



TS 2.5 Country Note Iberian Peninsula (Andorra, Spain, Portugal)

TS 2.5 **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 worldwide. 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 Iberian Peninsula (Andorra, Spain and Portugal). 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 stakeholders in Spain.

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 Andorran, Spanish and/or Portuguese 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 Andorran, Spanish and Portuguese industry.

This document is referred to as TS 2.5 *Country Note Iberian Peninsula* 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 6, addressing the following items:

- a) Production of GMP+ FSA assured feed and non-GMP+ FSA assured feed on one location,
- b) Purchase of processed materials from non-certified origin (in addition to the general GMP+ purchase requirements as laid down in TS 1.2 *Purchase*).
- c) Special requirements for transport

2.2. Application

Any feed company, located in Iberian Peninsula, with activities in the production, trade, stevedores or road transport of feed may apply this Country Note with the aim to obtain GMP+ FSA certification.

This GMP+ Country Note must always be applied in combination with a relevant GMP+ standard/scope.

Application of this Country Note is temporary (2019 – 2022).

2.3. Certification for companies

When a company shows compliance with both the requirements of the GMP+ standard and this Country Note, a GMP+ FSA certificate can be granted.

The scope and reference to this Country Note will be additionally stated on the certificate as well as in the registered information in GMP+ Certified Company in database. This additional scope is compiled by the regular scope formulation, supplemented with the addendum '-IP'.

The following additional scopes could apply:

- a) Production of compound feed - IP
- b) Production of premixtures - IP
- c) Production of feed materials - IP
- d) Production of feed additives - IP
- e) Trade in feed - IP (specified in compound feed/premixtures/feed additives/feed material)
- f) Road transport of feed - IP

See "FAQ on Country Note Iberian Peninsula" with some examples on application of the Country Note.

3. Terms and Definitions

See F 0.2 *Definition list*.

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4. Specific requirements for business locations

In the framework of this Country Note, it is allowed to produce in one location GMP+ FSA assured feed and non-GMP+ FSA assured feed.

Procedures must be implemented to assure the separation between GMP+ FSA assured feed and non-GMP+ FSA assured feed in order to ensure the safety of the feed products, covered under the scope of GMP+ FSA certification (= 'GMP+ FSA assured') is not negatively affected and that relevant feed safety limits are not exceeded, see TS 1.5 *Specific feed safety limits*.

These procedures must be the result of a hazard analysis (HACCP) of the products and process, and must be monitored. The FSMS must guarantee that these procedures are operated effectively.

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5. Purchase of non-assured feed materials ('gatekeeping')

In this chapter, specific requirements are laid down for purchasing of feed materials from a non-certified supplier ('gatekeeping').

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.

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).

5.1. General requirements

The gatekeeper (the GMP+ certified company) establishes and implements a gatekeeper system to assure that the feed material, which will be brought into the GMP+ feed chain under the conditions of gatekeeping,

- a) is safe for use in or as feed,
- b) complies with the relevant GMP+ FSA requirements, including the requirements in this Country Note,
- c) complies with all relevant feed legislation

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 an agreement.

From each type of feed material to be purchased or received, there must be a generic risk assessment in the Feed Support Products (FSP) and the feed material must be listed in TS 1.3 *Product list*.

5.2. Elements of the GMP+ gatekeeper system

5.2.1. Input for hazard analysis

Preliminary to the hazard analysis, the gatekeeper collects information about the feed material which it wants to purchase. This information should at least be focused on feed safety hazards and must include:

- a) specifications of the feed, the production process of the feed and the used equipment.
This can include the used of processing aids and feed additives.

- b) the pre-production phases of the feed insofar these are relevant for identifying and assessing possible feed safety hazards.
- c) all post-production activities until delivery to the gatekeeper, including transport, (temporary) storage, repackaging, etc.
- d) the feed safety requirements which are to be met.

