



TS 2.1 Country Note Italy

TS 2.1 *Final Draft*

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GMP+ Feed Certification scheme 2020



INDEX

WELCOME	3
1 INTRODUCTION.....	3
2 SCOPE, APPLICATION & CERTIFICATION	4
2.1 SCOPE OF THIS COUNTRY NOTE	4
2.2 APPLICATION	4
2.3 CERTIFICATION FOR COMPANIES	4
3 TERMS AND DEFINITIONS	5
4 PURCHASE OF NON-ASSURED FEED MATERIALS.....	6
4.1 GENERAL	6
4.2 HACCP HAZARD ANALYSIS.....	7
4.3 MONITORING AND SAMPLING	8
4.4 AUDITS	10
4.5 FILE	10
4.6 ACTION PLAN.....	10
5 PRODUCTION.....	12
6 TRANSPORT	13
7 LABELLING AND DELIVERY	14

FINAL DRAFT

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+ requirements and conditions for a feed company, located in Italy. These requirements are meant to provide a wider range of options for establishing a GMP+ feed safety management system for the assurance of the feed safety.

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 an Italian company to:
 - Implement a Feed Safety Management System, which meets the GMP+ FSA requirements
 - obtain a GMP+ FSA certificate
 - satisfy the specific needs of the Italian industry.

This document is referred to as TS 2.1 *Country Note Italy* and is part of the GMP+ FSA module.

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

2 Scope, Application & Certification

2.1 Scope of this Country Note

In this country note specific options are laid down in Chapter 4 to 7, addressing the following items:

- Purchase of processed and unprocessed 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 and non-GMP+ FSA assured feed on one location,
- Gatekeeper options for transport
- Labelling, when this country note is applied.

2.2 Application

Any feed company located in Italy can, within the framework of complying with GMP+ FC scheme requirements, apply this country note.

It also gives the GMP+ certified transport companies an option to –with approval of the feed company- use non-GMP+ FSA assured subcontractors.

This GMP+ country note must always be applied in combination with a relevant GMP+ standard/scope. This country note will be part of the GMP+ FC scheme until the end of 2021, and be applicable until that date.

2.3 Certification for companies

When a company shows compliance with both the requirements from the GMP+ standard and this country note, a GMP+ FSA certificate can be granted.

Certified companies will be registered with an additional scope in GMP+ Company database. Also, this scope will be stated on the certificate.

See for some examples for application of the country note refer to this document

The following additional scopes could apply:

- Production of compound feed - IT
- Production of premixtures - IT
- Production of feed material - IT
- Trade in feed - IT (specified in compound feed, premixtures, feed additives and/or feed material)
- Road transport of feed - IT

3 Terms and Definitions

See F 0.2 *Definition list*.

FINAL DRAFT

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 GMP+ certified company (the producer or trader of the compound feed, pre-mixture or feed material) 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 intermediate trader. If so, a specific agreement must be made.

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

4.1 General

The gatekeeper can purchase a non-GMP+ FSA assured feed material to trade of to process in feed for the Italian 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* provides 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;
- c) 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 of the feed material 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 country note 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 an indication 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.

Helpful tip:

On the GMP+ website an example of a [feed safety data sheet](#) is given, which can be used to summarize the results of the hazard analysis. See: *Certification scheme > GMP+ FSA certification > B documents > related forms.*

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. For this, reference is made to TS 1.6 *Sampling*.

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.

As a minimum for the monitoring frequency on a specific parameter, next formula must be used:

$$\text{Frequency} = \frac{\sqrt{\text{Volume}}}{100} * \text{'likely occurrence'} * \text{'seriousness'}$$

Helpful tip 1:	
VARIABLE	EXPLANATION
Frequency	The number of samples to be tested (on a yearly basis)
Volume	<p>Volume in tons of feed materials per year. In principle, the number of samples to be tested is based on the quantity of feed material which is produced, traded, processed or stored. As the quantity of feed material increases, the number of samples per ton will decrease.</p> <p>Kilograms must be assumed for some feed materials for which, on a yearly basis, only a small quantity is produced, traded or processed.</p>
Likely occurrence	<p>The standard value for likely occurrence is 1. The GMP+ certified company may raise or lower this value if reasons are given. The following considerations may apply to this:</p> <ol style="list-style-type: none"> History: see also below Seasonal influences Possibility of recontamination. This applies in particular to microbiological parameters. New source / new suppliers Have there been recent incidents. <p>It is up to the certified company to decide that the likely occurrence value can be lowered.</p>

