope and application of this standard

Analyzing on samples of feed additives, feed materials, premixes and feed in the context of the GMP+ FSA module must take place in such a way that the reliability of the results produced is controlled and assured. Compliance with performance criteria is an effective tool to demonstrate reliable and comparable results by different laboratories.

Within the GMP+ Feed Certification scheme performance criteria for laboratory testing on specific critical contaminants are laid down in GMP+ BA11 *Performance criteria for GMP+ Registered Laboratories*. The analysis of those critical contaminants must be done by a GMP+ Registered Laboratory.

This standard specifies the requirements for the GMP+ registration of laboratories wishing to become a GMP+ Registered Laboratory.

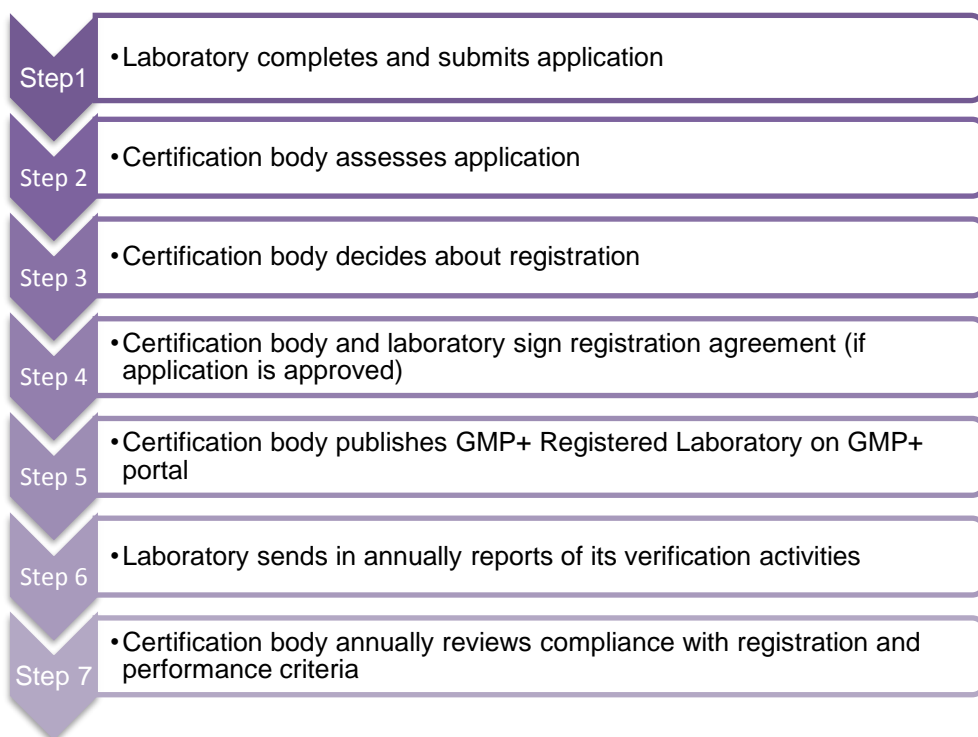
2. Requirements for GMP+ registration

A laboratory wishing to become a GMP+ Registered Laboratory must demonstrably comply with the following requirements:

- a. Having an independently verified quality management system in place which:
 1. is accepted* within the GMP+ Feed Certification scheme
 2. includes participation in proficiency testing in accordance with the requirements in Chapter 3 of GMP+ BA11.
 3. includes continual improvement of the laboratory's performance (for criteria see Chapter 3 of GMP+ BA11).
- b. Meeting the performance criteria for GMP+ Registered Laboratories as laid down in GMP+ BA11.

* See GMP+ BA10 *Minimum Requirements for Purchasing* for a list of accepted laboratory schemes.

3. Registration and verification process



3.1. Application for registration and assessment

A laboratory wishing to become a GMP+ Registered Laboratory submits an application to a certification body accepted by GMP+ International to perform audits for the scope 'Registered Laboratory'.

