GMP+ International

R 1.0 Feed Safety Management Systems Requirements

R 1.0 ***Final Draft***

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GMP+ Feed Certification scheme 2020

Feed Safety Worldwide

Index

Welcome

This Feed Certification Scheme document helps you to provide feed safety worldwide. 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.Scope of this document

This document enables a company to achieve its feed safety objectives. It specifies requirements for a Feed Safety Management System (FSMS) which enables a company to provide safe feed products and feed services.

All requirements in this standard are generic and are intended to be applicable to all companies with activities in the feed chain, regardless of size and complexity. This ranges from companies which produce feed additives, feed materials, premixtures, compound feed or pet food, to companies which are involved in the trade, storage and transshipment and transport by road or rail of these products.

This document allows any company, including smaller businesses, to set up a robust and reliable Feed Safety Management System. In addition, internal and/or external resources can be used to meet the requirements of this standard.

This document (together with the Technical Specifications) is part of the GMP+ FSA module. If a company demonstrates compliance with the requirements in this standard, a GMP+ FSA certificate can be granted by the certification body.

Image of the structure follows!

2. Normative references

Some of the requirements contained in this document (the Feed Safety Management Requirements) refer to the GMP+ Technical Specifications (TS). These Technical Specifications explain in more detail a specific element of the Feed Safety Management Requirement and must be considered as a normative part of the GMP+ FSA module.

Furthermore some Technical Specifications are additional to this document (the Feed Safety Management Requirements). These Technical Specifications must also be considered as a normative part of the GMP+ FSA module.

3. Terms and Definitions

See F 0.2 *Definition list*

4. The context of the GMP+ certified company

Every GMP+ certified company is part of the global feed and food chain. The certified company must therefore be very aware of this position. This relates not only to the locations where feed activities take place, but also to where the company's GMP+ FSA assured products are marketed.

4.1. Compliance with Feed legislation and this Standard

The certified company must comply with the applicable feed legislation. This relates to feed legislation:

a) in the country in which the certified company is located;
b) in the country where the feed is marketed.
c) The certified company must also comply with the relevant sections of the standard.

If the standard does not describe control measures for a specific situation, it is the responsibility of the GMP+ certified company to establish and implement additional control measures based on a HACCP study, as described in Chapter 8.

In all of the above cases, it is the most strict requirement which is applicable for GMP+ certified companies.

4.2. Understanding the Needs and Expectations of interested parties

The certified company must ensure that it has the ability to consistently provide products and services that meet the requirements of the standard. The certified company must determine:

a) the interested parties that are relevant for the Feed Safety Management System (FSMS) and;
b) the needs of the relevant interested parties for the FSMS.

Helpful tip:
There are a wide range of interested parties whose needs you need to think about regarding the GMP+ Feed Safety Management System. It can help to list them carefully. These interested parties can range from suppliers, customers, contracted transporters and providers of services like pest control, as well as silo cleaning, tank cleaning, harbour companies, certification schemes and port authorities.

4.3. Determining the scope of the Feed Safety Management System

The GMP+ certified company must describe all activities, processes, products or services in the Feed Safety Management System (FSMS) for which it is responsible.

The certified company must determine the scope of the FSMS, by specifying:

a) all its activities, processes, products or services related to feed. These include activities, processes, products and services carried out by/for third parties;
b) which of those activities, processes, products or services are subject to GMP+ certification;

Possibilities for exclusion from the GMP+ certification are:
1) all activities processes, products or services related to pet foods;
2) parts of the production. These parts must be ensured under another certification scheme that is accepted within the GMP+ Feed Safety Assurance module (see TS 1.2 *Purchase*), as long as the entire production is certified.
3) trading activities;
4) storage and transport activities;

c) all locations -- whether these are the property of the company or not -- including relevant administrative locations.

d) other (feed and non-feed related) activities, processes, products or services as defined under b) that can have an impact on feed safety. The certified company must ensure that these activities, processes, products or services do not have a negative impact on feed safety. This must be supported by a HACCP analysis as described in Chapter 8;

e) The certified company must always consider the requirements referred to in § 4.1 and § 4.2 when determining this scope.

All activities potentially influencing feed safety must be available for auditing. The scope must be available and updated as documented information.

Helpful tip:
This is complex material. A great place to start reading about the scope of activities concerning GMP+ certification is the document: GMP+ D3.5 "Where does GMP+ FSA certification start?"
Above we mention "activities and/or products which are not related to feed" here you can think about, for example, storage of fuels, agricultural vehicles, wood. These are not directly involved in the feed process but could potentially have a negative impact on feed safety.

