



Specific requirements for Iberian Peninsula (Andorra, Spain, Portugal)

GMP+ BCN - IP

Version EN: 15 May 2019/corr.11.12.2019



GMP+ Feed Certification scheme

- No initial audits or recertification audits will be possible after expiry of the validity date stated in this Country Note. Surveillance audits are still allowed.
- Existing GMP+ Country Note certificates will still be accepted until the expiration of the certificate or the switch to the GMP+ FC scheme 2020, whichever comes first.
- This Country Note will be available on our website until the validity date stated in this Country Note. After that it will remain available in section <u>FSA History documents</u>.
- See also the GMP+ newsletter for more information.

Feed Safety Worldwide

History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0/ 04-19	This is a new document	Entire document	15-05-2019
0.1/05-19	Footnote 5 was missing	6.4	
0.2 / 11-19	Content of Appendix 1 is moved to document GMP+ D2.6 (point 3.6)	5.4	



Index

1.	INT	FRODUCTION	4
1	.1.	General	4
1	.2.	STRUCTURE OF THE GMP+ FEED CERTIFICATION SCHEME	5
1	.3.	COUNTRY NOTES	5
2.	ВА	CKGROUND, SCOPE, APPLICATION & CERTIFICATION	7
2	.1.	Background	7
2	.2.	SCOPE OF THIS COUNTRY NOTE	7
2	.3.	APPLICATION	7
	2.3.	.1. Who can apply?	7
	2.3.	2. How to apply?	7
2	.4.	CERTIFICATION	8
3.	TEF	RMS AND DEFINITIONS	9
4.	SPE	ECIFIC REQUIREMENTS FOR BUSINESS LOCATIONS	11
5.	PU	RCHASE OF NON-ASSURED FEED MATERIALS ('GATEKEEPING')	12
5	.1.	GENERAL REQUIREMENTS	12
5	.2.	ELEMENTS OF THE GMP+ GATEKEEPER SYSTEM	13
	5.2.	1. Input for hazard analysis	13
5	.3.	SAMPLING AND MONITORING	15
	5.3.	1. Sampling	15
	5.3.	2. Monitoring	15
	5.3.	3. Inclusion of results in GMP+ Monitoring database	17
5	.4.	SUPPLIER AUDITS	17
5	.5.	SUPPLIER IMPROVEMENT PROGRAM	19
5	.6.	DOCUMENTATION	21
6.	RO	AD TRANSPORT	22
6	.1.	GATEKEEPING OF TRACTIONAIRS	22
6	.2.	GATEKEEPING FOR SUBCONTRACTING OF ROAD TRANSPORT BY TRANSPORT COMPANIES OR STEVEDORES	22
	6.2.	1. Introduction	22
6	.3.	SUPPLIERS IMPROVEMENTS PROGRAM	23
6	4	RELEASE PROCEDURE AFTER TRANSPORT OF FORRIDDEN LOADS	24



1. Introduction

1.1. General

In 1992, the GMP+ Feed Certification scheme was initiated and developed by the Dutch feed industry. It was in response to various incidents involving contamination in feed materials. Although it started as a national Good Manufacturing Practice Code for the mixed feed production, it has developed to an international scheme nowadays, which is managed by GMP+ International.

Even though the GMP+ Feed Certification scheme originated from a feed safety perspective, in 2013 the first feed responsibility standard has been published. For this purpose, two modules are created: GMP+ Feed Safety Assurance (focused on feed safety) and GMP+ Feed Responsibility Assurance (focused on responsible feed).

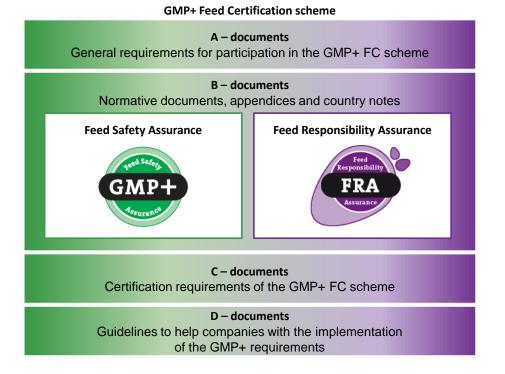
GMP+ Feed Safety Assurance (GMP+ FSA) is a complete module with standards for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA standards, such as requirements for a feed safety management system, for application of HACCP principles, to traceability, monitoring, prerequisites programs, chain approach and the Early Warning System. With the development of the GMP+ Feed Responsibility Assurance module (GMP+ FRA), GMP+ International was responding to requests of GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy which is produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible pro-duction and trade, a company can get certified for the GMP+ FRA standards. GMP+ International facilitates via independent certification the demands from the market.

