



Specific requirements for Italy

GMP+ BCN IT

Version EN: 26 July 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 [FSA History documents](#).
- See also the [GMP+ newsletter](#) for more information.

History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0 / 11-2015	This is a new document	Entire document	01-01-2016
0.1 / 07-2019	extension of the validity period	2.1.1	26-07-2019

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1 Introduction

1.1 General

The GMP+ Feed Certification scheme was initiated and developed in 1992 by the Dutch feed industry in response to various more or less serious incidents involving contamination in feed materials. Although it started as a national scheme, it has developed to become an international scheme that is managed by GMP+ International in collaboration with various international stakeholders.

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 (focussed on feed safety) and GMP+ Feed Responsibility Assurance (focussed on responsible feed).

GMP+ Feed Safety Assurance 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 programmes, chain approach and the Early Warning System.

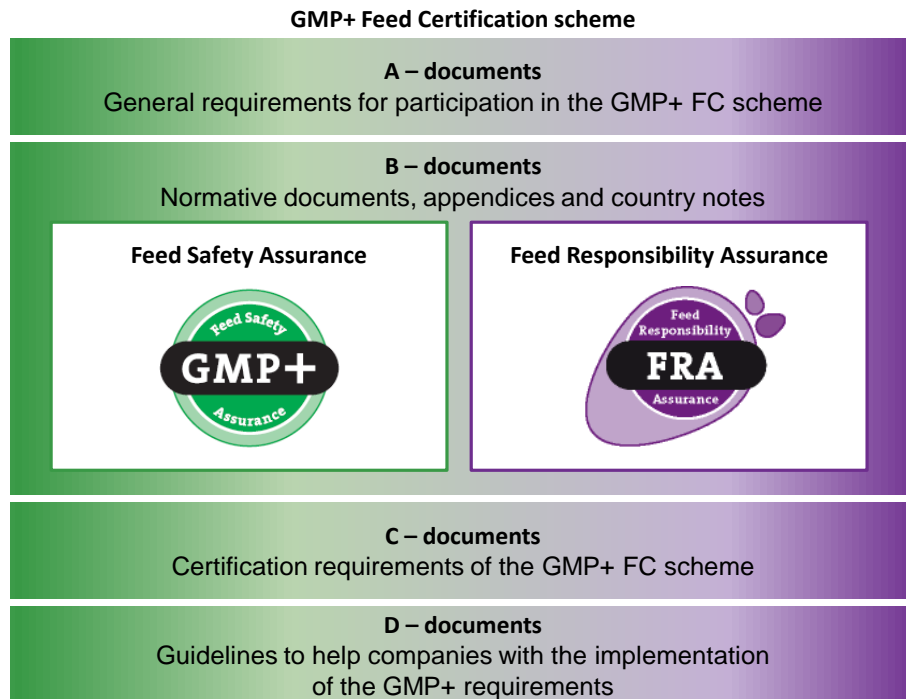
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance. GMP+ International facilitates via independent certification the demands from the market.

Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

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).

This document is referred to as GMP+ BCN- IT *Specific requirements for Italy* and is part of the GMP+ FSA module.

2 Background, scope, application & certification

2.1 Background

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.

Application (always in combination with a basic GMP+ FSA standard) should make it possible for a feed company to obtain a GMP+ FSA certificate.

Guidance

This country note must be considered as compatible to other standards of the GMP+ FC scheme, and gives the possibility to apply special options for the control of feed safety, applicable and suitable for the Italian feed industry.

The current strategy regarding country notes is (next to address special wishes and requests in a special market) to provide a *temporary* exemption of basic GMP+ FSA requirements. Compliance with these requirements is considered to contribute to achieving a sufficient level of feed safety assurance.

This country note will be part of the GMP+ FC scheme until the end of 2021, and be applicable until that date. ~~until the end of 2019, and be applicable until that date.~~ In the meantime, a Plan of Action will be carried out in cooperation with the Italian feed companies, with the aim to achieve the desired situation (certified feed safety assurance).

Application of this country note is accompanied with a specific scope, registered in the GMP+ Company Database. This improves the transparency in the market.

This country note is accompanied with a promotion plan which GMP+ International carries out in collaboration with the stakeholders in Italy.

Note: *Any feed company or any organization, certification body or consultant, representing feed companies, which are located in other countries than Italy, are invited to contact GMP+ International if they feel there is an interest for application of this country note in another country, as well.*

2.2 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 GMP+ BA10 *Minimum requirements for Purchasing*).
- 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.

Guidance

The focus for purchasing is especially on processed feed materials, as for a lot of processed feed materials the gatekeeper options in the GMP+ FC scheme are limited.

Gatekeeper options for purchasing of services (like all kind of transport and storage) are laid down in the GMP+ FC scheme, especially in GMP+ BA10 'Minimum requirements for purchasing'.

Purchasing

A basic principle in the GMP+ FC scheme is that every link in the feed chain identifies, controls and monitors the feed safety risks. The ultimate goal is that every link in the feed chain applies the same principles and standards for feed safety assurance and demonstrates compliance (by means of a certificate).

As a result of this principle, in the GMP+ FC scheme strict requirements are laid down regarding suppliers and purchase of feed/services. Basically, a company may only purchase feed/services covered under the scope of a GMP+ FSA (or equivalent) certificate. There are only a few exceptions defined to these basic requirements. In such cases, the purchasing GMP+ company is to be considered as a so-called gatekeeper.

In certain countries a lot of suppliers are not (yet) GMP+ FSA certified and therefore it is very hard for a company, who wants to apply GMP+ feed safety assurance, to comply with these basic GMP+ FSA purchase requirements. As a consequence, participation in the GMP+ FC scheme is difficult.

It should be kept in mind that - for example - in Western Europe complete certified feed chains have been achieved step-by-step over the years. Only when enough supply of assured feed and services was guaranteed, the strict requirement to purchase only from certified origins came into force.

