

# General Gatekeeper Protocol for purchasing products and services of non - GMP+ certified companies

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## 1 Introduction

Since 2000, the GMP+ FSA scheme stipulates the basic requirement that participants may only purchase animal feed (compound feedstuffs, feedstuffs, additives and premixes) as well as certain services related to animal feed (transport, storage), from suppliers providing these products or services under a GMP+ certificate<sup>1</sup>. A number of specific exceptions to this basic requirement were stated in the GMP+ FSA scheme, enabling participants to purchase non-GMP+ certified animal feed and related services. In such cases, the purchasing GMP+ company is designated as a so-called gatekeeper. A ubiquitous example is the so-called gatekeeper option for purchasing additives.

The above-mentioned basic requirement resulted in (GMP+) certification of many companies within the animal feed chain. Initially, this concerns companies that are part of a chain which eventually supplies animal feed to North-Western European animal feed companies. However, in the course of recent years, other companies have also taken an interest in certification for one or multiple GMP+ standards in order to discern themselves from their competitors and as an optimisation tool for their business.

For these companies, compliance with GMP+ requirements aimed at controlling their production process is normally not a problem. However, within a 'low GMP+ density' area, it has proven difficult to comply with the requirement for all suppliers to be GMP+ certified as well. There are simply not enough certified carriers or certified suppliers of animal feed ingredients in the relevant areas or countries.

This protocol contains supplementary conditions for a GMP+ certified company intending to perform the role of temporary gatekeeper with respect to non-GMP+ certified animal feedstuffs and services. The purpose of this protocol is to uniformly record the gatekeeper requirements. Compliance with these supplementary requirements ensures that the animal feed that the gatekeeper eventually brings into the market is of an equivalent level as when purchasing animal feed ingredients and services from GMP+ certified suppliers.

Application of this protocol is possible only in the event of and for the duration of an individual exemption issued by GMP+ International. Policy dictates that application of the gatekeeper role is a temporary situation, as the eventual purpose is for the entire chain to be demonstrably guaranteed, i.e. that the suppliers will be certified. The eventual purpose is for each link in the chain to demonstrably take its own responsibility.

## 2 Field of application

This protocol can be applied by a GMP+ certified participant (hereafter referred to as: gatekeeper) for purchasing non-GMP+ certified feedstuffs, pre-mixes, transport or storage, insofar such purchase is not regulated by the general GMP+ require-

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<sup>1</sup> Or certified for an approved equivalent standard

ments and insofar the relevant company has obtained individual permission from GMP+ International.

Please note:

A generic gatekeeper option is stated in GMP+ (GMP+ BA10 *Minimum requirements purchase*) with respect to non-GMP+ certified additives.

With respect to individual exemptions, GMP+ International exclusively grants permission for application of this protocol in consultation with the certification bodies involved. Exemptions may be issued subject to supplementary conditions. The purpose is aiming for certification of the relevant suppliers of animal feed products and services based on a targeted action plan.

Issuing such an exemption is based on GMP+ A1 *General regulations*, Article 11.

3. GMP+ International issues such an exemption subject to fulfilment of the following criteria:

- a with respect to the relevant product or service, less than 50% of the companies in the relevant country or continent participates in the GMP+ FSA scheme or approved equivalent certification scheme;
- b The company has an action plan with a clear schedule, aimed at encouraging suppliers and service providers to start a certification process for GMP+ or an approved equivalent scheme;
- c The company demonstrates adequate and accurate application and interpretation of the gatekeeper role;
- d Exemption is issued for a maximum period of two years and is renewed only if the company demonstrates sufficient effort to persuade suppliers to get certified.

## 3 Gatekeeper options

### 3.1 Purchasing feedstuffs

For a number of *specific* feedstuffs, gatekeeper requirements are stated in GMP+ BA10 *Minimum requirements purchase*. Individual exemption is not necessary if these feedstuffs are purchased on the basis of these conditions.

The following applies to purchasing other non-certified feedstuffs

#### 3.1.1 General

The gatekeeper can buy or receive a non-GMP+ certified animal feed from a producer, as long as the gatekeeper guarantees that the feedstuff brought into the GMP+ chain complies with GMP+ requirements. This implies that the gatekeeper actually serves as the producer's representative with respect to the relevant animal feed. The gatekeeper must conclude an agreement with the producer relating to the rights and obligations regarding compliance with GMP+ requirements.

The gatekeeper must at least comply with this protocol.

