



TS 2.4 Country Note China

TS 2.4 **Final Draft**

Version EN: July 2020



GMP+ Feed Certification scheme 2020



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Welcome

This Feed Certification Scheme document helps you to provide feed safety world-wide. By meeting the requirements set by GMP+ International together with our GMP+ Community, we aim to help you get the feed certification you need. Please read the information in this document carefully.

Let's make this work together!

1 Introduction

This Country Note provides requirements and conditions in order to enable premixtures and compound feed producers in China to participate in the GMP+ FSA module, and to become certified as such. These requirements are meant to provide a wider range of options for establishing a GMP+ feed safety management system of assurance of the feed safety.

The core principles of this Country Note:

- The specific options which are given, must result in a sufficient level of feed safety assurance;
- Provision of a temporary practical option for a Chinese company to:
 - Implement a Feed Safety Management System, which meets the GMP+ FSA requirements
 - obtain a GMP+ FSA certificate
 - satisfy the specific needs of the Chinese industry.

This document is referred to as TS 2.4 *Country Note China* and is part of the GMP+ FSA module.

2 Scope and Application & Certification

2.1 Scope of the Country Note

This Country Note provides specific GMP+ requirements for sourcing feed ingredients from non-GMP+ certified suppliers. This country note can be used by companies in China, that produce premixtures and compound feed. This Country Note also provides specific requirements for using non-certified services, like: transport, storage and laboratories.

Next to this, it provides specific guidance for application of some other GMP+-standards/requirements.

Helpful tip:

- In the GMP+ FC scheme, strict basic requirements are laid down regarding suppliers and the purchase of products. In essence, a compound feed or premixture company may only purchase feed materials, feed additives and other feed products/services from suppliers who are also GMP+ certified (or certified to some other approved schemes/ standards). In China most suppliers are not GMP+ certified and therefore it is very hard for a compound feed or premixture company to comply with these basic GMP+ purchase requirements.
- Therefore, specific purchase requirements are necessary for compound feed and premixture companies in China to implement a full operational feed safety system, and become GMP+ certified as such.
- These specific requirements are based on the General Gatekeeper Protocol for purchasing products and services from non - GMP+ certified companies. These requirements are considered to achieve a sufficient level of feed safety assurance.

2.2 Application

This Country Note is applicable for premixtures and compound feed companies, located in China. Application is only possible in combination with one or more of the next scopes.

- Production of compound feed - CN
- Production of premixtures - CN

Application of this Country Note will be extended to another period of 4 year (2019-2023). In the meantime, a Supplier Improvement Program will be carried out by the feed companies in China, with the aim to achieve the desired situation.

Helpful tip:

The specific purchase requirements, laid down in this Country Note, can be applied next to, or instead of, the regular Purchase Requirements as laid down in the GMP+ standards and in TS 1.2 *Purchase*.

It must be clear that this Country Note is meant to make it possible for Chinese pre-mixtures and compound feed companies to implement a feed safety assurance system that meets the GMP+ requirements.

The feed ingredients, that are necessary to produce these premixtures and the compound feed, can be bought in compliance with this Country Note. The requirements in this Country Note are strict and guarantee a sufficient level of feed safety. However, the basic principle in GMP+ is that every link in the chain defines and controls his own risks. The ultimate goal is that every link in the feed chain applies the same principles for feed safety assurance and is certified as such. With this in mind, application of this Country Note is limited for sourcing non-certified feed ingredients for one's own premixture or compound feed production. It is not meant for trade (= buying a feed ingredient from a non-certified origin and sell it under a GMP+ certificate to - for instance - Europe).

2.3 Certification for companies

Certification will be registered additionally in GMP+ Company Database and will be stated on the certificate.

The following additional scopes could apply:

- Production of compound feed - CN
- Production of premixtures - CN

3 Terms and Definitions

See F 0.2 *Definition list*.

As a differentiation, the following specific definition applies to this Country Note:
Feed ingredient includes also feed premixtures, next to feed materials and feed additives

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4 Gatekeeper requirements

In this chapter we refer to 'the gatekeeper' with which is meant the GMP+ certified company that applies the requirements from this country note (producer of compound feed or premixtures).

4.1 Purchase of feed ingredients

4.1.1 Scope

The following applies to purchasing feed materials, feed additives and premixtures (hereafter referred to as: feed ingredients) from non-GMP+ certified suppliers.

Helpful tip:

Meant are feed ingredients that are officially approved by feed legislation. Application of this Country Note is not meant for purchasing feed ingredients that are forbidden by applicable feed legislation.

Non-certified supplier: This is in most cases the producer. If there is a trader in between the gatekeeper and the producer, the required HACCP-analysis must be extended as far as the producer.

4.1.2 General

The gatekeeper can purchase a feed ingredient from a non-GMP+ certified supplier, as long as the gatekeeper guarantees that the feed ingredient brought into and used in the GMP+ chain complies with GMP+ requirements.