GMP+ International admits that it is only fair to give feed markets in other parts of the world a certain period of time to achieve the same density in certified companies and to reach the same level of feed safety assurance. Also, for these feed markets a step-by-step approach should be introduced, and for a certain period of time more general gatekeeper options should be applicable. This should give at least the most ambitious feed companies in those markets the possibility to start with GMP+ feed safety assurance.

With this in mind, in this country note specific requirements are laid down, mainly to give a company more possibilities to act as a gatekeeper. These specific purchase requirements, laid down in this country note, can be applied in combination with the basic purchase requirements as laid down in the GMP+ FSA standards and in GMP+ BA10 'Minimum Requirements for Purchasing'.

Production

For several reasons, the GMP+ FC scheme does not allow producers of feed to exclude in a location a part of the production from certification. This is clearly stated in GMP+ A1 General regulations, section 4.

However, to comply with this requirement in a market where requests for GMP+ FSA assured feed is still very limited, is very difficult for a company. This country note gives opportunities to produce GMP+ FSA assured feed, and non-GMP+ FSA assured feed in one location.

Conditions are laid down to assure that the GMP+ FSA assured feed is in compliance with all the relevant requirements, and is not affected by the production of any other feed or any other product. See for this chapter 5.

Special scopes have been defined, and labelling must assure that the market is unambiguous informed about what feed is delivered.

Transport

In the GMP+ Feed Safety scheme, it is allowed – under strict conditions - for producers and traders to implement and operate procedures for controlling safe transport, carried out by non-certified transport companies ('gatekeeper transport'). See for this GMP+ BA10, Annex 9.

In the framework of this country note, application of this annex is also allowed for a GMP+ certified transport company, but only when there is a clear and unambiguous written approval from the producer or trader, who are the owners of the goods. See for this chapter 7.

Labelling

When a company applies this country note, special labelling requirements are laid down.

2.3 Application

2.3.1 How to apply?

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

2.3.2 Who can apply?

Any feed company located in Italy may, 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.

Activity	Application of GMP+ standard		GMP+ scope
Compound feed production	B1	-	Production of compound feed
Compound feed production	B1	BCN-IT	Production of compound feed Production of compound feed GMP+ BCN-IT
Premixtures production	B1	-	Production of premixtures
Premixtures production	B1	BCN-IT	Production of compound feed Production of premixtures GMP+ BCN-IT
Feed materials production	B2 (or B1)	-	Production of feed materials
Feed materials production	B2 (or B1)	BCN-IT	Production of feed materials Production of feed materials GMP+ BCN-IT
Trade	B3 (or B1)	-	Trade in ... <i>(depending on the type of feed; according to regular scope descriptions)</i>
Trade	B3 (or B1)	BCN-IT	Trade in ... Trade in ... -IT <i>(depending on the type of feed; according to regular scope descriptions)</i>
Road transport	B4	-	Transport of animal feed, Road transport
Road transport	B4	BCN-IT	Transport of animal feed, Road transport Transport of animal feed, Road transport GMP+ BCN-IT

Note:

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 may only be distributed as GMP+ BCN-IT assured feed on the Italian market.

Premixtures may also be sold to customers outside the Italian market as long as these customers do not participate in the GMP+ FSA scheme or an approved, other feed safety scheme. See for approved other feed safety schemes GMP+ BA10 'Minimum requirements for Purchase'. These premixtures must be labelled according to chapter 7 of this country note.

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.

2.4 Certification

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

Certified companies will be registered with an additional scope in GMP+ International's Company Database. Also, this scope will be stated on the certificate. See for some examples for application of the country note Annex 2 of this document.

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 (most of the time referred to as 'gatekeeper')	<p>The company participating in the GMP+ FSA module. In this country note this company is most of the time referred to as: gatekeeper.</p> <p>This country note states that only a producer or trader can act as a gatekeeper. Besides that, a transport company may act as a gatekeeper, on behalf of the producer or trader.</p>
GMP+ FSMS	The feed safety management system, as required by the GMP+ FSA standards, which a participant must establish, implement and maintain in order to assure the safety of the feed. See respectively 'GMP+ FSA assured feed' and 'non-GMP+ FSA assured 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 or -limits.
Non-GMP+ FSA assured feed	A feed which does not necessarily comply with the relevant GMP+ standards or -limits. 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.
Supplier	Organisation or person who provides products or services.

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.

Guidance:

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 participant, (the producer or trader of the compound feed, premixture or feed material) is overall responsible for demonstrating compliance with the relevant requirements for the gatekeeper system. He 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 GMP+ BA10 'Minimum requirements for Purchasing'*

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).

Where GMP+ BA10 *Minimum requirements for Purchasing* provides gatekeeper protocols, these apply.

As an extra option, within the framework of application of this country note, Annex 5 of GMP+ BA10 can also be applied for buying unprocessed grains, (oil-) seeds and legumes from collectors in Italy.

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 grower*
- *Grains, (oil-) seeds and legumes in unprocessed form, from a collector. As laid down above, this protocol may also be applied for buying unprocessed primary products in Italy*
- *Palm oil (GMQ)*
- *(Former) foodstuffs*

Besides this, gatekeeper protocols are laid down for purchasing feed additives and for assuring non-certified transport and storage.

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.

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 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.

Guidance:

In appendix 1 of this country note, an example of a sheet is given, which can be used to summarize the results of the hazard analysis.

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 GMP+ BA4 *Minimum requirements for Sampling and Analysis* must be taken into account.