Together with its partners, GMP+ International transparently lays down clear requirements in internationally applicable standards in the GMP+ Feed Certification scheme. Authorized Certification Bodies are able to carry out GMP+ certification independently.



1.2. Structure of the GMP+ Feed Certification scheme

The documents within the GMP+ Feed Certification scheme are subdivided into a number of series. The next page shows a schematic representation of the content of the GMP+ Feed Certification scheme:



All these documents are available via the website of GMP+ International (www.gmpplus.org).

1.3. Country Notes

The GMP+ B standards (normative documents) in the GMP+ Feed Safety Assurance (GMP+ FSA) module are applicable worldwide. Some requirements, especially the purchase requirements, are not fully achievable in countries without or with a limited number of GMP+ FSA or equivalent certified suppliers. For sourcing of some feed ingredients (feed materials and additives) and services, a gatekeeper protocol is already applicable. However, the main GMP+ principle is that feed ingredients should be sourced from GMP+ FSA or equivalent certified suppliers. In some cases the gatekeeper protocol is applicable.

A GMP+ Country Note aims to enable companies in a certain country to comply with the GMP+ requirements but with respect to national legislation. Further, in order to get a GMP+ certificate, this Country Note gives deviating requirements with additional stipulations to provide enough safeguarding of the feed safety. Most of these deviating requirements will be needed temporarily. An example of such an important (additional) condition in this Country Note is that the Participant must introduce a Suppliers' Improvement Program to push the suppliers to take responsibility for assuring the feed safety of their products & services by obtaining a GMP+ FSA (or equivalent)



certificate themselves. If in time more suppliers are also participating in the GMP+ FC scheme, compliance with the inter-national GMP+ FSA core standards will be achievable.

A Country Note is established when obstacles to participate are identified and - at the other hand - a growing interest for proper feed safety assurance is expressed by the industry. Such a Country Note is developed in collaboration with stakeholders in the applicable country.

In Iberian Peninsula (Andorra, Spain and Portugal), a growing interest is perceived to comply with international standards like GMP+ FSA standards. Therefore, GMP+ International developed the current GMP+ Country Note for Iberian Peninsula. It is meant to apply as an add-on to the core GMP+ FSA standards, and successful implementation leads to a GMP+ FSA certificate.

This document is referred to as BCN- IP Specific requirements for Iberian Peninsula and is part of the GMP+ FSA module.

Guidance

Any feed company or any organization, certification body or consultant, representing feed companies, which are located in other countries than Andorra, Spain and/or Portugal (Iberian Peninsula), are invited to contact GMP+ International if they feel there is an interest for application of this Country Note in another country, as well.



2. Background, scope, application & Certification

2.1. Background

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 are meant to provide a wider range of options for establishing a GMP+ feed safety management system (GMP+ FSMS) for the assurance of the feed safety.

The core principles of this Country Note:

- The specific options which are given, shall result in a sufficient level of feed safety assurance;
- Provision of a practical option for an Andorran, Spanish and/or Portuguese company to:
 - o Implement a Feed Safety Management System, which meets the GMP+ FSA requirements
 - obtain a GMP+ FSA certificate
 - o satisfy the specific needs of the Andorran, Spanish and Portuguese industry.
- Application (always in combination with a basic GMP+ FSA standard) should make it possible for a feed company to obtain a GMP+ FSA certificate.
- Certification results in a specific scope on the certificate and registration in the GMP+ Company Database
- Application of this Country Note is temporary (2019 2022).

The gatekeeper option for processed feed materials is temporary, because in our vision every company should take responsibility for the assurance of the safety of the products and services provided to customers.

2.2. Scope of this Country Note

In this Country Note specific options are laid down in Chapter 4 to 6, addressing the following items:

- Production of GMP+ FSA assured feed and non-GMP+ FSA assured feed on one location,
- Purchase of processed materials from non-certified origin (in addition to the general GMP+ purchase requirements as laid down in GMP+ BA10 Minimum requirements for Purchasing).
- Special requirements for transport

2.3. Application

2.3.1. Who can apply?

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.

2.3.2. How to apply?

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



2.4. Certification

When a company shows compliance with both the requirements of the GMP+ standard and this Country Note, a GMP+ FSA certificate may 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 'GMP+-BCN-IP'.

