GMP+ International

FAQ GMP+ Registered Laboratory

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GMP+ Feed Certification scheme

Feed Safety Worldwide

INDEX

1 Introduction

This document was drawn up based on the standard GMP+ B11 *Protocol for GMP+ registration for laboratories* and the appendix GMP+ BA11 *Performance criteria for GMP+ Registered Laboratories*. In the process of developing these documents, GMP+ International received questions about the background, scope and implementation.

This document addresses the most frequently asked questions and is intended as a guidance to the GMP+ participant through the requirements of GMP+ B11 and GMP+ BA11.

2 General

2.1 Why are GMP+ B11 and GMP+ BA11 developed?

The standard GMP+ B11 and the appendix GMP+ BA11 are developed with the goal to improve the reliability of laboratory analysis by requiring a minimum level for the performance of laboratories.

Reliable laboratory analyses are crucial for a strong and trustworthy feed safety chain. Inaccurate or false analysis results will undermine the faith in the strength of our feed safety chain, as well as endanger feed safety itself. In fact, several incidents, related to inaccurate analysis results, have occurred over the years, which led to confusion and stress among companies within the feed chain.

The required level of performance is defined as stated in GMP+ BA11.

Laboratories who comply with the performance criteria become a registered laboratory within the GMP+ Feed Certification scheme. The registration and verification requirements are included in GMP+ B11.

2.2 What is the difference between GMP+ B11 and ISO 17025 accreditation regarding the performance of laboratories?

The main difference is that the standard GMP+ B11 requires a certain level of performance for laboratories, whereas ISO 17025 does not impose a specific level of performance.

Accreditation is a way to demonstrate quality and competence. Within the framework of ISO 17025 accreditation it is the laboratory that determines the level of performance and how it aims to reach and validate that level.
For their accreditation, laboratories need to define a level of performance, select their methods in order to reach the defined level of performance and validate. In practice, this means that a laboratory can establish its own performance criteria for its own situation. As a consequence, the performance of laboratories is different and not comparable. This leads to differences in testing results among laboratories.

2.3 Do the GMP+ B11 and GMP+ BA11 replace the GMP+ B10 standard?

No, GMP+ B11 and GMP+ BA11 exist next to the GMP+ B10 (and ISO 17025).

The GMP+ B10 standard sets requirements on the quality management system of a laboratory.

The new standard GMP+ B11 requires that laboratories have such a system in place which is accepted within the GMP+ Feed Certification scheme, but does not impose additional requirements on the quality management system. The requirements in GMP+ B11 and GMP+ BA11 address the performance of laboratories.

3 Laboratories

3.1 As a laboratory, is it required to become registered in accordance with GMP+ B11?

GMP+ B11 applies to all laboratories who carry out feed analyses for GMP+ FSA certified companies on specific contaminants. See question 2.4 for those contaminants.

3.2 Which laboratories can apply for registration?

Any laboratory that complies with the requirements in Chapter 2 of GMP+ B11 can apply for registration.

3.3 One of the requirements for application is to have 'an independently verified quality management system', which is accepted within the GMP+ Feed certification scheme. Which quality management system are accepted?

The accepted quality management systems are listed in GMP+ BA10 *Minimum Requirements for Purchasing* in section 3.9, part B.

These are laboratories certified / accredited for:

- GMP+ B10 *Laboratory testing*
- ISO17025
- ISO 9001
- TASCC Facilities Testing
- Other quality assurance system (as long as the laboratory produces results in a reliable fashion and that an independent third party has assessed this positively).

3.4 Which contaminants fall under the scope of GMP+ B11 and GMP+ BA11?

Performance criteria have been defined in the GMP+ BA11 for the following contaminants:

- Aflatoxin B1
- Dioxins
- Sum of dioxins and dioxin-like PCBs
- Dioxin-like PCBs
- Non-dioxin-like PCBs
- Heavy metals and fluorin
- Pesticides
  NOTE: Due to practical problems with the registration of pesticides, it is decided to postpone the obligation to use a GMP+ registered laboratory for pesticide analyses until further notice. Therefore, the following applies:

  - As from July 1st 2019, carrying out an analysis of pesticides is no longer restricted to a GMP+ registered laboratory. Instead, the analysis must be carried out by a laboratory with an accepted quality management system.

