



TS 2.3 Country Note Central & Eastern Europe

TS 2.3 *Final Draft*

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GMP+ Feed Certification scheme 2020



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Welcome

This Feed Certification Scheme document helps you to provide feed safety world-wide. By meeting the requirements set by GMP+ International together with our GMP+ Community, we aim to help you get the feed certification you need. Please read the information in this document carefully.

Let's make this work together!

1 Introduction

This GMP+ Country Note is meant to give specific GMP+ Feed Safety Assurance (GMP+ FSA) requirements and conditions for a feed company, located in Poland, Ukraine, Czech Republic and Slovakia. These requirements provide a wider range of options for establishing a GMP+ feed safety management system (GMP+ FSMS) for the assurance of the feed safety.

This standard is developed in close cooperation with interested parties in the mentioned countries.

The core principles of this Country Note:

- The specific options which are given, must result in a sufficient level of feed safety assurance;
- Provision of a temporary practical option for a feed company the mentioned countries to:
 - Implement a Feed Safety Management System, which meets the GMP+ FSA requirements
 - obtain a GMP+ FSA certificate
 - satisfy the specific needs of the feed industry in the mentioned countries.

This document is referred to as TS 2.3 *Country Note Central & Eastern Europe* and is part of the GMP+ FSA module.

Frequently asked questions and examples of the application of the country note can be mentioned in this document.

2 Scope, Application & Certification

2.1 Scope of this Country Note

This country note provides specific GMP+ FSA requirements for

- Purchase of processed feed materials from non-certified origin (in addition to the general GMP+ purchase requirements as laid down in TS 1.2 *Purchase*).
- Production of GMP+ FSA assured feed (compound feed and premixtures) and non-GMP+ FSA assured feed (compound feed and premixtures) on one location.
- Labelling.

2.2 Application

Companies, producing compound feed or premixtures and located in Poland, Czech Republic, Ukraine and Slovakia can apply this country note.

This country note must always be applied in combination with the R 1.0 *Feed Safety Management Systems Requirements*.

This country note is part of the GMP+ FC scheme until the end of 2021, and is applicable until that date.

Note: This country note cannot be applied for the production of mixtures of fat and oil products (fat blends). This type of compound feed shall be produced with application of the regular R 1.0 Feed Safety Management Systems Requirements.

2.3 Certification for companies

When a company shows compliance with both the requirements from the R 1.0 *Feed Safety Management Systems Requirements* and this country note, a GMP+ FSA certificate can be granted.

GMP+ certified companies will be registered with an additional scope in the GMP+ Company database. Also, this scope will be stated on the certificate issues by the certification body. This scope is defined as

- Production of compound feed - CEE
- Production of premixtures - CEE

Specification on the free part of the scope (on certificate and in the GMP+ Companies database) must give clear and unambiguous information under which scope the feed is assured.

3 Terms and Definitions

See F 0.2 *Definition list*.

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4 Purchase of non-assured feed materials

The following applies to purchasing feed materials, which are not assured under the GMP+ FSA certificate of a supplier.

In this chapter we refer to 'the gatekeeper' with which is meant the GMP+ certified company that applies the requirements from this country note (producer of compound feed or premixtures).

Helpful tip:

This supplier is in most cases the producer of the feed material. If there is also a trader involved, the scope of the gatekeeper system should of course also include the trader.

The compound feed producer or the premixture producer is overall responsible for demonstrating compliance with the relevant requirements for the gatekeeper system. The supplier may delegate specific tasks and responsibilities to the supplier, or the trader. If so, a specific agreement must be made.

Note 1: A feed material which is assured under a relevant certificate of another, approved scheme should also be considered as 'GMP+ FSA assured'. See for approved schemes/certificates TS 1.2 Purchase.

Note 2: The GMP+ Feed Certification scheme covers all links in the feed chain between growers (primary production) up to delivery to livestock farmers. For the purchasing of unprocessed primary products as feed materials see the relevant annex of TS 1.2 Purchase.

4.1 General

The gatekeeper can purchase a non-GMP+ FSA assured feed material to process in feed for the local market. From each type of feed material to be purchased or received, there must be a generic risk assessment in the Feed Support Products (FSP) database and the feed material must be listed in TS 1.3 *Product list*.

Where TS 1.2 *Purchase* gives gatekeeper protocols, the GMP+ certified company must decide between applying the protocols of TS 1.2 *Purchase* or the gatekeeper options in this country note.

For this, the gatekeeper must establish and implement a special written procedure ('gatekeeper system') which is in compliance with this country note and guarantees that the feed material complies with the relevant GMP+ FSA requirements.

The gatekeeper must demonstrate compliance with the requirements in this country note.

If - for whatever reason - responsibilities and tasks related to operational procedures of the gatekeeper system are delegated to the supplier (or the trader, if there is a trader involved), this must be clear and unambiguous laid down in a quality agreement.

4.2 HACCP hazard analysis

The gatekeeper must conduct a HACCP analysis per supplier and per feed material or group of feed materials.

Helpful tip:

It may be decided for reasons of effectiveness to form groups of feed materials. i.e. different feed materials originating from one production process;

Such a group can be assessed all as one. It is important that:

- a. specific differences between the individual feed materials are examined critically;
 - b. the production and storage conditions are equivalent;
- no major aspects relating to feed safety are forgotten.