Enough samples must be taken to carry out the monitoring plan. Sampling may 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 GMP+ BA13 *Minimum requirements for 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

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

<u>Guidance</u>	
VARIABLE	EXPLANATION
Frequency	<i>The number of samples to be tested (on a yearly basis)</i>
Volume	<p><i>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.</i></p> <p><i>Kilograms must be assumed for some feed materials for which, on a yearly basis, only a small quantity is produced, traded or processed.</i></p>
Likely occurrence	<p><i>The standard value for likely occurrence is 1. The participant may raise or lower this value if reasons are given. The following considerations may apply to this:</i></p> <ul style="list-style-type: none"> <i>a. History: see also below</i> <i>b. Seasonal influences</i> <i>c. Possibility of recontamination. This applies in particular to microbiological parameters.</i> <i>d. New source / new suppliers</i> <i>e. Have there been recent incidents.</i> <p><i>It is up to the participant to decide that the likely occurrence value can be lowered.</i></p> <p><i>The participant should select a likely occurrence value which is below one on the basis of (historical) testing results. The following must be kept in mind:</i></p> <ul style="list-style-type: none"> <i>a. Testing results should be representative. The historic testing results which are considered as representative may differ per undesirable substance.</i> <p><i>For some undesirable substances the testing results for an area can be considered to be representative while, for</i></p>

	<p><i>other undesirable substances, only testing results for the same production location is representative.</i></p> <p><i>b. Testing results from GMP+ International's GMP+ Monitoring database may also be used in determining testing frequency if the participant can show representativeness.</i></p>																						
seriousness	<p><i>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):</i></p> <p style="text-align: right;"><i>Seriousness is great factor 5</i> <i>Seriousness is moderate factor 3</i> <i>Seriousness is small factor 1</i></p> <p><i>This leads to the following factors:</i></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Undesirable substance</th> <th style="text-align: center;">Value</th> </tr> </thead> <tbody> <tr><td><i>Heavy metals</i></td><td style="text-align: center;"><i>5</i></td></tr> <tr><td><i>Pesticides</i></td><td style="text-align: center;"><i>5</i></td></tr> <tr><td><i>Insecticides</i></td><td style="text-align: center;"><i>5</i></td></tr> <tr><td><i>Feed medicines</i></td><td style="text-align: center;"><i>5</i></td></tr> <tr><td><i>Mycotoxins</i></td><td style="text-align: center;"><i>5</i></td></tr> <tr><td><i>Salmonella</i></td><td style="text-align: center;"><i>5</i></td></tr> <tr><td><i>Fungi</i></td><td style="text-align: center;"><i>3</i></td></tr> <tr><td><i>Animal components</i></td><td style="text-align: center;"><i>5</i></td></tr> <tr><td><i>Dioxin</i></td><td style="text-align: center;"><i>5</i></td></tr> <tr><td><i>Nitrites</i></td><td style="text-align: center;"><i>5</i></td></tr> </tbody> </table> <p><i>The established values are all high. This seems logical as these are risky undesirable substances.</i></p> <p><u>Note:</u></p> <p><i>a. Calculated frequencies should always be rounded upwards. The minimum frequency is 1.</i></p> <p><i>b. Calculation of the monitoring frequency of liquid or moist feed can be based on 88% dry matter content.</i></p>	Undesirable substance	Value	<i>Heavy metals</i>	<i>5</i>	<i>Pesticides</i>	<i>5</i>	<i>Insecticides</i>	<i>5</i>	<i>Feed medicines</i>	<i>5</i>	<i>Mycotoxins</i>	<i>5</i>	<i>Salmonella</i>	<i>5</i>	<i>Fungi</i>	<i>3</i>	<i>Animal components</i>	<i>5</i>	<i>Dioxin</i>	<i>5</i>	<i>Nitrites</i>	<i>5</i>
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Guidance:
Besides in GMP+ BA4 'Minimum requirements for sampling and analysing, on the GMP+ International's 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.

Guidance:

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.

It is important that auditors are carefully selected and well instructed. In appendix 1 of this country note, 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.

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 GMP+ BA10 *Minimum requirements 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, yearly.

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.

Guidance:

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

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 GMP+ BA1 'Specific feed safety limits' but also the standards laid down in GMP+ BA2 '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.

Guidance:

In GMP+ A1 'General regulations' 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 participant 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 6.

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 scheme
3. Application of a gatekeeper system, as laid down in Annex 9 of GMP+ BA10 'Minimum requirements for Purchasing'.

With regard to the third option, it is also possible for a GMP+ certified transport company to apply this Annex 9, 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 participant. The participant 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 Annex 9 of GMP+ BA10 'Minimum requirements for Purchasing'.

The transport company must assure that all the conditions of Annex 9 of GMP+ BA10 'Minimum requirements for Purchasing' are met.

This gatekeeper option may 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 GMP+ BA10 Minimum requirements Purchase (see for this chapter 4.6)

Guidance:

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 declaration

The gate keeper must provide his customer with relevant information, in accordance with national legislation and with GMP+ BA6 *Minimum requirements for labelling and delivery*. 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 GMP+ BA10 *Minimum Requirements for Purchasing*). 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 GMP+ BA6 *Minimum requirements for labelling and delivery*.
- 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').

When the declaration requirements for services will be included in GMP+ BA6 (to be expected from 2016), these will apply.

Annex 1: Example of a feed safety sheet

A feed safety sheet is intended to provide information in a structured way about the product, the production process and the safety measures used. A model of this is shown below.

Note:

- The model shown is an example. The basic point is that the information should be registered systematically.
- Also other sheets or files may be used, as long as all relevant elements are addressed
- Possibly not all the information has been provided by the manufacturer in full, certainly not if the feed comes to the end user via a trade channel. In that case each link can add to the information (for example with details of transport, interim storage, etc.).
- This sheet can also be used to report the audit results

FEED SAFETY SHEET		0.1. Product	
		0.2. Version number	
		0.3. Version date	
1. Responsibility for the feed safety sheet			
1.1.	Name		
1.2.	Address		
1.3.	Approved by		

