



# Additional requirements for Central & Eastern Europe

GMP+ BCN CEE

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 / 11-2014	This is a new document	Entire document	01-01-2015
0.1 / 05-2018	Correction reference	2.1.1	01-07-2018
0.2 / 08-2018	Scope of CN is further clarified: production of fat blend is excluded  Example of a feed safety data sheet moved to GMP+ D2.6	2.2  Annex	01-04-2019
0.3 / 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.

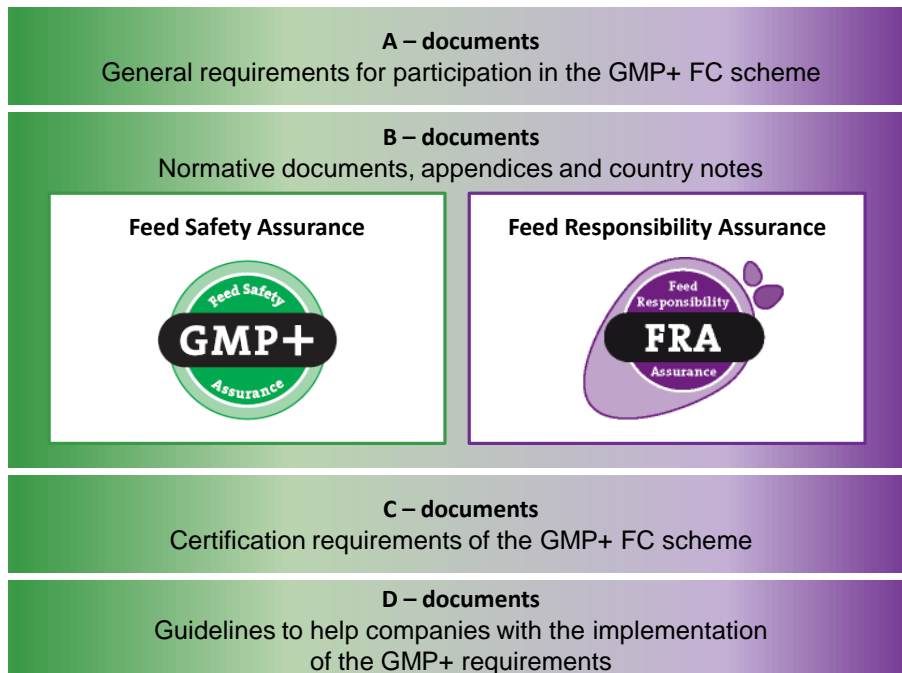
Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

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:

**GMP+ Feed Certification scheme**



All these documents are available via the website of GMP+ International ([www.gmpplus.org](http://www.gmpplus.org)).

This document is referred to as *GMP+ BCN- CEE Additional requirements for Central and Eastern Europe* and is part of the GMP+ FSA module.

## 2 Background, scope, application & certification

### 2.1 Background

#### 2.1.1 General

This GMP+ country note is meant to give specific GMP+ requirements and conditions for a feed company, located in a specified country (section 2.4) which seeks GMP+ FSA certification. These requirements are additional to the basic GMP+ FSA requirements and 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 the requirements as laid down in the GMP+ FC scheme, and gives a company the possibility to apply a wider range of purchase requirements ('gatekeeper options').*

*Further, specific conditions for production of feed are laid down, especially focussed on producing both GMP+ FSA assured feed and non-GMP+ FSA assured feed on one location.*

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 feed companies in specified countries, with the aim to achieve the desired situation.

Application of a 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 the concerned countries.

*Note: Any feed company or any organization, certification body or consultant, representing feed companies, which are located in other countries than mentioned in 2.3, are invited to contact GMP+ International if they feel there is an interest for application of this country note in another country, as well.*

### 2.1.2 Specific requirements

The requirements laid down in this country note are addressing the following:

#### 2.1.2.1 *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 with 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'.

#### 2.1.2.2 *Production*

For several reasons, the GMP+ FC scheme does not allow producers of feed to exclude for 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

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

in one location.

Regarding 'GMP+ assured feed', 2 types of feed can be identified

- 1a) GMP+ FSA assured feed, produced in compliance with the GMP+ B1-standard;
- 1b) GMP+ FSA assured feed, produced in compliance with the GMP+ B1-standard and the GMP-BCN-CEE Country Note .

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

The required feed safety management system should 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.

The next table the options are summarized. See for further details regarding scope section 2.3.2 and for labelling chapter 6

Feed product	Application of	Scope description	Labelling
GMP+ FSA assured compound feed	GMP+ B1	Production of compound feed	No specific labelling required
GMP+ FSA assured pre-mixtures	GMP+ B1	Production of pre-mixtures	No specific labelling required
GMP+ FSA assured compound feed	GMP+ B1 and GMP+ BCN CEE	Production of compound feed - CEE	GMP+ FSA assured - CEE
GMP+ FSA assured pre-mixtures	GMP+ B1 and GMP+ BCN CEE	Production of pre-mixtures - CEE	GMP+ FSA assured - CEE
Non-GMP+ FSA assured compound feed	-	-	Non-GMP+ FSA assured
Non-GMP+ FSA assured pre-mixtures	-	-	Non-GMP+ FSA assured

## 2.2 Scope

This country note provides specific GMP+ FSA requirements for

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

*Note: This country note cannot be applied for the production of mixes of fat and oil products (fat blends). This type of compound feed shall be produced with application of the regular GMP+ B1 standard.*



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

**2.3 Application and certification****2.3.1 Application**

This GMP+ country note must always be applied in combination with the GMP+ B1-standard. It gives a number of special options for purchasing processed feed materials and production of compound feed or pre-mixtures.

