GMP+ International

TS 2.2 Country Note Vietnam

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Feed Safety Worldwide

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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 TS 2.2 *Country Note Vietnam* is meant to give specific GMP+ requirements and conditions for a feed company, located in Vietnam. These requirements provide a wider range of options to establish a GMP+ Feed Safety Management System (GMP+ FSMS) which complies with the GMP+ FSA standards and can be certified as such.

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 Vietnamese company to:
    - Implement a Feed Safety Management System, which meets the GMP+ requirements, sufficiently to obtain a GMP+ FSA certificate
    - with respect to specific needs of the Vietnamese industry.

This document is referred to as TS 2.2 *Country Note Vietnam* and is part of the GMP+ FSA module.

Frequently asked questions and examples of the application of the country note are mentioned in this document.

2 Scope, Application & Certification

2.1 Scope of this Country Note

This Country Note provides specific GMP+ FSA requirements for:

a. The situation that several feed companies[1] are located at the same address[2]
b. A Business Locations with several feed activities while not all of these activities are ready or in need for GMP+ FSA certification
c. Purchase of feed materials from non-certified sources, if there is no standard GMP+ gatekeeper protocol applicable
d. Provision of information and delivery of products produced with feed products mentioned under c.

2.2 Application

Any feed company located in Vietnam, with activities in production or trade of feed products can apply this Country Note.

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

Application of this Country Note is temporary (2018 – 2022).

2.3 Certification for companies

When a company shows compliance with both the requirements of the core GMP+ FSMR standard and this Country Note, a GMP+ FSA certificate can be granted.

The scope and reference to this Country Note will be additionally stated on the certificate. This additional scope is compiled by the regular scope formulation, supplemented with the addendum '*-VN*'.

The following scopes apply:
a) Production of compound feed – VN
b) Production of premixtures - VN
c) Production of feed material - VN
d) Trade (in compound feed, premixtures, and/or feed material) - VN

This additional scope will also be registered in GMP+ Company database. Please, refer to the certification body for further details.

[1] Which have not any relationship of shared ownership
[2] In certain countries location identification is done by the name of a company and the name of the street or business zone name.

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.

3 Terms and Definitions

See F 0.2 *Definition list*.

4 Specific requirements for business locations

In deviation of the stipulation mentioned in F 0.1 *Rights and Obligations*, under § 5.4 this is not applicable, if the GMP+ certified company can prove sufficiently:

a) that there is not any relationship in ownership and or executive management with the other feed companies located at the same Business Location;
b) that there is not any business relationship with the other feed companies located at the same Business Location.

In deviation of the stipulation mentioned in R 1.0 *Feed Safety Management Systems Requirements*, under § 4.3: this is not applicable, if:

c) the other feed activity (feed activities) is classified under a different GMP+ FSA scope, and
d) in the free part of the scope on the GMP+ FSA certificate as well as in the GMP+ Company Database is clearly stated what is excluded from the scope of the certificate.

Procedures must be implemented to assure such a separation between the above mentioned activities that the safety of the feed products, covered under the scope of the GMP+ certificate, is not negatively affected and the relevant feed safety limits are not exceeded. These procedures must be the result of a HACCP risk analysis, and must be monitored. The FSMS must guarantee that these procedure are operated effectively.

Helpful tip:
As an example, a company produces compound feed and feed materials. This company can exclude production of feed materials from the scope of certification, and only bring the production of compound feed under the scope of certification.

5 Purchase of feed material from a non-GMP+ FSA certified supplier

In this chapter, specific requirements are laid down for purchasing of feed materials from a non-GMP+ FSA certified supplier.
Where TS 1.2 *Purchase* provides gatekeeper protocols, the GMP+ certified company must decide between applying the protocols of TS 1.2 *Purchase* or the gatekeeper options in this country note.

5.1 General

When a standard gatekeeper protocol is already applicable (see TS 1.2 *Purchase*), the GMP+ certified company is obliged to comply with these applicable requirements.

In other cases, the certified company can apply this Country Note for sourcing of feed materials from a non-GMP+ FSA certified supplier to trade as or to process in feed produced under GMP+ FSA certification which is destined for the Asian market.

The GMP+ certified company must assure that the feed material, which is - within the scope of his GMP+ FSA certification – brought into the feed chain, is safe for use in or as feed. For this, the certified company must establish and implement a gatekeeper system which is in compliance with this Country Note and guarantees that the feed material is safe and complies with the relevant GMP+ FSA requirements, at least with regards to the Specific Safety Limits in TS 1.5 *Specific feed safety limits*.

5.2 Assurance of safe feed materials

For each type of feed material to be purchased or received, there must be a generic risk assessment in the GMP+ Feed Support Products (FSP) database and the feed material must be listed in TS 1.3 *Product list*.