2. Identification of the product						
2.1.	Product name					
2.2.	Trade name					
2.3.	Article code					
2.4.	Permit number					
2.5.	Product description					
2.6.	Origin					
2.7.	Supplied by					
3. Product description						
3.1.	Production process					
3.2.	Raw materials and auxiliary substances used (including feed additives and processing aids)					
3.3.	Logistical process (transport, (interim) storage, packaging)					
3.4.	Storage life					
3.5.	Indicative analysis	Parameter	Unit	Average	Min.	Max.
4. Norms / requirements						
4.1.	Relevant legislation and other requirements.					
4.2.	Relevant norms / requirements (chemical, physical, microbiological)	Parameter	Unit	Statutory	Contractual	Internal
4.3.	Intended use					
4.4.	Storage and retention conditions					
4.5.	Transport requirements					
4.6.	Processing instructions					

5. Labelling						
6. HACCP						
6.1. Hazard	6.2. Risk assessment				6.3. Control measure	6.4. Reason
	Cat. (C, M, F)	Likely occurrence	Se- ver- ity	risk		
7. Monitoring						
7.1. Param- eter	7.2. Sampling moment / point				7.3. Frequency of analysis	
8. Remarks						

Explanatory note to the feed safety sheet

Field	Subject	Explanation
0.	Identification of the feed safety sheet	Field 0 identifies the feed safety sheet. For the purposes of correct identification this field is repeated on each page of the feed safety sheet.
0.1.	Product	Product name
0.2.	Version number	Version number of the feed safety sheet.
0.3.	Version date	Date on which the version was adopted and put into circulation.
1.	Person responsible for the feed safety sheet	This field identifies the author of the feed safety sheet. This will generally be the producer of the product
1.1.	Name	Identify the organisation which is responsible for the feed safety sheet.
1.2.	Address	Specify the full address, telephone number, etc. Preferably also specify the E-mail address and website.
1.3.	Approved by	Specify the person who authorised the feed safety sheet.
2.	Product identification	Field 2 gives an accurate identification of the product.
2.1.	Product name	Identify the product. Use the designation as prescribed in the legislation.
2.2.	Trade name	State here the usual brand name of the product.
2.3.	Article code	Internal company article number. Specify "n/a" if no use is made of an internal company article number.
2.4.	Permit number	Statutory certification number. State "n/a" if the legislation does not recognise a permit number.
2.5.	Product description	Description of the product, preferably in accordance with the descriptions in the Feed Safety Database
2.6.	Origin	Describe the origin as accurately as possible. Possibilities are: <ul style="list-style-type: none"> - Name and address details of the producer - Address details of the production location - Country of origin
2.7.	Supplied by	If different to 2.6.

Field	Subject	Explanation
3.	Product description	Field 3 describes the characteristics of the product.
3.1.	Production process	Brief but as accurate as possible description of the production process of the product including a flow chart.
3.2.	Used raw materials and auxiliary substances	All the raw materials and auxiliary substances used (including processing aids)
3.3.	Logistical process	<p>Describe the logistical process gone through by the product from the (primary) production up to and including delivery to the end-user.</p> <p>State the method of transport of the product, any (interim) storage and the method of packaging in the various stages in the logistical process.</p> <p>NOTE: the standards and requirements with respect to storage, retention, packaging and transport conditions are described in fields 4.4 and 4.5.</p>
3.4.	Storage life	Indication of the storage life (number of days, weeks, months) of the product (for example, after production).
3.5.	Indicative analysis	This should include a number of relevant characteristics which classify the product. These will generally be non-binding nutritional parameters (such as dry-matter content, raw protein, raw fat, raw cellulose, ash) or the level of active substances (for example in feed additives).
4.	Norms / Requirements	Field 4 describes the norms and requirements.
4.1.	Relevant legislation and other requirements.	<p>Summary of the relevant parts of the feed legislation. This may be the applicable European directives and regulations but may also be national legislation and regulations.</p> <p>'Other requirements' may be specific requirements which apply within the framework of a specific feed safety system in which the customer participates. For example the GMP+ FSA module</p>
4.2.	Relevant product standards / requirements	This relates to the detailed data and not a reference to the legislation or to the GMP+ FSA module. The binding nutritional parameters are included here and also the parameters which are considered to be important