Helpful tip 1:

- the supplier
 - guarantees:
 - Is there a safety standard implemented?
 - What certification does supplier have?
 - legal license (e.g. Feed registration number)
 - other relevant information (e.g. an audit report)
- the feed: a complete specification
 - MSDS
- the production process:
 - a clear process description/process diagram
 - which raw materials and processing aids or feed additives are used
 - other activities or circumstances (transport, storage)
 - the risks/ hazards: Which are the identified risks/ hazards of the production process?
 - the controls: Which control measures have been taken?
 - the monitoring: Which monitoring is carried out? Results?

Questionnaires can be very helpful to obtain information in a structured way.

The gatekeeper must conduct a hazard analysis per supplier and per (group of) feed materials.

Important steps are:

- e) Identification of possible feed safety hazards;
- f) Assessment to determine if the feed safety hazards are controlled.

Where proper control cannot be guaranteed, the gatekeeper must decide about implementation of additional control measures to assure the feed safety.

Helpful tip 2 :

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:

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

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

- iv. Specification of the feed material, including origin and production method.
- v. Process diagram (general/specific) of the feed material's production up to physical delivery to the gatekeeper.
 - 1) The hazard analysis shall 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 shall also include all post-production of the feed material phases until delivery to the gatekeeper, including transport, (temporary) storage, repackaging etc.,
- vi. Identification and assessment of hazards.
- vii. Overview of the available general and specific control measures for controlling identified risks.
- viii. Monitoring plan and results. Compliance with minimum sampling and testing requirements as laid down in this Country Note is required.

Helpful tip 3:

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 shall be given sufficient attention. Modifications in generic risk assessment, to adapt it to specific conditions of each company, must be properly justified and registered by GMP+ FSA applicants.

5.3. Sampling and Monitoring

5.3.1. Sampling

GMP+ FSA certified companies, who act as gatekeeper, must sample each batch which is purchased under scope of this Country Note. Sampling must be done in compliance with generally accepted sampling methods. For this, reference is made to TS 1.6 *Sampling*.

5.3.2. Monitoring

Based on the results of hazard analysis, the gatekeeper must decide about monitoring. The considerations and general requirements for monitoring, laid down in TS 1.7 *Monitoring* must be taken into account

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, the next formula must be used

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

During first delivery (= a new supplier and/or a new feed), an analysis (focussed on relevant safety parameters) must be conducted before first use. The monitoring plan must be assessed and updated when required to include new information (from scientific researches, legislation, incidents, etc.).

Helpful tip:

For reasons of efficiency it is recommended to join a so-called joint monitoring plan. There are several of these initiatives in Iberian Peninsula. Joining such an initiative will result in more information against less costs.

Note: Information provided by a so-called joint monitoring plan must be representative and lined with GMP+ monitoring requirements. Each GMP+ FSA certified company is responsible of ensuring this representativity.

Helpful tip: Find below information about the calculation of the monitoring	
VARIABLE	EXPLANATION
Frequency	The number of samples to be tested (on a yearly basis)
Volume	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. Kilograms shall be assumed for some feed materials for which, on a yearly basis, only a small quantity is produced, traded or processed.
Likelihood of occurrence	The standard value for likelihood of occurrence is 1. The gatekeeper may raise or lower this value if reasons are motivated. The following considerations may apply to this: <ul style="list-style-type: none"> • History: see also below • Seasonal influences • Possibility of recontamination. This applies in GMP+ certified company to microbiological parameters. • New source / new suppliers • Have there been recent incidents. It is up to the gatekeeper to decide that the likelihood of occurrence value can be lowered.