The accepted quality management systems are listed in GMP+ BA10 Minimum. Requirements for Purchasing in section 3.9, part B. These are laboratories certified / accredited for:

- GMP+ B10 Laboratory testing
- ISO17025
- ISO 9001
- TASCC Facilities Testing
- Other quality assurance system (as long as the laboratory produces results in a reliable fashion and that an independent third party has assessed this positively).

- Related to the previous point, if laboratories want to bring all their pesticide analyses under the GMP+ registration and comply with the performance criteria they can still apply for registration. Feed companies are allowed to have their pesticide analyses carried out by this laboratory. Read this newsletter for more details

3.5 Which performance criteria are addressed?

a. LOQ (limit of quantification)
b. Reproducibility (limit of accuracy)
c. Bias (limit of trueness))
d. Measurement uncertainty

3.6 What steps do I need to do as a laboratory?

As a laboratory you need to:

- Comply with the performance criteria (GMP+ BA11 Performance criteria for GMP+ Registered Laboratories).
- Register at GMP+ International as a Registered Laboratory. Follow for this the special procedure (GMP+ B11 Protocol for GMP+ registration for laboratories).
- Assure compliance in the quality management system.

3.7 As a laboratory, am I allowed to outsource analyses for which a registration is required?

Yes. Outsourcing of analyses to a subcontracted laboratory is common practice and is still possible within the framework of the registration of laboratories.

3.8 Under which conditions is outsourcing of analyses possible?

The (internal) laboratory that outsources must be registered for the analysis in questions and must have proof that the subcontracted laboratory is also registered for the outsourced analysis. The laboratory that outsources does not necessarily carry out this analysis by itself, but must obtained a registration for this specific analysis. The outsourcing laboratory and the subcontracted laboratory must arrange their cooperation in a contract.

It is not possible to outsource an analysis for which you yourself have no registration. For example, a laboratory registered for heavy metals and pesticides cannot outsource the analyses on Aflatoxin B1 to a subcontracted laboratory. ~~This also applies in case the subcontracted laboratory is registered for Aflatoxin B1.~~

4 GMP+ FSA certified feed companies

4.1 What is the consequence of GMP+ B11 and GMP+ BA11 for GMP+ FSA certified companies?

As from 1st of July 2019, the GMP+ FSA certified company has to select a GMP+ Registered Laboratory if he wants to have his feed product analyzed on the contaminants mentioned above. See 2.4 for the contaminants that fall under the scope of GMP+ B11 and GMP+ BA11.

4.2 Will there be sufficient GMP+ Registered Laboratories as from 1st of July 2019?

This question is difficult to answer. The number of registered laboratories and the spread across the world depends largely on:

- communication and explanation in the market by GMP+ International and GMP+ FSA certified companies, and
- GMP+ FSA certified companies stimulating laboratories to become registered.

GMP+ International will monitor and regularly communicate about the registration of laboratories.

4.3 If I as a feed company take more samples than is required within the framework for my GMP+ certification, do I have to select a GMP+ Registered Laboratory for the analysis of those additional samples on, for example, Aflatoxin B1?

No. The analysis of samples that do fall under the framework of GMP+ certification must be done by a GMP+ Registered Laboratory. This, of course, only applies when the analysis is on a contaminant for which performance criteria are established in GMP+ BA11.

GMP+ International
Braillelaan 9
2289 CL Rijswijk
The Netherlands
t. +31 (0)70 – 307 41 20 (Office)
+31 (0)70 – 307 41 44 (Help Desk)
e. info@gmpplus.org