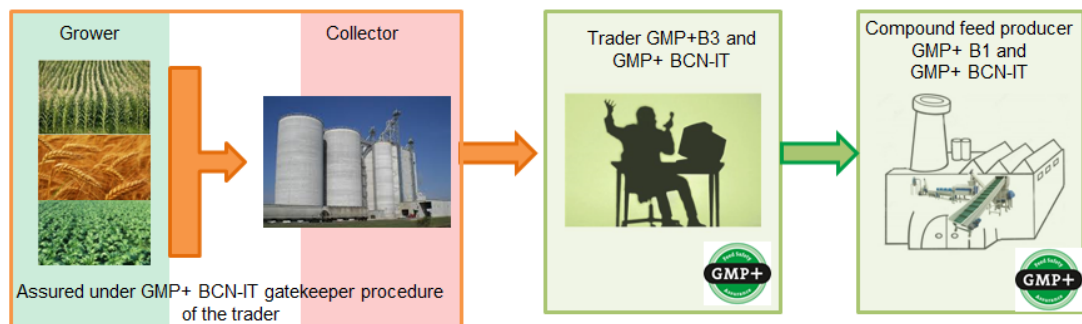
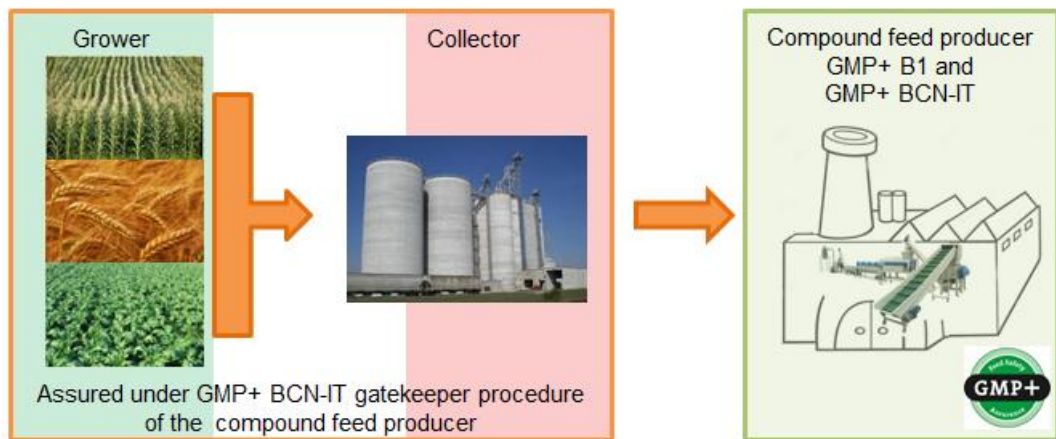
Field	Subject	Explanation
		in the risk assessment (such as heavy metals in minerals, mycotoxins in grains, PCBs in fats).
4.3.	Intended use	Describe the intended use of the product. For example <ul style="list-style-type: none"> - processing in compound feeds - direct feeding to animals - only processing in premixes - possibly the animal type if this is important. - etc.
4.4.	Storage and retention conditions	Binding requirements for storage and retention. For example: <ul style="list-style-type: none"> - storage at a particular temperature - ventilation during storage - acidification before storage - air-tight closure
4.5.	Transport requirements	Binding requirements for transport.
4.6.	Processing instructions	The measures are indicated here which must be taken to be able to use the product correctly and safely. For example: <ul style="list-style-type: none"> - to be used within x days of delivery - maximum processing percentage - minimum or maximum processing temperature
5.	Labelling	Statement of the way in which the product information is issued. This may be a sample label, a description of the legally-prescribed specifications or an accurate and specific reference to relevant legislation and regulations (a general reference to legislation or regulations is not enough).
6.	HACCP	This field provides a summary of the risk analysis for the product. At least the CCPs (Critical Control Points) are given and also general control measures.
6.1.	Hazard	Precise description of the hazard.
6.2.	Risk assessment	For the risk assessment one should preferably use the system which is prescribed in the GMP+ FSA module. NOTE: If another system is used then you should indicate this explicitly (in field 8).
6.3.	Control measure	Description of the (specific) control measures which have been established by way of HACCP for the product.

Field	Subject	Explanation
6.4.	Reason	Motivation and argument for the risk assessment, especially with respect to the elements “likely occurrence” and “seriousness”.
7.	Monitoring	This field provides a detailed description of the monitoring used in the company (checks, analyses) at the indicated critical points and general control measures.
7.1.	Parameter	Describe the characteristic to be examined (for example Aflatoxin B1, Salmonella, Lead, Prussic Acid).
7.2.	Sampling moment / point	Describe the point in the production process where the sample is taken or the inspection takes place (for example free on wagon reception, check before delivery).
7.3.	Frequency of analysis	Describe the frequency at which the monitoring is carried out (for example every batch, 4 times per year, every 10 th batch).
8.	Remarks	
8.	Remarks	Other comments may be placed in this field which are important for this feed safety sheet If a different HACCP system is used than that which is described in the GMP+ FSA module, then this can be described in this field.

Annex 2: Examples for application of the country note

These are some examples for application of the country note. Application is however not limited to these examples.

1. a) Purchase of unprocessed agricultural products directly from collectors



A compound feed producer applies the GMP+ B1-standard. He establishes a feed safety management system to assure the production of compound feed. Under this country note the compound feed producer may apply the gatekeeper protocol from Annex 5 of GMP+ BA10 to purchase unprocessed agricultural products directly from non-certified collectors. The compound feed producer must demonstrate overall compliance with the relevant requirements of this country note.

These feed materials are processed in all his compound feed.

The scope of the certificate states:

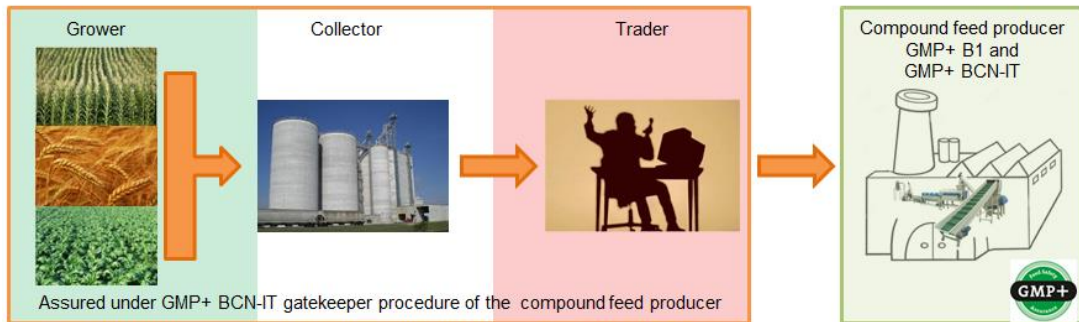
- Production of compound feed – GMP+ BCN-IT
- The free part for scope description on the certificate states the specific compound feed.

The above requirements are also applicable for a GMP+ B3 certified trader who purchase unprocessed agricultural products directly from non-certified collectors.

The scope of the certificate states:

- Trade in feed materials- GMP+ BCN-IT
- The free part for scope description on the certificate states the specific feed materials.