The following additional scopes could apply:

- Production of Compound Feed GMP+ BCN-IP.
- Production of Premixtures GMP+ BCN-IP
- Production of Feed Materials GMP+ BCN-IP
- Production of Feed Additives -GMP+ BCN-IP
- Trade (in compound feed, premixtures, feed additives and/or feed materials) GMP+ BCN-IP
- Road transport of feed GMP+ BCN-IP

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



3. Terms and definitions

See GMP+ A2 *Definitions and Abbreviations* for definitions. As a derogation or addition, the following specific definitions apply to this Country Note:

Term	Explanation
Participant	The company holding a valid GMP+ FSA certificate. Note: In the framework of application of this Country Note this company may act as the gatekeeper and be referred to as 'the gatekeeper'.
Gatekeeper	The participant who establishes and operates a gatekeeper system for purchasing a feed product or feed service from a non-certified supplier for: • processing in or sale as GMP+ FSA assured feed, or • carrying out a service with GMP+ FSA assured feed under the scope of the participant's GMP+ FSA certification
Gatekeeper system	A coherent set of procedures and controls, operated in the framework of the participant's GMP+ Feed Safety Management System (GMP+FSMS), to assure the safety of the non-GMP+ FSA assured feed/feed service, purchased under gatekeeper conditions
GMP+ Feed Safety Management System (FSMS)	The feed safety management system, as required by the GMP+ FSA standards, which a participant shall establish, implement and maintain in order to assure the safety of the feed.
GMP+ FSA assured feed	A feed which is produced and assured under the GMP+ FSMS of the participant in order to comply with the relevant GMP+ standards.
Non-GMP+ FSA assured feed	A feed which does not necessarily comply with the relevant GMP+ standards (nor certified according to another accepted feed safety certification scheme). With the GMP+ FSMS, a participant assures strict separation between GMP+ FSA assured feed and non-GMP+ FSA assured feed in order to avoid contamination.
Assured supplier	Organisation or person who provides products or services which are covered under a GMP+ certificate, a certificate which is accepted as being equivalent or under so-called Gatekeeper conditions.



Term	Explanation
Sealed loading unit/compartment	Loading compartment which is properly sealed (it cannot be open) and considered to be packaged products. Loading compartment is property of GMP+ certified company that must: - manage the cleaning and inspection of loading units - close and seal the loading compartments - use its own loading /unloading equipment (pipes, hoses, etc.) Non-certified external carrier has no influence on the transported raw materials or feed ingredients.
Tractionair	It can be defined as: - Single tractor with driver. The truck or tractor does not have a loading compartment and the loading compartment which is used is owned by the client, and/or - A company that owns one or more traction units. The company does not have its own loading compartments. Note: It does not matter if the driver owns the tractor, or hires, rents or leases it. He offers the traction service to transport companies. He brings loading compartments from the supplier to the customer.
Subcontractor	In framework of this Country Note, this is the individual or company that signs an agreement with a GMP+ FSA certified transport company (contractor) to carry out the service of road transport. The GMP+ FSA certified company is responsible of complying with GMP+ FSA requirements.
Stevedores	Storage and transhipment companies responsible for loading and unloading ship's cargoes, storage and transport.



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 shall 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.

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

Guidance:

In GMP+ A1 'General regulations' (clause 3.2) is laid down that all feed, produced in one location, shall be produced according to the GMP+ FSA requirements, and shall 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+ FSA assured feed meets the relevant GMP+FSA standards.

A production company that uses this Country Note to separate between GMP+ FSA assured feed and non-GMP+FSA assured feed shall have an additional scope on its certificate as well as in the GMP+ certified companies database..



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') for which there is no gatekeeping protocol in GMP+ BA10 *Minimum requirements for purchasing*. These requirements can be used by producers as well as traders.

Guidance:

In this way, this chapter can be considered as a general gatekeeping protocol. It can be applied for all feed materials for which there is no gatekeeping protocol in the core GMP+FSA standards, for instance in GMP+BA10 Minimum requirements for Purchasing.

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.

5.1. General requirements

The gatekeeper (the participant) establishes and implements a gatekeeper system to assure that the feed material, which he brings into the GMP+ feed chain under the conditions of gatekeeping,

- is safe for use in or as feed,
- complies with the relevant GMP+ FSA requirements, including the requirements in this Country Note.
- 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 shall be clear and unambiguous laid down in an agreement.

From each type of feed material to be purchased or received, there shall be a generic risk assessment in the Feed Support Products (FSP).