	<p>The gatekeeper should select a likelihood of occurrence value which is below one on the basis of (historical) testing results. The following shall be kept in mind:</p> <ul style="list-style-type: none"> • 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/region/country can be considered to be representative while, for other undesirable substances, only testing results for the same production location is representative. • Testing results from GMP+ GMP+ Monitoring database or from a joint monitoring plan (there are several of these initiatives in Iberian Peninsula) may also be used in determining testing frequency if the gatekeeper can show representativeness. 																								
<p>Seriousness</p>	<p>This factor expresses the degree of harmfulness of an undesirable substance. Information from Feed Support Products (FSP) can be used for the seriousness value. Especially the Risk Assessments and the Fact Sheets give useful information. To be found on the GMP+ International website.</p> <p>Seriousness is great factor 5 Seriousness is moderate factor 3 Seriousness is small factor 1</p> <p>Find in the table below the values of some of the most important undesirable substances</p> <table border="1" data-bbox="448 1137 1326 1709"> <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>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>Artificial fertiliser</td> <td>3</td> </tr> <tr> <td>Prohibited animal proteins (according to GMP+TS6)</td> <td>5</td> </tr> <tr> <td>Dioxin</td> <td>5</td> </tr> <tr> <td>Packaging materials</td> <td>3</td> </tr> <tr> <td>Tannins</td> <td>3</td> </tr> <tr> <td>Salts (Chloride, Potassium)</td> <td>1</td> </tr> </tbody> </table>	Undesirable substance	Value	Heavy metals	5	Pesticides	5	Feed medicines	5	Mycotoxins	5	Salmonella	5	Artificial fertiliser	3	Prohibited animal proteins (according to GMP+TS6)	5	Dioxin	5	Packaging materials	3	Tannins	3	Salts (Chloride, Potassium)	1
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	<p><u>Keep in mind:</u></p> <ul style="list-style-type: none"> • Calculated frequencies should always be rounded upwards. The minimum frequency is 1. • Calculation of the monitoring frequency of liquid or moist feed can be based on 88% dry matter content. 																								

5.3.3. Inclusion of results in GMP+ Monitoring database

In the framework of this Country Note, the inclusion of monitoring results in the GMP+ Monitoring database is mandatory for GMP+ FSA certified companies.

5.4. Supplier audits

Based on the hazard analyses, the gatekeeper must also decide if auditing of the supplier of feed materials is necessary. If so, the frequency depends on:

- a) the risk profile of the feed material,
- b) the results of the hazard analysis,
- c) the results of the monitoring and
- d) the quality assurance applied by the supplier.

A supplier of a processed feed material must be audited at least once every year. A definition of 'processed feed material' is mentioned in the F 0.2 *Definition list*.

The audit must result in a clear decision about:

- e) the assurance of the safety of the feed or feed service;
- f) the compliance with the conditions of the agreement met.

When necessary, control measures needs to be adapted and implemented.

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

Helpful tip:

Examples of the person conducting the supplier audit:

- 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 in order to simplify the process. In this case, results of audits must be available for the whole group.

5.5. Supplier improvement programme

The gatekeeper must set up a Supplier Improvement Program aiming to achieve that all his feed material suppliers¹ will establish and operate a certified GMP+ Feed Safety Management System within a determined timeframe.

¹ Meant are the feed material suppliers which are not certified

This Supplier Improvement Program must have

- a) Calculation of the initial situation of the gatekeeper
 1. calculation of total feed production volume,
 2. % of this total volume which is meant to be GMP+ FSA assured, and
 3. % GMP+FSA assured feed materials coming from already assured sources
- b) clear actions and activities ('milestones') to stimulate suppliers to meet the relevant requirements, and clear end dates when results are achieved, yearly.
- c) clear criteria for evaluation and decision about continuation of the relation between gatekeeper and supplier. Once a year an evaluation must be made.
- d) Yearly assessment of achieved results and updating of proposed goals on % volume of feed materials which comes from assured sources
- e) if initial situation changes, for instance due to new products and/or new suppliers, the Supplier Improvement Program must be reviewed and adapted to the new situation

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

The Supplier Improvement Program may last for max. 4 years as long as the % of volume of feed materials from assured suppliers for GMP+ assured feed:

- must increase every year
- must result within 4 years in 100%.

The gatekeeper must take clear actions towards his suppliers to achieve this.

Helpful tip:

The gatekeeper shall at the end of each year calculate which volume of the feed materials used in the production of GMP+ FSA assured feed, is supplied by a certified supplier. As previously commented in the criteria, the percentage shall be higher than the percentages reached on previous years and, always higher than % set at the beginning of its Supplier Improvement Program.

Keep in mind:

- It is about the GMP+ FSA assured feed (volume of production outside the GMP+ FSA chain is not considered)
- 'from certified suppliers' includes feed materials:

- which are supplied by suppliers who are certified according to another, accepted scheme
- purchases via a regular gatekeeper option. See for regular gatekeeper options TS 1.2 *Purchase*.