4.4. Feed Safety Management System

The certified company must establish, implement, maintain, update and continually improve a the Feed Safety Management System, in accordance with the requirements of the GMP+ standards. Attention must be paid to (the interaction between) the processes. Your Feed Safety Management System must control your processes, including the interaction between these processes.

When you use externally developed elements to establish your Feed Safety Management System, you must ensure, based on an assessment, that these elements are (made) suitable for your specific Feed Safety Management System.

Helpful tip:
Externally developed elements can be (part of) a quality manual developed by a consultant or a HACCP study or Code of Practice carried out by a association, for example. Also think of the generic risk assessments, provided by GMP+ International as part of the Feed Support Products.

5. Leadership

5.1. Leadership and Commitment

Top management of GMP+ certified companies must demonstrate leadership and commitment with respect to the Feed Safety Management System (FSMS) by:

a) ensuring that the feed safety policy and objectives of the FSMS are established;
b) ensuring that FSMS requirements are integrated into the organisation's business processes;
c) ensuring that the resources are made available for compliance with FSMS;
d) communicating the importance of an effective FSMS and by conforming to the FSMS requirements and the mutually agreed customer requirements relating to feed safety;
e) ensuring that the FSMS is evaluated and maintained to achieve its intended result(s);
f) directing and supporting persons to contribute to the effectiveness of the FSMS;
g) promoting continual improvement;
h) supporting other relevant managers to demonstrate their leadership as it applies to their areas of FSMS responsibility.

5.2. Feed safety policy

5.2.1. Establishing feed safety policy

Top management must establish, implement and maintain a feed safety policy that:

a) ensures commitment to the requirements of this GMP+ FSA module;
b) is appropriate to the purpose and context of the organisation;
c) provides a framework for setting and reviewing the objectives of the FSMS, as described in Chapter 6;
d) includes a commitment to satisfy applicable feed safety requirements including requirements from national and international legislation and the mutually agreed customer requirements relating to feed safety;
e) addresses internal and external communications;
f) includes a commitment to continual improvement of the FSMS;
g) addresses the need to ensure competencies relating to feed safety.

5.2.2. Communicating feed safety policy

Feed safety policy must:

a) be available and updated as documented information;
b) be communicated, understood, and applied at all levels of the organisation;
c) be available to relevant interested parties, as appropriate.

5.3. Organisational Roles, Responsibilities and Authorities

5.3.1. Top management's Responsibilities and Authorities

Top management must ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organisation. Top management is ultimately responsible for the Feed Safety Management System.

Top management must assign responsibilities and authority for:

a) ensuring that the FSMS conforms to the requirements as described in this document;
b) reporting on the performance and any need for improvement of the FSMS to Top management;
c) appointing the Feed Safety Team(s) and the Feed Safety Team leader(s). If there is more than one Feed Safety Team, a coordinator must be assigned;
d) appointing the Validation Team(s) and the Validation Team leader(s). If there is more than one Validation Team, a coordinator must be assigned;
e) designating persons with defined responsibilities and give them the authority to initiate and document action(s).

5.3.2. Responsibilities of the Feed Safety Team leader

The Feed Safety Team Leader is responsible for:

a) ensuring the FSMS (incl. Hazard control plan as described in § 8.5) is established, implemented, maintained and updated;
b) managing and organising the work of the Feed Safety Team;
c) ensuring relevant training and competencies for the Feed Safety Team (§ 7.2);
d) reporting to Top management on the effectiveness and suitability of the FSMS and pointing out any needs for improvement;
e) the coordination of the progress and for the proper set-up and maintenance of the FSMS, in the event of more than one Feed Safety Team.

Helpful tip:
Some staff members can fulfil multiple roles within a Feed Safety Team. You are also permitted to use resources from outside the company. But Top management always remains ultimately responsible for the FSMS.

5.3.3 Responsibilities of the Validation Team

Top management must establish a Validation Team. The members of the Feed Safety Team can also be members of the Validation Team, but the Validation Team must include at least one independent member in order to avoid undue influence. If this is not possible, Top management may deviate from this as long as valid reasons are given. The persons involved in the validation and the activities which they carry out must be clearly documented.

5.3.4 Responsibilities of all persons involved

All persons at the GMP+ certified company must have the responsibility to report potential and actual problem(s) with regards to the FSMS to assigned person(s)/roles.

6 Planning

6.1 The Objectives of the Feed Safety Management System and how to plan to achieve them

The GMP+ certified company must establish objectives for the FSMS at relevant functions and levels.