Guidance:

In GMP+ BA10 'Minimum Requirements for Purchasing' gatekeeper protocols are laid down for purchasing specific feed materials:

- Unprocessed agricultural products and by-products of harvest, directly from a arower
- Unprocessed grains, (oil-) seeds and legumes from a collector.
- Palm oil (GMQ)
- (Former) foodstuffs



Besides this, gatekeeper protocols are laid down for

- purchasing feed additives, and for assuring
- non-certified transport and storage by producers and/or traders.

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 he wants to purchase. This information should at least be focused on feed safety hazards and shall include:

- specifications of the feed, the production process of the feed and the used equipment. This may include the used of processing aids and feed additives.
- the pre-production phases of the feed insofar these are relevant for identifying and assessing possible feed safety hazards.
- all post-production activities until delivery to the gatekeeper, including transport, (temporary) storage, repackaging, etc.
- the feed safety requirements which are to be met.

Guidance:

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

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

GMP+ D2-6 provides an example of a form (sheet) which can be used to register information about the feed in a structured way.



The gatekeeper shall conduct a hazard analysis per supplier and per (group of) feed materials. Important steps are:

- Identification of possible feed safety hazards
- Assessment to determine if the feed safety hazards are controlled.

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

Guidance:

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 shall 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 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.,
- c. Identification and assessment of hazards.
- 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.

A useful document is GMP+ D2,1 'Guideline HACCP GMP+', to be found on the GMP+ website.

Guidance:

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.



The example of feed safety sheet given in GMP+D2.6 can be used to summarize the results of the hazard analysis.

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 shall be done in compliance with generally accepted sampling methods. For this, reference is made to GMP+ BA13 *Minimum requirements for sampling*.

5.3.2. Monitoring

Based on the results of hazard analysis, the gatekeeper shall decide about monitoring. The considerations and general requirements for monitoring, laid down in GMP+ BA4 *Minimum requirements for Sampling and Analysis* shall 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 shall be used

During first delivery (= a new supplier and/or a new feed), an analysis (focussed on relevant safety parameters) shall 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.)

Guidance

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.



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, tradea 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.
Likely occurrence	The standard value for likely occurrence is 1. The gatekeeper may raise or lower this value if reasons are motivated. The following considerations may apply to this: • 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. It is up to the gatekeeper to decide that the likely occurrence value can be lowered.
	 The gatekeeper should select a likely occurrence value which is below one on the basis of (historical) testing results. The following shall be kept in mind: 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+ International's 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.
Seriousness	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.



Seriousness is great factor 5
Seriousness is moderate factor 3
Seriousness is small factor 1

Find in the table below the values of some of the most important undesirable substances

Undesirable substance	Value
Heavy metals	5
Pesticides	5
Feed medicines	5
Mycotoxins	5
Salmonella	5
Artificial fertiliser	3
Prohibited animal proteins	5
(according to GMP+BA1)	
Dioxin	5
Packaging materials	3
Tannins	3
Salts (Chloride, Potassium)	1

Keep in mind:

- 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.<u>Inclusion of results in GMP+ Monitoring database</u>

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 shall also decide if 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,
- the results of the monitoring and
- the quality assurance applied by the supplier.

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



Guidance

Unprocessed: An unprocessed feed is any type of feed found in its natural state that has not been altered.

So the physical, chemical or nutritional composition of the product is still the same.

Examples of activities that result in still a unprocessed feed are:

- Drying
- Cooling
- Cleaning/sieving
- Packaging

Processed: A processed feed is any type of feed where its natural state has been altered

So the physical, chemical or nutritional composition of the product has been changed.

Examples of activities that result in a processed feed material:

- Crushing
- Pressing
- Milling
- Pelleting
- Cooking
- Fermentation
- Extrusion
- Expansion
- Extraction
- Toasting
- Chopping
- Grinding
- Dehulling
- Acidification

The audit shall result in a clear decision about

- the assurance of the safety of the feed or feed service
- 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.

Guidance:

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.



It is important that auditors are carefully selected and well instructed. In appendix 1 of this Country Note GMP+ D2.6 Guidance documents for specific GMP+ application an example of a sheet is given, which can be used to summarize the results of the hazard analysis. However, this sheet can also be used to summarize/report the results of an audit.

5.5. Supplier Improvement Program

The gatekeeper shall 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.