The application will be considered when the application is complete and all the requested documents have been sent to the certification body:

- a. A recent original excerpt of the registration at the official business registration authority.
- b. A copy of a valid certificate (if applicable) which is accepted within the GMP+ Feed Certification scheme with a copy of the most recent scope of certification and/or accreditation.
- c. A list of operations and associated matrices that fall under the scope of the relevant accepted laboratory scheme(s).
- d. The latest validation report of each analysis for which the applicant laboratory wants to become registered.
- e. The results of the latest proficiency testing program for each analysis for which the applicant laboratory wants to become registered.
- f. In case of outsourcing of an analysis to a subcontracted laboratory, documentation that demonstrates that the subcontracted laboratory is registered for the analysis in question.

- g. In case of outsourcing, the outsourcing laboratory and the subcontracted laboratory must arrange their cooperation in a contract.

Following submission of a fully-completed application and all the required documents, the certification body will carry out an assessment.

3.2. Independent verification

Verification of compliance with the requirements in this document is done by the certification body. Upon request, the applicant laboratory provides the certification body with relevant (additional) information that is necessary to perform the verification.

The assessment is a desk study. An additional on-site verification can take place in case results of the validation report cause doubts regarding compliance with the performance criteria for GMP+ Registered Laboratories.

In case the laboratory can demonstrate that compliance with the performance criteria has been assessed in the annual audit as part of an accepted laboratory scheme, the certification body can use this proof in the verification. The laboratory sends his proof to the certification body. If the laboratory does not have such proof, the certification body carries out the verification as described above in order to verify whether the laboratory complies with the performance criteria for GMP+ Registered Laboratories.

3.3. Decision about registration

The certification body will, within 6 weeks after receipt of the application, inform the applicant laboratory in writing about (non-) compliance with the requirements in this document.

If the application is approved, a registration agreement will be concluded, which needs to be signed by the certification body and the applicant laboratory. The approval is complete following receipt of the signed agreement.

After receiving a signed registration agreement by both parties, the certification body publishes all relevant information about the GMP+ Registered Laboratory in the GMP+ company database and issues a statement of compliance to the GMP+ Registered Laboratory.

3.4. Annual verification

3.4.1. [Information Certification Body](#)

The GMP+ Registered Laboratory provides and keeps the certification body up to date about the information and evidence as requested in 2 and 3.1 above.

At least once per year, the GMP+ registered Laboratory sends in the results of its internal audit of activities to verify that its performance continue to comply with the performance criteria as laid down in GMP+ BA11.

3.4.2. [Annual verification](#)

Every year, verification of compliance with the requirements in this document is done by the certification body on behalf of GMP+ International.

The assessment by the certification body is a desk study. An additional on-site verification can take place in case the results of internal audit by the laboratory cause doubts regarding compliance with the performance criteria for GMP+ Registered Laboratories.

In case the laboratory can demonstrate that compliance with the performance criteria has been assessed in the annual audit as part of an accepted laboratory scheme, the certification body can use this proof in the verification. The laboratory sends his proof to the certification body. If the laboratory does not have such proof, the certification body carries out the verification as described above in order to verify whether the laboratory complies with the performance criteria for GMP+ Registered Laboratories.

3.5. Other provisions

3.5.1. [GMP+ documents](#)

The GMP+ Registered Laboratory is considered a participant of the GMP+ Feed Certification scheme. In addition to the requirements in this document, the GMP+ Registered Laboratory complies with relevant requirements as laid down in the GMP+ FC scheme.

3.5.2. [Annual license fee](#)

Every year, the GMP+ Registered Laboratory pays an annual financial contribution to GMP+ International. The GMP+ Registered Laboratory pays this contribution through the certification body.

The amounts hereof are specified in the GMP+ C4 document of the GMP+ FC scheme. If VAT is applicable, this is borne by the GMP+ Registered Laboratory. Any local and/or other taxes, governmental fees or dues, if applicable, are also borne by the GMP+ Registered Laboratory. The annual contribution is determined by GMP+ International. GMP+ International reserves the right to unilaterally adjust the amounts in the GMP+ C4 document of the GMP+ FC scheme.

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