Only feed companies, located in certain countries (see the table below for specification) may, within the framework of complying with GMP+ FC scheme requirements, apply this country note.

Country	Company	Standard
Poland	Producer of compound feed	GMP+ B1
	Producer of pre-mixtures	GMP+ B1
Czech Republic	Producer of compound feed	GMP+ B1
	Producer of pre-mixtures	GMP+ B1
Ukraine	Producer of compound feed	GMP+ B1
	Producer of pre-mixtures	GMP+ B1
Slovakia	Producer of compound feed	GMP+ B1
	Producer of pre-mixtures	GMP+ B1

**2.3.2 Certification**

When a company shows compliance with both the requirements from the GMP+ B1-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. This scope is defined as

- Production of compound feed - CEE
- Production of pre-mixtures - CEE

**Note:**

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

GuidanceExamples

- 1) *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 scope of the certificate states*
  - *Production of compound feed – CEE*

*The free part for scope description on the certificate states the specific compound feed.*
  
- 2) *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 – CEE*

*The free part for scope description on the certificate states the specific compound feed for both scopes.*
  
- 3) *A compound feed producer applies the GMP+ B1-standard. He establishes a feed safety management system to assure a part of 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 scope of the certificate states*
  - *Production of compound feed*
  - *Production of compound feed – CEE*

*The free part for scope description on the certificate states the GMP+ FSA assured/non-GMP+ FSA assured compound feed.*
  
- 4) *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, 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 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+ requirements. The scope of the certificate states*
  - *Production of compound feed*
  - *Production of compound feed – CEE*

*The free part for scope description on the GMP+ FSA certificate states the specific compound feed for both scopes.*

### 3 Terms and definitions

See GMP+ A2 *Definitions and Abbreviations* for definitions. As a differentiation or addition, the following specific definitions apply to this country note:

Term	Explanation
Participant (most of the time referred to as gatekeeper)	The company participating in the GMP+ FSA module. In this country note this company is most of the time referred to as: gatekeeper.  This country note states that only a compound feed producer or a premixture producer can act as a gatekeeper.
GMP+ FSMS	The feed safety management system, as required by the GMP+ FSA standards, which a feed company 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 feed company 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. With the GMP+ FSMS, a feed company assures strict (physical) separation between GMP+ FSA assured feed and non-GMP+ FSA assured feed.
Supplier	This is in most cases the producer of the processed feed material

## 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 compound feed producer or the pre-mixture producer 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 trader. If so, a specific agreement must be made.*

*Note: A feed material which is assured under a relevant certificate of another, approved scheme should also be considered as 'GMP+ FSA assured'. See for approved schemes/certificates GMP+ BA10 'Minimum requirements for Purchasing'*

*Note: The GMP+ Feed Certification scheme covers all links in the feed chain between growers (primary production) up to delivery to livestock farmers. For the purchasing of unprocessed primary products as feed materials see the relevant annex of GMP+ BA10 'Minimum requirements for Purchasing'.*

### 4.1 General

The gatekeeper can purchase a non-GMP+ FSA assured feed material to process in feed for the local market.

Note: Where GMP+ BA10 *Minimum requirements for Purchasing* gives gatekeeper protocols, these apply.

**Guidance:**

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

- *Unprocessed goods, directly from a grower*
- *Unprocessed goods, from collectors*
- *Palm oil (GMQ)*
- *(former) foodstuffs*

*Besides this, gatekeeper protocols are laid down 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 phases until delivery to the gatekeeper, including transport, (temporary) storage, repackaging etc.,
- c. Hazard analysis: identification of hazards and risk assessment.
- d. Overview of the available general and specific control measures for controlling identified risks.
- e. Monitoring plan and results. Compliance with minimum sampling and testing requirements as laid down in this protocol is required.

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

Further, the generic risk assessments of feed materials, published on the website of GMP+ International, give 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.

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

**Guidance:**

*On the GMP+ International's website a lot of information is available to support companies in defining risks, controlling risks and monitoring CCP's  
For example, in GMP+ BA4 'Minimum requirements for sampling and analysing' a formula is give for calculating a realistic frequency for monitoring.*

**Note:**

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

### 4.4 Audits

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

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

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

**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 to stimulate suppliers to meet the relevant requirements, and clear end dates when results or sub results are achieved, yearly.

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

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

Note: The activities and processes related to the production of non-assured feed/pre-mixtures 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.*

*Note: See also the labelling requirements in chapter 6.*



## 6 Labelling

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

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

- GMP+ FSA assured compound feed or pre-mixtures must meet the requirements as laid down in GMP+ BA6 *Minimum requirements for labelling and delivery*.
- GMP+ FSA assured compound feed or pre-mixtures- CEE must be clearly labelled as such ('GMP+ FSA assured-CEE')
- Non-GMP+ FSA assured compound feed or pre-mixtures must be clearly labelled as such ('non-GMP+ FSA assured')

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