Guidance

S9.36 - Registered Laboratories FAQ

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1. Introduction

This document addresses the most frequently asked questions and is intended as a guidance to the GMP+ certified company through the requirements of TS 4.2.

2. General

2.1. Why is the TS 4.2 developed?

The document TS 4.2 is 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 the document TS 4.2.

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 TS 4.2.

2.2. What is the difference between TS 4.2 and ISO 17025 accreditation regarding the performance of laboratories?

The main difference is that the document TS 4.2 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. Does the TS 4.2 replace the TS 4.1 document?

No, TS 4.2 exists next to the TS 4.1 (and ISO 17025).

The TS 4.1 document sets requirements on the quality management system of a laboratory.

The document TS 4.2 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 TS 4.2 address the performance of laboratories.

3. Laboratories

3.1. As a laboratory, is it required to become registered in accordance with TS 4.2?

The document TS 4.2 applies to all laboratories who carry out feed analyses for GMP+ FSA certified companies on specific contaminants. See question *3.4* for those contaminants.

3.2. Which laboratories can apply for registration?

Any laboratory that complies with the requirements in Chapter 2 of TS 4.2 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 TS1.2 *Purchase* in section 3.8, part A.

These are laboratories certified / accredited for:

- TS 4.1 *Laboratory testing*
- ISO17025
- ISO 9001 (no longer approved under the GMP+ FSA module as from the 1st of July 2022)
- 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). (no longer approved under the GMP+ FSA module as from the 1st of July 2022)

3.4. Which contaminants fall under the scope of TS 4.2?

Performance criteria have been defined in TS 4.2 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
- All Pesticides.

Note: In order to become registered laboratory, the laboratory must comply with the performance criteria included in de shortlist (see TS 4.2 par. 4.7)

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
e. Recovery

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

As a laboratory you need to:

- Comply with the performance criteria (see TS 4.2 Registered Laboratories – chapter 4).
- Register at GMP+ International as a Registered Laboratory. Follow for this the special procedure (see TS4.2 -chapter 3).
- 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.

4. GMP+ FSA certified feed companies

4.1. What is the consequence of TS 4.2 for GMP+ FSA certified companies?

As from 1st of January 2020, 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 *3.4*). This obligation will apply to pesticides from January 1, 2023.

4.2. 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 TS 4.2.

We enable every company in the feed chain to take responsibility for safe and sustainable feed.

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