The GMP+ certified company must make a clear and unambiguous agreement with the supplier about:

a) compliance with relevant conditions of this Country Note
b) responsibilities ('who is doing what')
c) exchange of relevant information, including information as required in this protocol.
d) any other issue, relevant for assuring the safety of the feed product.

Helpful tip:
The gatekeeper is overall responsible for demonstrating compliance with the relevant requirements of 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, in which responsibilities are laid down clearly and unambiguously

5.3 Elements of the GMP+ gatekeeper system

When establishing a gatekeeper system, at least the next elements must be addressed.

5.3.1 Scope

The gatekeeper system is applicable for the purchase of any feed material from any origin, as far as not covered under standard gatekeeper protocols in TS 1.2 *Purchase* .

The gatekeeper system must cover all operations and activities, from original production up to delivery, and this must result in controlling all safety hazards related to the:

a) supplier,
b) specific feed material concerned
c) production process of this feed material
d) other (logistic) operations and activities like storage and transport

5.3.2 Desk study

The gatekeeper must gather and assess information about:

a) the supplier
b) the feed material: a complete specification/MSDS (see website ->
   i. *related forms*)
c) the production process:
   1. a clear process description/process diagram
   2. which raw materials and processing aids are used
   3. other activities or circumstances (transport, storage)

Helpful tip:
Information should at least be focused on safety aspects and must encompass
- *the pre-production phases of the feed material insofar these are relevant for identifying and assessing possible hazards. This may concern (production of) raw materials, use of processing aids and technological additives used in the production of the feed material.*
- *all post-production activities of the feed material phases until delivery to the GMP+ certified company, including transport, (temporary) storage, repackaging etc.*

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

d) the results of the supplier's HACCP study
    4. The risks: What are the identified risks of the production process?
    5. The controls: What control measures have been taken?
    6. The monitoring: What monitoring is carried out?

e) guarantees:
    7. Is there a safety standard implemented?
    8. What certification does supplier have?
f) legal license (e.g. Feed registration number)
g) other relevant information

5.3.3 Initial supplier audit

Before first delivery, the GMP+ certified company must perform an initial supplier's audit. For this, a checklist must be prepared, aiming to:

a) Complete the relevant and necessary information
b) Confirm results of the desk study,

5.3.4 HACCP analysis

Based on the results of the desk study and the supplier audit, the GMP+ certified company conducts a HACCP analysis per supplier and per feed material (or group of feed materials). The HACCP analysis must be in compliance with the requirements and conditions of the GMP+ FSA standards.

The certified company must decide about additional implementation of controls in order to assure the feed safety.

Helpful tip:
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.

The HACCP analysis must be carried out in a structured way, in compliance with the steps of the core GMP+ B standards (hazard → risks → controls → monitor).
The generic risk assessments of feed materials, published on the website of GMP+ International under Feed Safety Products, give an indication about generic defined hazards. Assessing and – if appropriate - controlling these hazards must be given sufficient attention.

5.3.5 Monitoring and product Verification

The GMP+ certified company must decide about monitoring and product verification. The considerations and general requirements for monitoring, laid down in TS 1.7 *Monitoring* must be taken into account.

Enough samples must be taken to carry out a risk based monitoring plan. Sampling must 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 TS 1.6 *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.

For determining the minimum for the monitoring frequency on a specific parameter, the next formula is to be used:

$$\text{Frequency} = \frac{\sqrt{\text{Volume}}}{100} * \text{likelihood of occurrence} * \text{seriousness}$$

Note: *On first delivery (= a new supplier and/or a new feed), an analysis (focused on relevant safety parameters) must be conducted. Reduction of the monitoring frequency must be motivated with clear proof.*

Helpful tip 1:	
VARIABLE	EXPLANATION
Frequency	The number of samples to be tested (on a yearly basis)
Volume	Volume in tons of feed materials per year. In principle, the number of samples to be tested is based on the quantity of feed material which is produced, traded, processed or stored. As the quantity of feed material increases, the number of samples per ton will decrease. Kilograms must be assumed for some feed materials for which, on a yearly basis, only a small quantity is produced, traded or processed.
Likelihood of occurrence	The standard value for likelihood of occurrence is 1. The GMP+ certified company may raise or lower this value if reasons are given. The following considerations may apply to this: a. History: see also below b. Seasonal influences c. Possibility of recontamination. This applies in particular to microbiological parameters. d. New source / new suppliers e. Have there been recent incidents.