b) Purchase of unprocessed agricultural products from a non-certified trader

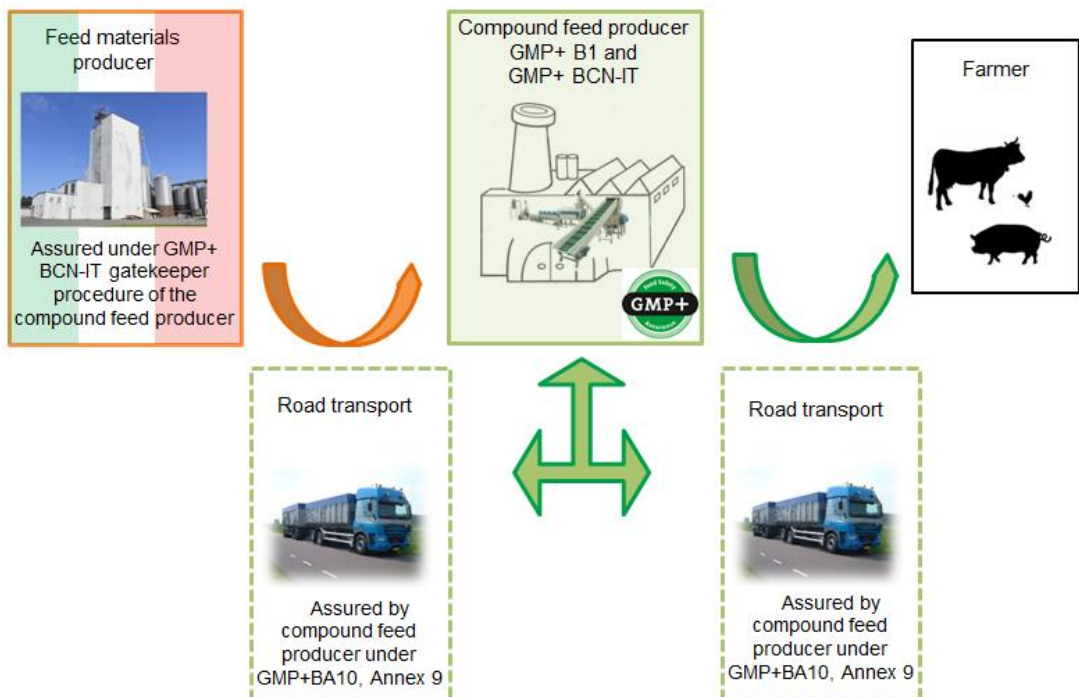


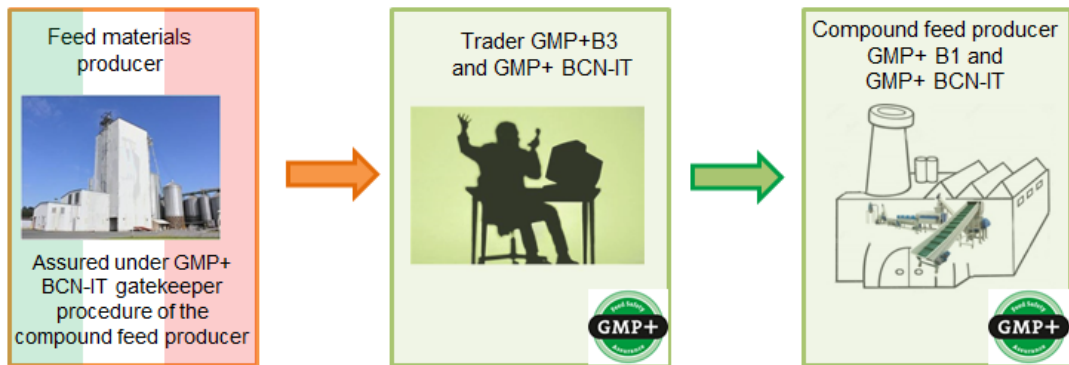
A compound feed producer applies the GMP+ B1-standard. He establishes a feed safety management system to assure the production of compound feed. He applies this country note for purchasing unprocessed agricultural products non-certified collectors, but there is a trader involved. This trader must be included in the gatekeeper system. Responsibilities must be made clear. The compound feed producer must demonstrate overall compliance with the relevant requirements of this country note. These feed materials are processed in all his compound feed.

The scope of the certificate states:

- Production of compound feed – GMP+ BCN-IT
- The free part for scope description on the certificate states the specific compound feed.

2. Purchase of processed feed materials from non-certified feed material suppliers





A compound feed producer applies the GMP+ B1-standard. He establishes a feed safety management system to assure the production of compound feed. He applies this country note for purchasing feed materials from non-certified feed material suppliers. These feed materials are processed in all his compound feed. The compound feed producer assures the road transport under the gatekeeper protocol laid down in Annex 9 of GMP+BA10.

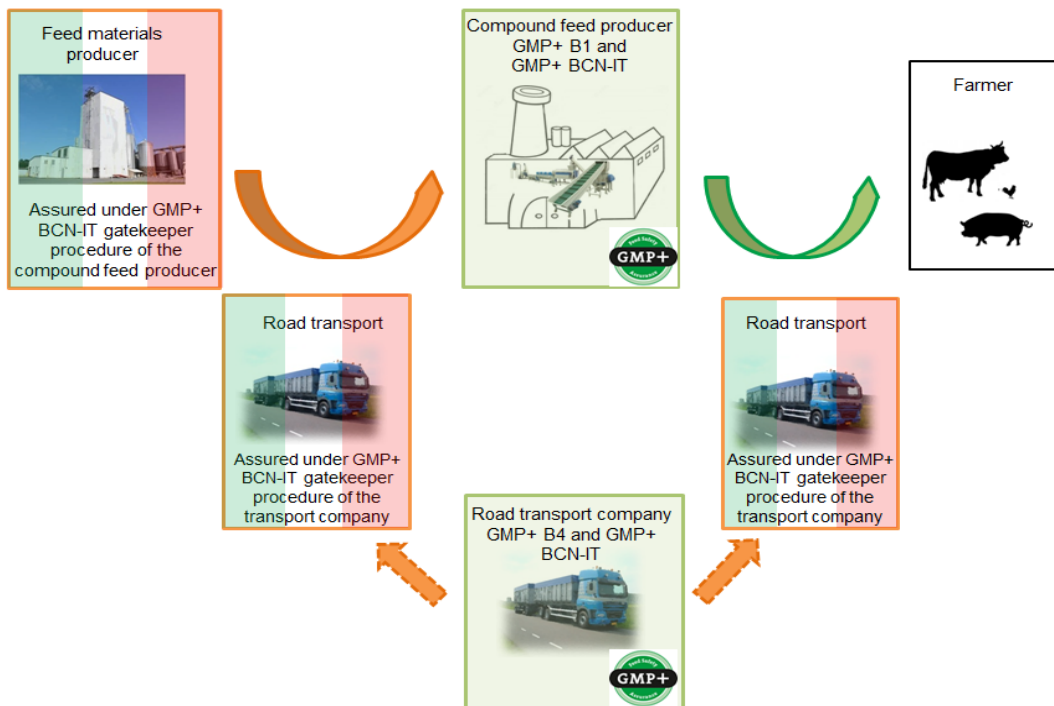
The scope of the certificate states:

- Production of compound feed – GMP+ BCN-IT
- The free part for scope description on the certificate states the specific compound feed.