The gatekeeper must conclude a quality agreement with the supplier relating to the rights and obligations regarding compliance with GMP+ requirements, and thus the feed safety.

4.1.3 HACCP hazard analysis

The gatekeeper must conduct a HACCP-based hazard analysis per supplier and per feed ingredient or group of feed ingredients.

Helpful tip:

It may be decided for reasons of effectiveness to form groups of feed ingredients. Examples: 1) different feed materials originating from one production process; 2) premixtures, from one supplier and produced for one animal group (pigs, cows, poultry)

Such a group can be assessed all as one. It is important that:

- a. specific differences between the individual feed ingredients are examined critically;
- b. the production and storage conditions are equivalent;
- c. no major aspects relating to product safety are forgotten.

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

- a. Specification of the feed ingredient, including origin and production method.

- b. Process diagram (general/specific) of the feed ingredient's production up to and including its physical delivery to the gatekeeper.
 1. The hazard analysis must also include the pre-production phases of the feed ingredient insofar these are relevant for analysing possible hazards. This can concern (production of) raw materials used in the production of the feed ingredient.
 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.

Information, provided by the supplier, can be used.

Further, the generic risk assessments of feed materials, published on the GMP+ International Portal (GMP+ Monitoring database) give an insight into 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.

Helpful tip:

On the GMP+ website an example of a [feed safety data sheet](#) is given, which can be used to summarize the results of the hazard analysis. See: *Certification scheme > GMP+ FSA certification > B documents > related forms.*

4.1.4 Monitoring and Auditing

Monitoring

The gatekeeper must also decide if additional monitoring is necessary.

The frequency of sampling & analysing depends on the risk profile of the feed ingredient, the results of the hazard analysis and the quality assurance applied by the supplier.

Sampling must be done in compliance with generally accepted sampling methods.

Furthermore, the following applies:

- a. If feed ingredients 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).
- b. Sampling can take place in the production, loading or delivery site.
- c. During first delivery (= a new supplier and/or a new feed ingredient), an analysis must be conducted before first use.

The samples must be analysed in compliance with TS 1.7 *Monitoring*, and additionally - if it becomes apparent from the hazard analysis conducted by the gatekeeper – on other relevant parameters as well.

Audits

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

Audits can be carried out by:

1. The gatekeeper's qualified staff;
2. An appropriately accredited inspection or certification body contracted by the gatekeeper or supplier.

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

4.1.5 File

The gatekeeper must further compile a file with at least (results of) the above mentioned items. This file must also include:

- 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.

4.1.6 Supplier improvement programme

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

This Supplier Improvement Program must have:

- calculation of the initial situation of the gatekeeper
 - calculation of total feed production volume,
 - % of this total volume which is meant to be GMP+ FSA assured, and
 - % GMP+FSA assured feed ingredients coming from already assured sources
- clear actions and activities ('milestones') to stimulate suppliers to meet the relevant requirements, and clear end dates when results are achieved, yearly.
- clear criteria for evaluation and decision about continuation of the relation between gatekeeper and supplier. Once a year an evaluation must be made.
- yearly assessment of achieved results and updating of proposed goals on % volume of feed ingredients which comes from assured sources.

¹ Meant are the feed ingredients suppliers which are not certified

- if initial situation changes, for instance due to new products and/or new suppliers, the Supplier Improvement Program must be reviewed and adapted to the new situation.

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

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

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

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

4.2 Purchase of transport

4.2.1 Scope

Transport in (big) bags does not have to be certified. For this, the general requirements in 4.3.2 are applicable.

Bulk transport has to be carried out by a certified transporter.

If the GMP+ certified company

- has means of bulk transport itself, it must additionally be certified for this scope. See for this R 1.0 *Feed Safety Management Systems Requirements*.
- contracts a transporter, preferably this transporter must be GMP+ certified.
- Next to this, also non-certified transport can be used. If so, the requirements in 4.2.2 and 4.2.3 are applicable. The certified company acts as a gatekeeper.

4.2.2 General

All means of transport (whether by ship, barge, road vehicle, rail, container or other transport system) whether owned or contracted to carry any kind of feed (feed ingredients, compound feed, premixtures), whether in bulk or packed, must be appropriate and adequately controlled with specific regard to hygiene and potential contamination with previous loads.

If the GMP+ certified company is responsible for the transport it must control this by itself, and at least comply with the requirements in this chapter. If a third party (for example: a supplier) is responsible for the transport, the certified company must make proper and clear arrangements to make sure the transport is carried out in compliance with the requirements in this chapter, and the certified company must also check that the arrangements are met.

In the case of transporting feed in sealed containers or packaging, risk assessments must consider any potential hazards and ensure that controls effectively preclude any serious risk of contamination.

Helpful tip:

It is very important to implement an appropriate cleaning procedure if the means of transport are used for subsequent transport. This is of course the case when a bulk carrier is used, or a container.