Example:

Following table can be used as example of evolution/goals in a Supplier Improvement Program set by a compound feed company. It include the % of volume of feed materials, which is already from assured supplier in the production:

At the end of year	2019	2020	2021	2022
Estimated % set at beginning of Supplier Improving Program	40	60	80	100

Taking as example a compound feed producer which produces 80.000 tonnes of compound feed and wants to have 20% of this production under the scope of the GMP+ FSA certification → it means that 16.000 tonnes of compound feed shall be GMP+ assured.

Applying aims proposed on previous table, at the end of 2019 at least 40% of these 16.000 tonnes (= 6.400 tonnes) should be delivered by certified suppliers or bought via a regular gatekeeper option as laid down in TS 1.2 *Purchase*.

At the end of 2020, at least the 60% of these 16.000 tonnes (=9.600 tonnes) should be delivered by certified suppliers or bought via a regular gatekeeper option as laid down in GMP+ TS1.2 *Purchase*; and same process for whole period of application of Supplier Improvement Program.

If at the end of 2019 the resulting % volume of feed materials from certified suppliers is 64% (instead of 40% set as aim), the aim for 2020 must be updated to higher % than the obtained result in the previous year. Consequently, the table of aims must be yearly updated by gatekeeper in order to include obtained results and readjusted aims for next year. For instance, the new updated table could be:

At the end of year	2019	2020	2021	2022
Resulting % volume obtained thanks to Supplier Improving Program	64			
Readjusted/updated aims for coming years		>64	80	100

5.6. Documentation

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 agreement (such as a contract) with the supplier;
- c. All results of monitoring and audits conducted by or on behalf of the gatekeeper;
- d. All relevant registrations of the Suppliers Improvement Program. The registration must give a clear overview of the goals, the progress and the results.

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

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6. Road transport

In the GMP+ FC scheme is laid down, that transport of all incoming and outgoing feed must be carried out under road transport certification. The options are:

- a) A company which is GMP+ FSA certified for transport;
- b) A company with another transport certificate, which is accepted within the GMP+ FSA scheme. See for accepted transport certificates TS 1.2 *Purchase*;
- c) Application of a gatekeeper system, as laid down in TS 1.2 *Purchase*. Gatekeeping of transport
 1. is only allowed in certain countries, and;
 2. only applicable for a trader or a producer of the feed.

There are some exceptions to these options, and there are special requirements for tractionairs. The next paragraphs give special options for road transport of feed.

6.1. Gatekeeping of tractionairs

In the framework of this Country Note, tractionairs may be considered as own drivers and part of the GMP+ certified transport company (the gatekeeper) under the next requirements:

- a) There is a clear and unambiguous long-lasting agreement between the transport company (the gatekeeper) and the tractionair;
- b) The role of the tractionair is exclusively transporting feed on behalf of the gatekeeper;
- c) The gatekeeper is responsible of complying with GMP+ requirements;
- d) The tractionair receives proper training about GMP+ rules for transport (cleaning, registration, loading/unloading, etc);
- e) Subcontracted tractionairs may also transport non-feed loading compartments for other companies when it is authorized by the gatekeeper in advance.

6.2. Gatekeeping for subcontracting of road transport by transport companies or stevedores

6.2.1. Introduction

Next to subcontracting of tractionairs, on the Iberian Peninsula subcontracting of drivers with complete trucks (tractor and loading compartment) is very common. The above mentioned third option (gatekeeping as laid down in TS 1.2 *Purchase*) could be very convenient but is only available for a GMP+ FSA certified trader or a GMP+FSA certified producer, and not for a GMP+ FSA certified transport company.

This third option could be very convenient for GMP+ certified storage and transshipment companies, specifically operating within the Spanish, Portuguese and Andorran port premises (called stevedores) where normally only a very limited number of transport companies/transport cooperatives can operate.

Stevedores do normally not have an alternative to these transport companies/cooperatives. It would be very helpful if this Country Note allows stevedores to apply the gatekeeper conditions for transport.