#### 3.1.2 HACCP hazard analysis and case file

The gatekeeper must conduct a HACCP-based hazard analysis per producer and per feedstuff. This hazard analysis must at least consist of the following phases:

- Specification of the feedstuff, including origin and production method.
- Process diagram (general/specification) of the feedstuff's production up to and including its physical delivery to the gatekeeper.
  - o The hazard analysis must also include the pre-production phases of the feedstuff insofar these are relevant for analysing possible hazards. This may concern (production of) ingredients used in the production process of the feedstuff.
  - o The hazard analysis must also include all post-production phases, including transport, (temporary) storage, repackaging etc.
- Identification of hazards and risk assessment per process phase.
- Overview of the available general and specific control measures for controlling identified risks.
- Monitoring plan and results. Compliance with minimum sampling and testing requirements as laid down in this protocol is required.
- The written agreement (such as a contract) with the producer.
- All results of audits of the producer conducted by or on behalf of the gatekeeper, and any sites where the feedstuff is stored before being delivered to the gatekeeper company. The audits may be carried out by:
  - o The gatekeeper's qualified staff;
  - o An appropriately accredited inspection or certification body commissioned by the gatekeeper or supplier.

Please note: Audits may also be conducted on behalf of a group of companies.

The frequency of sampling, testing and auditing depends on the risk profile of the animal feed, the production process and the quality assurance applied by the producer, but this must at least fall within the minimum requirements of this protocol.

The gatekeeper must compile a case file and update at least the components as mentioned. This case file must be complete before the first delivery takes place. The audit may not be conducted before first delivery and the audit results must be added to the case file within latest 3 months. Sampling and testing must start at first delivery and the results must be available before delivery takes place. This case file must form part of the GMP+ documentation and must be controlled and updated as such.

The generic hazard analyses published on the GMP+ International website give an insight into generically defined hazards. Controlling these hazards must be given sufficient attention.

### 3.1.3 Lot size and sampling

In accordance with this protocol, the lot must be inspected prior to purchasing. The lot size must be defined in advance.

If possible, a lot must be defined in a practical quantity, for example the hold of a sea vessel, a coaster or train. A sample must be taken for each defined lot by a person free of coercion, using a method that complies with generally accepted sampling methods.

#### Note 1)

Transport by truck always concerns relatively small parties. For direct transport by truck, it is possible to first separate a larger lot in a storage or production site. Subsequently, an independent sampler can take a representative sample of this lot for analytical testing. The results of this sampling may be deemed representative for this lot. Subsequently, this lot may be delivered using multiple trucks.

This is subject to the following conditions:

- The lot may not exceed the maximum defined tonnage.
- The lot must be kept in quarantine at the storage location (i.e. separate and identifiable).
- The location must be designed to enable taking representative samples (cross-section samples)

#### Note 2)

This implies that each truck carrying the feedstuff will be sampled from a pre-identified lot (as described under 1). This partial sample does not need to be tested. Only the representative sample taken from the pre-identified bulk lot is subject to mandatory testing.

Furthermore, the following applies:

- If feedstuffs are bought in bags or big-bags, sampling is based on the number of bags or big-bags (the general basis is the square root of the number of bags).
- Sampling may take place in the production, loading or delivery site.
- During first delivery, an analysis must be conducted before first use.

#### 3.1.4 Parameters for sample testing

The samples must always be analysed for parameters listed in GMP+ BA4 *Minimum requirements for sampling and analysis*. If it becomes apparent from the hazard analysis conducted by the gatekeeper, analysis focused on the relevant factors must be conducted as well.

Please note: Compliance with production standards as set out in legal requirements is mandatory at all times. With respect to animal feed (for example feedstuffs) to be exported to the European Union, the product standards as set out in GMP+ BA1 *Product standards* shall apply as a minimum requirement.

#### 3.1.5 Reporting analysis results

The GMP+ certified gatekeeper applying this protocol must deliver the results of the analyses to the GMP+ International Database Undesirable Substances and Products (DUS) at least once per month, adhering to the relevant instruction issued by GMP+ International, which can be viewed on: <http://dos.gmpplus.org/>

### **3.2 Purchasing pre-mixes**

#### 3.2.1 General

The gatekeeper can buy or receive a non-GMP+ certified premix from a producer, as long as the gatekeeper guarantees that the premix brought into the GMP+ chain complies with GMP+ requirements. This implies that the gatekeeper actually serves as the producer's representative with respect to the relevant premix. The gatekeeper must conclude an agreement with the producer relating to the rights and obligations regarding compliance with GMP+ requirements.

The gatekeeper must at least comply with this protocol.