The above requirements are also applicable for a GMP+ B3 certified trader who purchase feed materials from non-certified feed material suppliers. The scope of the certificate states:

- Trade in feed materials- GMP+ BCN-IT
- The free part for scope description on the certificate states the specific feed materials.

3. Purchase of road transport



A compound feed producer applies the GMP+ B1-standard. He establishes a feed safety management system to assure the production of compound feed. He applies this country note for purchasing feed materials from non-certified feed material suppliers. These feed materials are processed in all his compound feed. The road transport is assured by a GMP+ certified transport company which obtained a written approval from the compound feed producer. For this purpose the road company applies the gatekeeper protocol laid down in Annex 9 of GMP+BA10.

The scope of the certificate of the compound feed producer states:

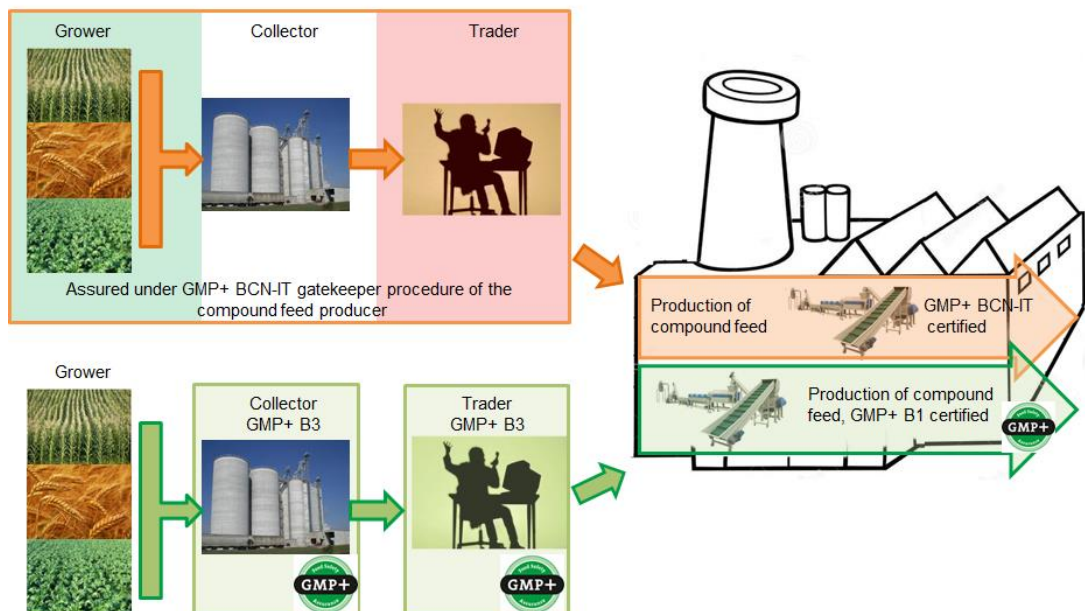
- Production of compound feed – GMP+ BCN-IT
- The free part for scope description on the certificate states the specific compound feed.

The scope of the certificate of the transport company states:

- Transport of animal feed, Road transport - GMP+ BCN-IT

4. Production of non-GMP+ assured feed and GMP+ assured feed in the same location/facility:

a) production of GMP+ B1 certified compound feed and GMP+ BCN-IT certified compound feed