This hazard analysis must at least consist of the following phases:

- a. Specification of the feed material, including origin and production method.
- b. Process diagram (general/specific) of the feed material's production up to physical delivery to the gatekeeper.
 1. The hazard analysis must also include the pre-production phases of the feed material insofar these are relevant for analysing possible hazards. This may concern (production of) raw materials, use of processing aids and technological additives used in the production of the feed material.
 2. The hazard analysis must also include all post-production phases until delivery to the gatekeeper, including transport, (temporary) storage, repackaging etc.,
- c. Hazard analysis: identification of hazards and risk assessment.
- d. Overview of the available general and specific control measures for controlling identified risks.
- e. Monitoring plan and results. Compliance with minimum sampling and testing requirements as laid down in this protocol is required.

Note: Information, provided by the supplier, can be used.

Further, the generic risk assessments of feed materials, published on the website of GMP+ International, give information about generically defined hazards. Assessing and – if appropriate - controlling these hazards must be given sufficient attention.

The gatekeeper must decide if additional control measures are necessary.

4.3 Monitoring and Sampling

The gatekeeper must also decide if additional monitoring is necessary. The considerations and general requirements for monitoring, laid down in TS 1.7 *Monitoring* must be taken into account.

Enough samples must be taken to carry out the monitoring plan. Sampling must take place in the production, loading or delivery site of the feed. Sampling must be done in compliance with generally accepted sampling methods.

The frequency of monitoring depends on the risk profile of the feed material, the results of the hazard analysis and the quality assurance applied by the supplier

Helpful tip:

On the GMP+ website a lot of information is available to support companies in defining risks, controlling risks and monitoring CCP's

For example, in TS 1.7 *Monitoring* a formula is given for calculating a realistic frequency for monitoring.

Note: During first delivery (= a new supplier and/or a new feed material/feed additive), an analysis (focussed on relevant safety parameters) must be conducted before first use.

4.4 Audits

The gatekeeper must also decide if additional auditing of the supplier of feed materials is necessary. If so, the frequency depends on the risk profile of the feed material, the results of the hazard analysis and the quality assurance applied by the supplier.

A supplier of a processed feed material must be audited at least once every year.

Audits may be carried out by or on behalf of the gatekeeper.

Helpful tip:

Examples:

- A qualified member of the gatekeeper's staff;
- An appropriately accredited inspection or certification body contracted by the gatekeeper or the supplier.
- An external company (e.g. consultant) providing audit services

Audits may also be conducted on behalf of a group of companies.

4.5 File

The gatekeeper must further compile a file with at least (results of) the above mentioned items. This file must also include:

- a. All relevant records or approvals of the supplier in accordance with national and international legislation;
- b. The written quality agreement (such as a contract) with the supplier.
- c. All results of monitoring and audits conducted by or on behalf of the gatekeeper.

This file must be part of the GMP+ documentation, and must be controlled and updated as such.

4.6 Action Plan

The gatekeeper must set up an Action Plan to achieve that suppliers meet the basic GMP+ requirements, as laid down in TS 1.2 *Purchase*. This means that each supplier assures his own products and activities, and is certified as well.

This Action Plan must have clear actions and activities to stimulate suppliers to meet the relevant requirements, and clear end dates when results or sub results are achieved, once per year.

This Plan of Action may be set up together with other companies, and may include the support of, for instance, GMP+ International.

Helpful tip:

The above described gatekeeper's principle can be applied only temporary. The ultimate aim must be that each link in the feed chain takes his responsibility and assures his activities and products by his own feed safety assurance system, and be certified as such.

It should not be necessary to apply a general gatekeeper option as it is laid down in this country note for years and years.

5 Production

This country note gives opportunities to produce

- 1) GMP+ FSA assured feed, and
- 2) non-GMP+ FSA assured feed

in one location.

Regarding 'GMP+ assured feed', two types of feed can be identified

- 1a) GMP+ FSA assured feed, produced in compliance with the R 1.0 *Feed Safety Management Systems Requirements*
- 1b) GMP+ FSA assured feed, produced in compliance with the R 1.0 *Feed Safety Management Systems Requirements* and the TS 2.3 *Country Note Central & Eastern Europe*.

The gatekeeper is allowed to produce non-GMP+ assured compound feed/ premixtures in the same location/facility where GMP+ assured compound feed/ premixtures are produced. The Feed Safety Management system must assure a strict and complete physical and organisational separation at all stages of processing, producing, (internal) transportation and storage.

When such a complete separation cannot be realized, a HACCP risk analysis must demonstrate that the safety of the GMP+ FSA assured products is not affected negatively.

Note 1: The activities and processes related to the production of non-assured feed/premixtures must be available for auditing to verify compliance with the above requirements.

Helpful tip:

In F 0.1 *Rights and Obligations* is laid down that all feed, produced in one location, must be produced according to the GMP+ requirements, and must meet the relevant GMP+ FSA standards.

In the framework of this country note, however, this strict condition does not apply. See also the labelling requirements in chapter 6.

6 Labelling & Delivery

The gatekeeper must provide his customer with relevant information, in accordance with national legislation.

When applying this this country note, additionally unambiguous information must provide. This means:

- GMP+ FSA assured compound feed or premixtures must meet the requirements as laid down in TS 1.8 *Labelling*.
- GMP+ FSA assured compound feed or premixtures- CEE must be clearly labelled as such ('GMP+ FSA assured-CEE')
- Non-GMP+ FSA assured compound feed or premixtures must be clearly labelled as such ('non-GMP+ FSA assured')

A compound feed or premixture processed with a feed material which is purchased by applying this country note, must only be distributed as GMP+FSA assured feed on the local market, and must be specific labelled according to the requirements, laid down in this country note.

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