This Supplier Improvement Program shall have

- Calculation of the initial situation of the gatekeeper
 - o calculation of total feed production volume,
 - o % of this total volume which is meant to be GMP+ FSA assured, and
 - % GMP+FSA assured feed materials coming from already assured sources
- clear actions and activities ('milestones') to stimulate suppliers to meet the relevant requirements, and clear end dates when results are achieved, yearly.
- clear criteria for evaluation and decision about continuation of the relation between gatekeeper and supplier. Every year an evaluation shall be made.
- Yearly assessment of achieved results and updating of proposed goals on % volume of feed materials which comes from assured sources
- 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 shall last for max. 4 years as long as the % of volume of feed materials from assured suppliers for GMP+ assured feed:

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

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

¹ Meant are the feed material suppliers which are not certified



Version EN: 15 May 2019/corr.11.12.2019

19/26

Guidance

The gatekeeper shall at the end of each year calculate which volume of the feed materials which he has used in the production of GMP+ FSA assured feed, is supplier 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
 - o which are supplied by suppliers who are certified according to another, accepted scheme
 - o purchases via a regular gatekeeper option. See for regular gatekeeper options GMP+ BA10

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	40	60	80	100
beginning of Supplier				
Improving Program				

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 \rightarrow 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 GMP+ BA10.

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+ BA10; 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	64			
thanks to Supplier Improving Program				
Readjusted/updated aims for		>64	80	100
coming years				



5.6. Documentation

The gatekeeper shall further compile a file with at least (results of) the above mentioned items. This file shall 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 shall give a clear overview of the goals, the progress and the results.

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



6. Road transport

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

- 1. A company which is GMP+ FSA certified for transport
- 2. A company with another transport certificate, which is accepted within the GMP+ FSA scheme. See for accepted transport certificates GMP+ BA10 'Minimum requirements for Purchasing'.
- 3. Application of a gatekeeper system, as laid down in Annex 9 of GMP+ BA10 'Minimum requirements for Purchasing'. Gatekeeping of transport
 - is only allowed in certain countries, and
 - 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

- There is a clear and unambiguous long-lasting agreement between the transport company (the gatekeeper) and the tractionair
- The role of the tractionair is exclusively transporting feed on behalf of the gatekeeper
- The gatekeeper is responsible of complying with GMP+ requirements.
- The tractionair receives proper training about GMP+ rules for transport (cleaning, registration, loading/unloading, etc).
- 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 Annex 9 of GMP+BA10) 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 transhipment companies, specifically operating within the Spanish 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 CN allows stevedores to apply the gatekeeper conditions for transport.

In the framework of this Country Note, the annex 9 of GMP+ BA10 'Minimum requirements for Purchasing' can also be applied by

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

under the next conditions:

- The subcontracted non-certified transport company must be located in Iberian Peninsula
- 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 via non-GMP+ FSA certified transport companies shall be available for the gatekeeper.
- The gatekeeper shall assure that all the conditions of Annex 9 of GMP+ BA10 'Minimum requirements for Purchasing' are met.
- The gatekeeper shall assess whether or not the agreement is met, and if the transport meets all the requirements.
- If necessary, additional control measures shall be agreed.

6.3. Suppliers improvements Program

The gatekeeper shall 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 shall have

- calculation of the initial situation of gatekeeper
 - o and calculation of total volume of transported feed.
 - o % of this total volume which is meant to be GMP+ FSA assured,
 - % of the transport which is already GMP+ FSA assured
- clear actions and activities ('milestones') to stimulate non-certified transporters to meet the relevant requirements, and clear end dates when results are achieved, yearly.
- clear criteria for evaluation and decision about continuation of the relation between gatekeeper and the non-certified transport company. Every year an evaluation shall be made.
- Yearly assessment of achieved results and updating of proposed goals on % volume of feed transported under GMP+ FSA assurance

² Meant are the transport companies which are not certified



Version EN: 15 May 2019/corr.11.12.2019 23/26

• 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 shall last for max. 4 years if the % of volume of transported feed materials from assured suppliers for GMP+ assured feed:

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

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

Guidance

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 on the ICRT website (https://www.icrt-idtf.com/en/downloads/vrijgaveprocedure_-_eng.pdf).

³ ICRT (international Committee Road Transport). See additional information <u>here</u> as well as access to IDTF (International Database Transport (for) Feed).



_

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.

⁵ European Cleaning Document



Version EN: 15 May 2019/corr.11.12.2019

25/26

⁴ See <u>Procedure for the acceptance of loading compartments after the transport of prohibited loads</u> (Version 2016-04-01) for extra information.



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

Disclaimer:

This publication was established for the purpose of providing information to interested parties with respect to GMP+-standards. The publication will be updated regularly. GMP+International B.V. is not liable for any inaccuracies in this publication.

© GMP+ International B.V.

All rights reserved. The information in this publication may be consulted on the screen, downloaded and printed as long as this is done for your own, non-commercial use. For other desired uses, prior written permission should be obtained from the GMP+ International B.V.