The objectives of the FSMS must:
a) be consistent with the feed safety policy;
b) be measurable;
c) take into account applicable legal and regulatory feed safety requirements as mentioned in Chapter 4;
d) be monitored and verified;
e) be communicated;
f) be maintained and updated as appropriate.

The certified company must keep documented information on the objectives for the FSMS.

Helpful tip:
When you first start to plan how to achieve the objectives for the FSMS at your company, it's a good idea to set out the following as part of your project plan:

- what needs be done?
- what resources will be required to achieve that?
- who will be responsible?
- when it will be completed?
- how the results will be evaluated?

6.2 Planning of changes

When the certified company determines that changes need to made relating to feed safety the certified company must consider:

a) the purpose of the changes and their potential consequences;
b) the continued integrity of the FSMS;
c) the availability of resources;
d) the allocation or re-allocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

The certified company must determine and provide the resources needed for setting up, implementing, maintaining, updating and continually improving the FSMS. The certified company must consider the:

a) capability of - and any constraints on - existing internal resources;
b) need for external resources.

Helpful tip:
By "resources" here we mean the people, infrastructure, work environment and other things which are required in order to set up a workable Feed Safety Management System.

7.1.2 People

The certified company must ensure that the persons who are given the responsibility to operate and maintain an effective FSMS are competent. This competence should be backed up with documented information as evidence.

If external experts are used to assist with the development, implementation, operation or assessment of the FSMS, evidence of agreements or contracts defining their competency, responsibility and authority must be documented and kept.

7.1.3 Infrastructure

The certified company must provide the resources for determining, establishing and maintaining the infrastructure necessary to achieve conformity with the requirements of the FSMS. Infrastructure can include:

a) facilities (such as production and storage areas, loading compartments);
b) equipment (including hardware and software);
c) information and communication technology.

Note: See TS 1.1 *Prerequisite programme, § 1.1 Infrastructure for more details.*

7.1.4 Work environment

The certified company must determine, provide and maintain the resources for establishing, managing and maintaining a work environment necessary to achieve conformity with the requirements of the FSMS.

Helpful tip:
Suitable work environment can be a combination of human and physical factors (consider, for example, factors like temperature, heat, humidity, light, air flow, hygiene, noise).

Note: See TS 1.1 *Prerequisite programme, § 1.2 Maintenance for more details.*

7.1.5 Management of suppliers

The certified company must:
a) establish and apply criteria for evaluating, selecting, monitoring of performance, and re-evaluation of external providers of processes, products and/or services which can have an impact on feed safety. These criteria must be based on a hazard analysis (see Chapter 8). At least the following requirements must be met. The certified company must purchase processes, products and/or services from the suppliers, which:
   1. GMP+ FSA certified or;
   2. certified for another accepted standard or;
   3. assured by the certified company via gatekeeper conditions. See TS 1.2 *Purchase* for specific requirements.
b) ensure adequate communication of requirements to external provider(s);
c) ensure that externally provided processes, products or services do not adversely affect the certified company's ability to consistently meet the requirements of the FSMS.

Feed materials that are produced or purchased must be included in TS 1.3 *Product list*. This does not apply to feed materials which are only processed in feed for non-food producing animals. Products that are not allowed to be used in feed are listed in TS 1.4 *Forbidden Products and Fuels*.

Keep documented information of these activities and any necessary actions as a result of evaluations and re-evaluations.

Helpful tip:
When we say "external providers", we mean all processes, products and services, which you buy from suppliers which are needed to help you produce and/or deliver GMP+ assured feed. This also includes providers of raw materials, veterinary medical products, cleaning agents, and outsourced services such as pest control and maintenance.

The guidance documents *Where does GMP+ FSA certification start* and *Guide for the supplier assessment* are very useful and provide more information.

7.2 Competence

The certified company must:

a) clearly describe how it organises its personnel in relation to FSMS;
b) determine the necessary competence of persons -- including external providers -- doing work under its control that affects feed safety performance and the effectiveness of the FSMS;
c) ensure that these persons -- including the Feed Safety Team and those responsible for the operation of the hazard control plan -- are competent by appropriate education, training, and/or experience;
d) ensure that the Feed Safety Team has multi-disciplinary knowledge and experience in developing and implementing the FSMS. This includes (but is not limited to) the organisation's products, processes, equipment and feed and food safety hazards within the scope of the FSMS;
e) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
f) keep appropriate documented information as evidence of this competence.

Helpful tip:
When we talk about "actions to acquire the necessary competence" think about your personnel who may have had relevant education, training, and coaching. If you do not have that knowledge in-house, consider hiring or contracting competent persons. One way to provide appropriate evidence of competence is to have up-to-date task descriptions.