The cleaning procedure must at least ensure that the feed transported is not contaminated with harmful substances of previous loads.

4.2.3 Controlling non-certified bulk transport

Contracting non-GMP+ certified bulk transport of feed is subject to the following conditions:

- a. The gatekeeper must adequately instruct non-GMP+ certified transporters about the relevant GMP+ requirements regarding transport, including all requirements regarding cleaning and/or disinfection. The requirements in de IDTF-database² are applicable, as a minimum.
Also, there must be instructions about registration of loads, inspections and cleaning. See for details about inspections and registration the next items.
- b. The gatekeeper is responsible and must guarantee that load compartments (railway wagons, road bulk carriers, containers) are sufficient cleaned before loading. In ports, only food grade containers can be used
- c. Before the load compartment can be loaded, it must be inspected and released by a load inspector. A 'load inspector' is someone with the required knowledge and skills (based on training and experience) for inspecting a load compartment for suitability with respect to loading/transporting feed products.
- d. The load inspector must have clear instructions and his activities must be controlled in the gatekeeper's quality system.
- e. The gatekeeper and/or transport company contracted must record the following details with regard to the transport of the feed products:
 1. A transport record for each load compartment with details regarding prior loads;
 2. Details regarding each load compartment with respect to all cleaning and disinfection procedures carried out;
 3. Details of the inspections carried out per load compartment, including the cleaning inspection of the load compartment prior to loading.
The inspection is conducted by a load inspector prior to loading the vehicle.
- f. The gatekeeper and the transport company contracted are to confirm their agreement in writing.
- g. The gatekeeper conducts periodical inspections ('internal audit') ensuring compliance with agreements as concluded.

² The IDTF-database may be consulted via the GMP+ website.

- h. The above details must be available for an audit as part of a third party certification.

If another company (for example the producer of a feed material, who supplies the feed material to the GMP+ company) is responsible for arranging the bulk transport, the GMP+ company must make clear arrangements with this other company the transport complies with the above mentioned requirements.

Carry over

If non-GMP+ certified bulk transport is contracted for the transport of compound feed or premixtures, the gatekeeper must adequately instruct the non-GMP+ certified to control the risk of carry-over of veterinary medicinal products and feed additives. An appropriate instruction must comply with the relevant residue level for veterinary medicinal products and feed additives. Control and cleaning measures must ensure that the relevant residue levels are met.

4.3 Purchase of storage

4.3.1 General

All means of storage whether owned or contracted to store either raw materials or feed ingredients, whether in bulk or packed, must be appropriate and adequately controlled with specific regard to hygiene and potential contamination.

In the case of storage of raw materials or feed ingredients in sealed containers or packaging, risk assessments must consider any potential hazards and ensure that controls effectively preclude any serious risk of contamination. Storage in (big) bags does not have to be certified.

4.3.2 Storage in bulk

GMP+ requires storage in bulk to be carried out by certified storage companies. Next to this, also non-certified storage can be used. If so, the next requirements are applicable.

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

- a. The gatekeeper carries out an inspection (or has one carried out) focusing on aspects relating to feed safety, such before use of the storage facilities.
- b. The gatekeeper must instruct 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 to be carried out. This is meant to provide guarantees regarding storage of feed ingredients equivalent to GMP+.
- c. The gatekeeper conducts periodical inspections ('internal audit') ensuring compliance with agreements as concluded.

4.4 Purchase of laboratory analysis

If measurement and monitoring takes place by way of an analysis this must – preferably -be carried out by a laboratory that is accepted within the GMP+ FSA module as described in TS 1.2 *Purchase*.

It is important to verify that the analysis concerned, is covered under the scope of the certification.

If it is not reasonably possible to make use of a laboratory with as described in TS 1.2 *Purchase* for the analysis in question then a company can also make use of a laboratory which is accredited by the government.

If a laboratory does not comply with the above then it is in any event important that the laboratory produces results in a reliable fashion and that an independent third party has assessed this positively.

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5 Specific remarks regarding application of GMP+

- 1) The TS 1.5 *Specific Feed Safety Limits* is applicable unless the Chinese feed legislation has laid down stricter product standards.

Helpful tip:

Within the GMP+ FSA module, the safety of the feed is particularly specified in (maximum) limits for so-called undesirable substances and maximum limits for residues of veterinary medicinal products. These so-called product standards are laid down in TS 1.5 *Specific Feed Safety Limits* and TS 1.11 *Control of residues*, which is an important document and applicable for all GMP+-certified companies.

The TS 1.4 *Forbidden Products and Fuels* is applicable unless the Chinese feed legislation has stricter requirements

- 2) If a compound feed company produces also premixtures, this must be assured under GMP+ certification.
- 3) The feed products, used as a carrier in premixtures, can be purchased under gatekeeper conditions laid down in chapter 4 of this Country Note.

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