### 3.2.2 HACCP hazard analysis and case file

The gatekeeper must conduct a HACCP-based hazard analysis per producer and per premix. This hazard analysis must at least consist of the following phases:

- Specification of the premix, including origin and production method.
- Process diagram (general/specification) of the premix's production up to and including its physical delivery to the gatekeeper.
  - o The hazard analysis must also include the pre-production phases of the premix insofar these are relevant for analysing possible hazards. This may concern (production of) ingredients used in the production process of the premix.
  - o The hazard analysis must also include all post-production phases, including transport, (temporary) storage, repackaging etc.
- Identification of hazards and risk assessment per process phase.
- Overview of the available general and specific control measures for controlling identified risks.
- Monitoring plan and results. Compliance with minimum sampling and testing requirements as laid down in this protocol is required.
- The written agreement (such as a contract) with the producer.
- All results of audits of the producer conducted by or on behalf of the gatekeeper, and any sites where the premix is stored before being delivered to the gatekeeper company. The audits may be carried out by:
  - o The gatekeeper;
  - o An appropriately accredited inspection or certification body commissioned by the gatekeeper or supplier.

Please note: Audits may also be conducted on behalf of a group of companies.

The frequency of sampling/testing and auditing depends on the risk profile of the pre-mixes and the quality assurance demonstrably applied by the producer, but this must at least fall within the minimum requirements of this protocol.

The gatekeeper must compile a case file containing at least the components as mentioned. This case file must be complete before the first delivery takes place. The audit may not be conducted before first delivery and the audit results must be added to the case file within latest 3 months. Sampling and testing must start at first delivery and the results must be available before delivery takes place. This case file must form part of the GMP+ documentation and must be controlled and updated as such.

The generic hazard analyses published on the GMP+ International Website give an insight into generically defined hazards. Controlling these hazards must be given sufficient attention.

### 3.2.3 Lot size and sampling

In accordance with this protocol, the lot must be inspected prior to purchasing. A lot consists of a single delivery from 1 batch (in bags, big-bags or bulk).

A sample must be taken from each defined lot by a person free of coercion, using a method that complies with generally accepted sampling methods.

Furthermore, the following applies:

- If premixes are bought in bags or big-bags, sampling is based on the number of bags or big-bags (the general basis is the square root of the number of bags).
- Sampling may take place in the production, loading or delivery site.
- During first delivery, an analysis must be conducted before first use.

### 3.2.4 Parameters for sample testing

The samples are analysed on the basis of parameters derived from the hazard analysis conducted by the gatekeeper.

Please note: Compliance with production standards as set out in legal requirements is mandatory at all times. With respect to animal feed (for example premixes) to be exported to the European Union, the product standards as set out in GMP+ BA1 *Product standards* shall apply as a minimum requirement.

### 3.2.5 Reporting analysis results

The GMP+ certified gatekeeper applying this protocol must deliver the results of the analyses to the GMP+ International Database Undesirable Substances and Products (DUS) at least once per month, adhering to the relevant instruction issued by GMP+ International, which can be viewed on: <http://dos.gmpplus.org/>

## 3.3 **Purchasing transport**

Commissioning non-GMP+ certified transport is subject to the following conditions:

- The gatekeeper must adequately instruct non-GMP+ certified carriers relating to the relevant GMP+ requirements regarding transport, including all requirements regarding cleaning and disinfection which are applicable unabated.
- The gatekeeper and the transport company commissioned are to confirm their agreement in writing.
- Before the transport vehicle may be deployed, it must be released by a load inspector.
- The gatekeeper and/or transport company commissioned must record the following details with regard to the transport of the animal feedstuffs:
  - o A transport list for each loading compartment with details regarding prior loads;
  - o Details regarding each loading compartment with respect to all cleaning and disinfection procedures carried out;
  - o Details of cleaning inspection for the loading compartment prior to loading;
  - o Details of the inspections carried out per loading compartment.

- The inspection is conducted by a load inspector prior to loading the vehicle. No prohibited prior loads are allowed.
- A 'load inspector' is a role stated in the gatekeeper quality system. This role is fulfilled by an employee with the required knowledge and skills (based on training and experience) for inspecting a load compartment for suitability with respect to loading animal feedstuffs.
- The above details must be available for inspection by the receiving company (for example during inspection on delivery).
- The agreements must be audited and inspected by the gatekeeper by means of an internal audit.

### 3.4 Purchasing storage

When outsourcing storage to a non-GMP+ certified storage company, the gatekeeper must comply with the following requirements:

- The gatekeeper conducts an inspection (or has one carried out) focusing on aspects relating to animal feed safety, such before use of the products.
- The gatekeeper determines that the storage company complies with all applicable obligations pursuant to animal feed legislation.
- The gatekeeper must record agreements in a contract concluded with the storage company relating to compliance with the relevant basic requirements (hygiene, pest control, tracing and tracking etc), the control measures to be implemented and the audits and inspections. This serves to provide guarantees regarding storage of animal feedstuffs equivalent to GMP+.
- The gatekeeper conducts periodical inspections ensuring compliance with agreements as concluded.

## 4 Other issues

Other relevant GMP+ requirements relating to purchasing, storage, transport, sampling and analysis shall apply unabated.

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