<table>
<tr><td></td><td>It is up to the certified company to decide that the likelihood of occurrence value can be lowered.
The certified company should select a likelihood of occurrence value which is below one on the basis of (historical) testing results. The following must be kept in mind:
a. Testing results should be representative. The historic testing results which are considered as representative may differ per undesirable substance.
For some undesirable substances the testing results for an area can be considered to be representative while, for other undesirable substances, only testing results for the same production location is representative.
b. Testing results from GMP+ Monitoring database may also be used in determining testing frequency if the certified company can show representativeness.</td></tr>
<tr><td>Seriousness</td><td>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):
Seriousness is great factor 5
Seriousness is moderate factor 3
Seriousness is small factor 1

This leads to the following factors:

<table>
<tr><th>Undesirable substance</th><th>Value</th></tr>
<tr><td>Heavy metals</td><td>5</td></tr>
<tr><td>Pesticides</td><td>5</td></tr>
<tr><td>Insecticides</td><td>5</td></tr>
<tr><td>Feed medicines</td><td>5</td></tr>
<tr><td>Mycotoxins</td><td>5</td></tr>
<tr><td>Salmonella</td><td>5</td></tr>
<tr><td>Fungi</td><td>3</td></tr>
<tr><td>Animal components</td><td>5</td></tr>
<tr><td>Dioxin</td><td>5</td></tr>
<tr><td>Nitrites</td><td>5</td></tr>
</table>

The established values are all high. This seems logical as these are risky undesirable substances.</td></tr>
<tr><td colspan="2">Note:
a. Calculated frequencies should always be rounded upwards. The minimum frequency is 1.
b. Calculation of the monitoring frequency of liquid or moist feed can be based on 88% dry matter content.</td></tr>
</table>

Helpful tip 2:
On the GMP+ I website a lot of information is available to support companies in defining risks, controlling risks and monitoring CCP's.

5.3.6 Periodical supplier audit

The GMP+ certified company must also decide if regular auditing of the supplier of feed materials is necessary. The frequency depends on the risk profile of the feed material, the results of the hazard analysis, the quality assurance applied by the supplier and the results of sampling and laboratory testing.

A supplier of a processed feed material must be audited at least once a year. Audits may be carried out by or on behalf of the certified company.

Helpful tip:
An auditor can be:

- A qualified member of the GMP+ certified company'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.
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.*

5.4 Supplier's improvement programme

The GMP+ certified company must set up a Supplier's Improvement Programme aiming to achieve that all his feed material suppliers[3] will established and operate a certificated GMP+ Feed Safety Management System within a determined timeframe.

The certified company must define:

- clear actions and milestones to stimulate the feed material suppliers to meet the relevant requirements and become GMP+ FSA certified.
- clear criteria for evaluation and decision about continuation of the relation between certified company and supplier.
- clear end dates when results are achieved. Once a year an evaluation must be made.

[3] Meant are the feed material suppliers which are not certified and cannot be safeguarded according the specific standard gatekeeper protocols in TS 1.2 *Purchase* .

The Supplier's Improvement Programme may last for max. four years as long as the next criteria are met:

At the end of year	% of the volume is sourced from GMP+ FSA certified suppliers or under standard gate-keeper protocol
1	50
2	60
3	80
4	100

Note: This Supplier's Improvement Programme may be established together with other companies.

Helpful tip:
In Vietnam, a substantial volume of soybean meal is imported from Argentina, Brazil and USA, and sometimes also India. In these countries the producers are (almost) all already GMP+ FSA certified. Many of the international traders in these commodities are also GMP+ FSA certified.
Substantial volumes of corn is also imported, and can be purchased under the standard gatekeeper protocol in TS1 .2 *Purchase* .
A lot of additives sourced from Europe and China are produced under GMP+ FSA or FAMI-QS certificate.
Conclusion:

a. Already a substantial part of the used feed ingredients could be produced by already GMP+ FSA certified companies or can be purchased under the standard gatekeeper protocols.
b. The Supplier's Improvement Programme should be focused on the not yet certified companies in the chain of custody of the products mentioned under a, and on the domestically located producers and suppliers.

5.5 Country Note documentation

The GMP+ certified company must further compile documentation with at least (results of) the above mentioned items. Documentation 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 certified company.
d. All relevant registrations of the Supplier's Improvement Programme. The registration must give a clear overview of the goals, the progress and the results.
e. Any other proof of compliance with this Country Note.

This documentation must be part of the GMP+ FSMS documentation, and must be controlled and updated as such.

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.*

6 Declaration and Delivery

When applying this Country Note, additionally unambiguous information must be provided.

6.1 Declaration

Feed, produced or delivered by application of this Country Note must be clearly declared as such: '*GMP+ FSA assured-Country Note Vietnam*'

This applies in the event of delivery to GMP+ FSA certified customers or customers who are certified in another certification scheme which has been approved equivalent to the GMP+ FC scheme[4].

This information must be specified in the sales contract or in some other written form by the time of delivery at the latest.

Non-GMP+ FSA assured feed (see chapter 4) must be clearly declared as such ('non-GMP+ FSA assured').

6.2 Delivery

Correct operation of the established GMP+ Feed Safety Management System assures the production and delivery of safe feed. If a feed company applies one or more of the conditions from this Country Note for production, processing or distribution of a feed product, this feed product can only be distributed as TS 2.2 *Country Note Vietnam* assured feed on the Asian market.

[4] See for approved other feed safety schemes TS 1.2 *Purchase*.

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