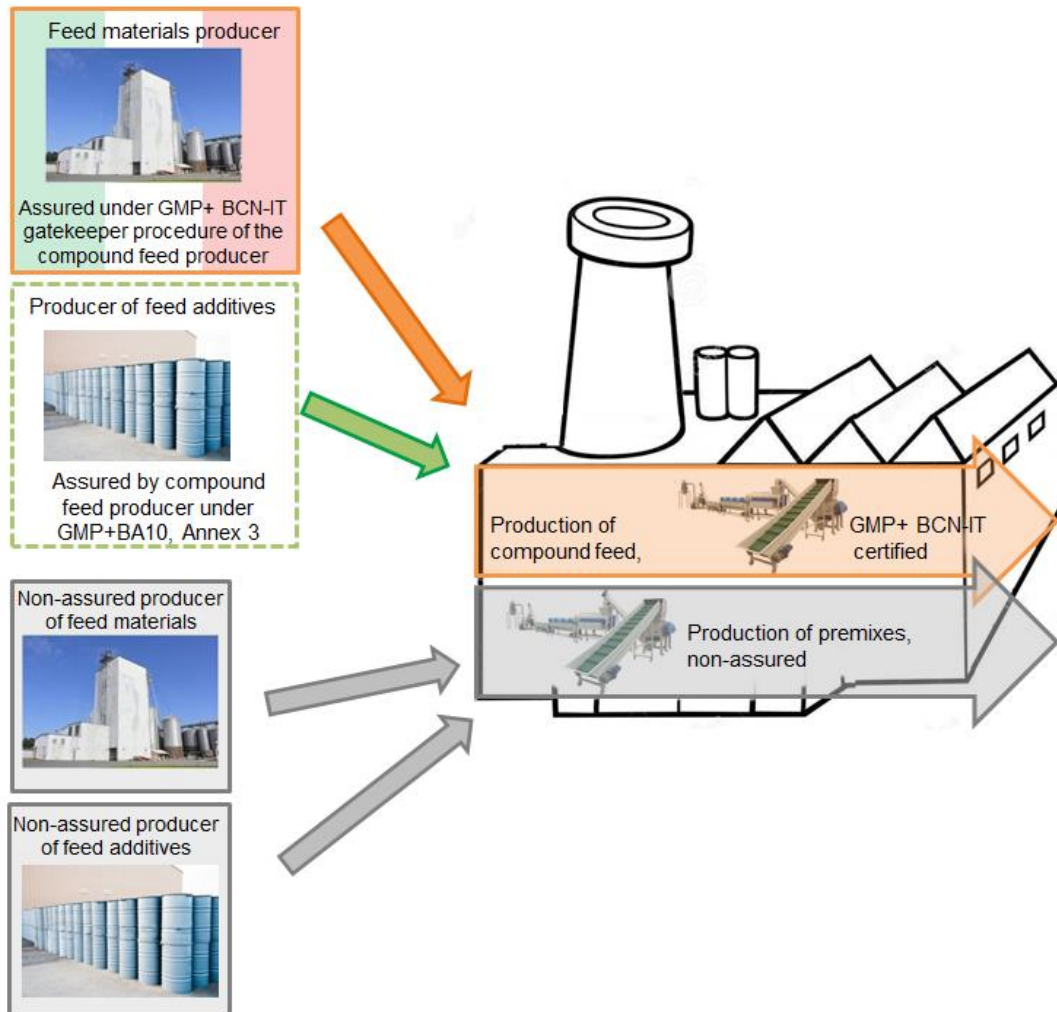
A compound feed producer applies the GMP+ B1-standard. He establishes a feed safety management system to assure the production of compound feed. He applies this country note for purchasing feed materials from non-certified feed material suppliers. These feed materials are processed in a part of his compound feed, for example only in compound feed for pigs. All other compound feed production is in compliance with the regular GMP+ FSA requirements.

The scope of the certificate states:

- Production of compound feed

- Production of compound feed – GMP+ BCN-IT
- The free part for scope description on the certificate states the specific compound feed for both scopes.

b) production of GMP+ BCN-IT certified compound feed and non-assured premixes



A compound feed producer applies the GMP+ B1-standard. He establishes a feed safety management system to assure the production of compound feed. He applies this country note for purchasing feed materials from non-certified feed material suppliers. These feed materials are processed in his compound feed.

He also applies the gatekeeper protocol laid down in Annex 3 of GMP+BA10 for purchase of feed additives. The compound feed producer also produces premixes which are not covered by his feed safety management system.

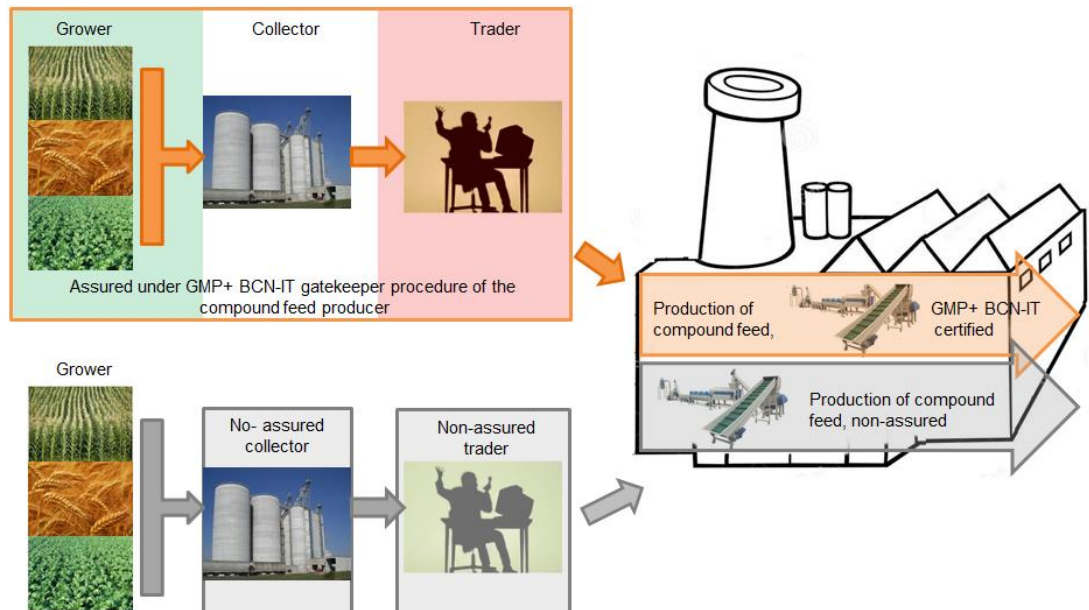
The feed safety management system must assure a strict and complete physical and/or organisational separation between the production of compound feed and the production of premixes at all stages of processing, producing, (internal) transportation and storage.

The compound feed producer must demonstrate overall compliance with the relevant requirements of this country note.

The scope of the certificate states:

- Production of compound feed – GMP+ BCN-IT
- The free part for scope description on the GMP+ FSA certificate states the specific compound feed.

c) production of GMP+ BCN-IT certified compound feed and non-assured compound feed



A compound feed producer applies the GMP+ B1-standard. He establishes a feed safety management system to assure the production of compound feed. He applies this country note for purchasing feed materials from non-certified feed material suppliers. These feed materials are processed in his compound feed.

The compound feed producer also produces compound feed which are not covered by his feed safety management system.

The feed safety management system must assure a strict and complete physical and/or organisational separation between the production of compound feed assured under this country note and the production of non-assured compound feed at all stages of processing, producing, (internal) transportation and storage.

The compound feed producer must demonstrate overall compliance with the relevant requirements of this country note.

The scope of the certificate states:

- Production of compound feed – GMP+ BCN-IT
- The free part for scope description on the GMP+ FSA certificate states the specific compound feed.

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