	<p>The certified company should select a likely occurrence value which is below one on the basis of (historical) testing results. The following must be kept in mind:</p> <p>a. Testing results should be representative. The historic testing results which are considered as representative may differ per undesirable substance. For some undesirable substances the testing results for an area can be considered to be representative while, for other undesirable substances, only testing results for the same production location is representative.</p> <p>b. Testing results from GMP+ Monitoring database may also be used in determining testing frequency if the certified company can show representativeness.</p>																												
Seriousness	<p>This factor expresses the degree of harmfulness of an undesirable substance. For the value for seriousness use can be made of information of the Feed Support Products (FSP):</p> <table data-bbox="724 887 1209 999"> <tr> <td>Seriousness is great</td> <td>factor 5</td> </tr> <tr> <td>Seriousness is moderate</td> <td>factor 3</td> </tr> <tr> <td>Seriousness is small</td> <td>factor 1</td> </tr> </table> <p>This leads to the following factors:</p> <table border="1" data-bbox="635 1115 1433 1559"> <thead> <tr> <th>Undesirable substance</th> <th>Value</th> </tr> </thead> <tbody> <tr> <td>Heavy metals</td> <td>5</td> </tr> <tr> <td>Pesticides</td> <td>5</td> </tr> <tr> <td>Insecticides</td> <td>5</td> </tr> <tr> <td>Feed medicines</td> <td>5</td> </tr> <tr> <td>Mycotoxins</td> <td>5</td> </tr> <tr> <td>Salmonella</td> <td>5</td> </tr> <tr> <td>Fungi</td> <td>3</td> </tr> <tr> <td>Animal components</td> <td>5</td> </tr> <tr> <td>Dioxin</td> <td>5</td> </tr> <tr> <td>Nitrites</td> <td>5</td> </tr> </tbody> </table> <p>The established values are all high. This seems logical as these are risky undesirable substances.</p>	Seriousness is great	factor 5	Seriousness is moderate	factor 3	Seriousness is small	factor 1	Undesirable substance	Value	Heavy metals	5	Pesticides	5	Insecticides	5	Feed medicines	5	Mycotoxins	5	Salmonella	5	Fungi	3	Animal components	5	Dioxin	5	Nitrites	5
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	<p><u>Note:</u></p> <p>a. Calculated frequencies should always be rounded upwards. The minimum frequency is 1.</p> <p>b. Calculation of the monitoring frequency of liquid or moist feed can be based on 88% dry matter content.</p>																												

Helpful tip 2:

Besides in TS 1.7 *Monitoring*, on the GMP+ website a lot of information is available to support companies in defining risks, controlling risks and monitoring CCP's.

Note: During first delivery (= a new supplier and/or a new feed), 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 ('milestones') to stimulate suppliers to meet the relevant requirements, and clear end dates when results or sub results are achieved, once a year.

Further, this action plan must have clear criteria for evaluation and decision about continuation of the relation between gatekeeper and supplier. Every year an evaluation must be made.

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.

FINAL DRAFT

5 Production

The gatekeeper is allowed to produce non-GMP+ assured feed in the same location/facility where GMP+ assured feed (either regular GMP+ or GMP+ IT assured feed) is produced. The Feed Safety Management system must assure a strict and complete physical and/or 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. Carry over, and its risk for contamination, must be part of the HACCP study.

The system must assure that GMP+ feed meets the GMP+ standards, This include not only the standards as laid down in TS 1.5 *Specific feed safety limits* but also the standards laid down in GMP+ TS 1.11 *Control of residues*.

Note: The activities and processes related to the production of non-assured feed 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, on the condition that GMP+ assured feed meets the relevant GMP+ standards.

For example:

A certified company is allowed to assure the production of compound feed under the GMP+ certificate, and to exclude the production of the premixtures.

Special attention is required to assure that carry-over is controlled and does not lead to a breach of the GMP+ standards.

Note: See also the labelling requirements in chapter 7.

6 Transport

Transport of all incoming and outgoing feed must preferably be carried out under GMP+ transport certification. Options are:

1. A company which is GMP+ certified for transport
2. A company with another transport certificate, which is approved within the GMP+ FSA module as described in TS 1.2 *Purchase*.
3. Application of a gatekeeper system, as laid down in TS 1.2 *Purchase* .

With regard to the third option, it is also possible for a GMP+ certified transport company to apply this gatekeeper protocol, but only when there is a clear and unambiguous written approval from the producer or trader, who are the owners of the goods.

All the information about the transport, and how it is controlled by the GMP+ certified transport company, must be available for the company. The GMP+ certified company must assess whether or not the agreement is met, and if the transport meets all the requirements.

Conditions for transport company

The GMP+ certified transport company, who –with approval of the feed company - assures safe transport, may use subcontractors by applying The transport gatekeeper protocol as laid down in TS 1.2 *Purchase*.

The transport company must assure that all the conditions of the transport gatekeeper protocol as laid down in TS 1.2 *Purchase* are met.

This gatekeeper option can only be applied for transport within Italy.

Action Plan

The transport company must set up an Action Plan to achieve that suppliers meet the basic GMP+ requirements, as laid down in TS 1.2 *Purchase* (see for this chapter 4.6 of this document)

Helpful tip:

This means that this part of the Country Note can be applied by a GMP+ certified transport company, when there is a clear agreement with a feed producer or trader

7 Labelling and Delivery

The gatekeeper must provide the customer with relevant information, in accordance with national legislation and with TS 1.8 *Labelling*. This applies in the event of delivery to GMP+ certified customers or customers who are certified in another certification scheme which has been declared to be equivalent to the GMP+ FC scheme (see TS 1.2 *Purchase*). This information must be specified in the sales contract or in some other written form by the time of delivery at the latest.

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

- GMP+ FSA assured feed must meet the requirements as laid down in TS 1.8 *Labelling*.
- GMP+ FSA assured feed- IT must be clearly declared as such ('GMP+ FSA assured-IT')
- Non-GMP+ FSA assured feed must be clearly declared as such ('non-GMP+ FSA assured').

If a feed company applies one or more of the conditions from this Country Note for production, processing, trade or transport of a compound feed or a feed material, this feed products can only be distributed as TS 2.1 *Country Note Italy* assured feed on the Italian market.

Premixtures can also be sold to customers outside the Italian market as long as these customers do not participate in the GMP+ FSA module or an approved, other feed safety scheme. See for approved other feed safety schemes TS 1.2 *Purchase*.

Any feed product, produced, processed, traded or transported by applying one or more of the conditions from this Country Note, must be specific labelled according to the requirements, laid down in this country note. 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.

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