7.3 Awareness

The certified company must ensure that all relevant people doing work under the certified company's control must be aware of:

a) the feed safety policy;
b) the objectives of the FSMS relevant to their task(s);
c) their individual contribution to the effectiveness of the FSMS, including the benefits of improved feed safety performance;
d) the implications of not conforming with the FSMS requirements.

7.4 Communication

7.4.1 General

The certified company must determine the internal and external communications relevant to the FSMS, including:

a) what it will communicate;
b) when to communicate;
c) who it will communicate to;
d) how to communicate;
e) who communicates.

The certified company must ensure that the requirement for effective communication is understood by all the persons whose activities have an impact on feed safety.

7.4.2 External communication

The certified company must ensure that sufficient information regarding feed safety is communicated externally. The certified company must establish, implement and maintain effective communications about feed safety with:

a) suppliers of products and services, contractors and customers in relation to:
    1) product information to enable the correct handling, display, storage, preparation, distribution and use of the product within the feed chain;
    2) the status of GMP+FSA feed and services. (See TS 1.8 *Labelling* for specific requirements);
    3) identified feed safety hazards that need to be controlled by other organisations in the feed chain;
    4) contractual arrangements, enquiries and orders including their amendments;
    5) feedback -- including complaints;
    6) not meeting / exceeding of standards or other irregularities/nonconformities (see § 8.4 Emergency preparedness and response).
b) statutory and regulatory authorities;
c) other organisations that have an impact on, or will be affected by, the effectiveness or updating of the FSMS.

You must keep evidence of any external communication on file as documented information.

Helpful tip:
It is perhaps helpful to be aware that the Certification Body of the certified company is *also* seen as a contractor.

Note: See TS 1.8 *Labelling for more details.*

7.4.3 Internal communication

The certified company must establish, implement and maintain effective arrangements for communicating on issues which might have an impact on feed safety.
To maintain the effectiveness of the FSMS, the certified company must ensure that the Feed Safety Team is informed on time of changes that can have an impact on feed safety.

The Feed Safety Team must ensure that this information is included when updating the FSMS (§ 4.4 and § 10.3).

Top management must ensure that relevant information is included as input to the management review (§ 9.3).

7.5 Documented information

7.5.1 General

The certified company's Feed Safety Management System must include:

a) documented information concerning the feed safety policy and feed safety objectives;
b) documented information required by the GMP+ standard;
c) documented information determined by the certified company as being necessary for the effectiveness of the FSMS;
d) all relevant documented information required by national and international legislation and customers;
e) documented information concerning the scope of the FSMS (Chapter 4).

Helpful tip:
The amount of documented information which certified companies include in an FSMS can differ from one organisation to another. This can be for a number of reasons, including:

- the size of organisation and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons;

7.5.2 Creating and Updating

When creating and updating documented information, the certified company must ensure appropriate:

a) identification (e.g. a title, date, author, or reference number);
b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
c) review, update and approval for suitability and adequacy of the information.

7.5.3 Control of documented information

Documented information required by the FSMS and by this GMP+ document must be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;
b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the certified company must take into account the following, where relevant:

c) distribution, access, retrieval and use;
d) storage and preservation, including preservation of legibility;
e) control of changes (e.g. version control);
f) retention and disposition. Documented information must be kept at least three years unless a longer storage period is required according to the applicable feed legislation or other regulations.

Documented information of external origin - determined by the certified company to be necessary for the planning and operation of the FSMS - must be identified, as appropriate, and controlled. Documented information retained as evidence of conformity must be protected from unintended alterations.

8 Operation

8.1 Operational Planning and Control

The GMP+ certified company must plan, implement, control, maintain and update the processes needed to meet requirements for the realisation of safe feed products by:

a) establishing criteria for the processes;
b) implementing control of the processes in accordance with the criteria;
c) keeping documented information to the extent necessary to be able to demonstrate that the processes have been carried out as planned.

The certified company must control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse influences.

The certified company must ensure that outsourced processes are controlled (see § 4.3).

8.2 Prerequisite programmes (PRPs)

The certified company must establish, implement, maintain and update Prerequisite Programmes (PRPs) to prevent and/or reduce the risk of contamination (including feed safety hazards) of the products, product processing and work environment.

The Prerequisite programmes (PRPs) must be:

a) appropriate to the organisation and its context with regard to feed safety;
b) appropriate to the size and type of the operation and the nature of the products being manufactured, stored and/or transported;
c) implemented across the entire organisation, either as a general programme or as programme applicable to a particular product or process;
d) approved by the Feed Safety Team.