In the framework of this Country Note, the gatekeeper protocol as laid down in TS 1.2 *Purchase* can also be applied by

- an Iberian Peninsula GMP+ certified transport company or GMP+ certified storage and
- a transshipment company (stevedores)

under the next conditions:

- a) The subcontracted non-certified transport company must be located in Iberian Peninsula
- b) There is a clear and unambiguous written approval from the producer or trader, who are the owners of the goods.
- c) All the information about the transport via non-GMP+ FSA certified transport companies must be available for the gatekeeper.
- d) The gatekeeper must assure that all the conditions of the gatekeeper protocol for transport as laid down in TS 1.2 *Purchase* are met.
- e) The gatekeeper must assess whether or not the agreement is met, and if the transport meets all the requirements.
- f) If necessary, additional control measures must be agreed.

6.3. Suppliers improvements programme

The gatekeeper must set up a Suppliers Improvement Program aiming to achieve that all the subcontracted transport companies² will establish and operate a certified GMP+ Feed Safety Management System within a determined timeframe.

This Supplier Improvement Program must have:

- a) calculation of the initial situation of gatekeeper:
 1. and calculation of total volume of transported feed;
 2. % of this total volume which is meant to be GMP+ FSA assured;
 3. % of the transport which is already GMP+ FSA assured.

² Meant are the transport companies which are not certified

- b) clear actions and activities ('milestones') to stimulate non-certified transporters to meet the relevant requirements, and clear end dates when results are achieved, yearly.
- c) clear criteria for evaluation and decision about continuation of the relation between gatekeeper and the non-certified transport company. Once a year an evaluation must be made.
- d) Yearly assessment of achieved results and updating of proposed goals on % volume of feed transported under GMP+ FSA assurance.
- e) if initial situation changes, for instance due to new customers into the GMP+ FSA chain, the Supplier Improvement Program must be reviewed and adapted to the new situation.

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

The Supplier Improvement Program must last for max. 4 years if the % of volume of transported feed materials from assured suppliers for GMP+ assured feed:

- 1) must increase every year (no applicable to stevedores that only work with 1 or 2 subcontracted transport companies into ports)
- 2) must result within 4 years in 100%.

The gatekeeper must take clear actions towards his suppliers to achieve this.

Helpful tip:

Following table can be used as example of evolution/aims in a Supplier Improvement Program set by a transport company:

At the end of year	% of volume of subcontracted transport, which is already certified
2019	40
2020	65
2021	85
2022	100

This table must be updated yearly with obtained results and updated suggested aims.

6.4. Release procedure after transport of forbidden loads

The GMP+ release procedure for load compartments after forbidden loads have been transported, are quite strict. These procedures have been established in cooperation with other European feed safety transport schemes under ICRT³ umbrella.

The best option is to separate the transport fleet in vehicles (load compartments/trailers) used for GMP+ transport of feed and in vehicles used for other transport including transport of, for instance, forbidden loads. The GMP+ feed safety management scheme should guarantee a clear separation.

However, in case necessary, procedures are available to make a load compartment suitable for GMP+ FSA certified transport of feed after a forbidden load have been transported. These procedures can be found In TS 1.9 *Transport activities*.

There are 3 options:

- 1) Release via an independent inspection (ISO17021)⁴.
- 2) Release via a loading inspector, after an independent cleaning (ECD)⁵
- 3) Release via the following sequence of actions/controls:
 - a. Transport of 5 neutral loads (with cleaning A or B)
 - b. Demonstrate the performance of the cleaning and/or disinfection by means of a European cleaning Document (ECD)
 - c. Take samples of cleaning water before and after use it for last cleaning the loading compartment
 - d. Analyse both samples of cleaning water in a laboratory. If composition of both samples is the same, the loading compartment can be considered as clean, and be released.

³ ICRT (international Committee Road Transport). See additional information [here](#) as well as access to IDTF (International Database Transport (for) Feed).

⁴ See [Procedure for the acceptance of loading compartments after the transport of prohibited loads](#) (Version 2016-04-01) for extra information.

⁵ European Cleaning Document

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