When selecting and/or establishing Prerequisite programmes (PRPs), the certified company must ensure that applicable feed safety regulations and customer requirements are identified (see Chapter 4).

When establishing Prerequisite programmes (PRPs) the certified company must consider:
e) construction, layout of buildings and associated utilities;
f) layout of premises, including zoning, workspace and employee facilities;
g) supplies of air, water, energy and other utilities;
h) pest control, waste and sewage disposal and supporting services;
i) the suitability of equipment and its accessibility for cleaning and maintenance;
j) measures for the prevention of cross-contamination;
k) cleaning and disinfecting;

l) personal hygiene;
m) product information/consumer awareness;
n) other factors, as appropriate.

The Prerequisite programmes (PRPs) must at least be in accordance with TS 1.1 *Prerequisite programme*. The certified company is responsible to select the applicable requirements.

Documented information must specify the selection, establishment, applicable monitoring and verification of the Prerequisite programmes (PRPs).

8.3 Traceability system

All products that can have an impact on feed safety (GMP+ FSA assured or non-GMP+ FSA assured feed) must be traceable in all stages of production, processing and distribution. The traceability system must be able to uniquely identify incoming material from the suppliers and the first stage of the distribution route of the end product.

See TS 1.1 Prerequisite Programme, § 10 Traceability system for more details.

The required information must be available for GMP+ International and competent authorities within 4 hours unless the authorities determine a shorter timeframe.

Documented information as evidence of the traceability system must be retained for a defined period, as stated in § 7.5. The GMP+ certified company must verify the effectiveness of the traceability system.

If the certified company is the owner of the goods, samples must be taken from incoming and/or outgoing feed in accordance with TS 1.6 *Sampling*. A sample needs to be taken of the incoming and outgoing feed if it is sent out in a different form than it was received in. Samples must be kept available for the competent authority. The certified company can make written agreements with third parties on taking and storing of samples.

Helpful tip 1:
The document GMP+ D2.4 *Guideline for Traceability*, is very useful and provides more information about how to set up an internal traceability procedure.

Helpful tip 2:
The 4-hour period noted above means that as soon as the certified company receives the request to provide the required information -- it has a maximum of 4 (consecutive) hours to provide that information.

8.4 Emergency Preparedness and Response

8.4.1 General

Top management must ensure procedures are in place to respond to potential emergency situations or incidents that can have an impact on feed safety and are relevant to the role of the organisation in the feed chain.

Documented information must be established and maintained to manage these situations and incidents.

8.4.2 Handling of emergencies and Incidents

The certified company must:

a) respond to actual emergency situations and incidents by:
   1) ensuring applicable statutory and regulatory requirements are identified;
   2) communicating internally;
   3) communicating externally (e.g. suppliers, customers, appropriate authorities, media);
b) take action to reduce the consequences of the emergency situation, appropriate to the magnitude of the emergency or incident and the potential feed safety impact (see § 8.9.4);
c) review and, where necessary, update the documented information after the occurrence of any incident, emergency situation or tests.

Note: Examples of emergency situations that can affect feed safety and/or production are: natural disasters, accidents in the local environment, bioterrorism, workplace accidents, public health emergencies and other accidents such as the interruption of essential services like water, electricity or refrigeration.

8.5 Hazard control

8.5.1 Preliminary Steps to enable Hazard analysis

8.5.1.1 Characteristics of ingredients

The GMP+ certified company must maintain documented information concerning all feed materials, feed additives and processing aids as far as needed for identifying hazards and do a risk assessment (see § 8.5.2.2). The following information must be documented:

a) microbiological, chemical and physical characteristics;
b) composition of the feed ingredients, including additives and processing aids;
c) source (e.g. animal, mineral, vegetable, fermentation etc.);
d) place of origin (provenance);
e) method of production;

f) packaging; method of delivery;
g) storage conditions and shelf life;
h) preparation and/or handling before use or processing;
i) feed safety limits for feed ingredients, feed additives and processing aids (TS 1.5 *Specific feed safety limits*);
j) legal requirements (see § 4.1);
k) product name or similar identification.

8.5.1.2 Characteristics of end-products

The certified company must maintain documented information concerning the characteristics of end-products to the extent needed to conduct a risk assessment (see § 8.5.2.2). The following must be documented:

a) product name or similar identification;
b) composition of the feed: ingredients and auxiliary substances used (incl. feed additives and processing aids);
c) biological, chemical and physical characteristics;
d) storage conditions and shelf life;
e) packaging;
f) labelling relating to feed safety and/or instructions for handling, preparation and intended use;
g) method of distribution and delivery;
h) legal requirements (see § 4.1);
i) feed safety limits for feed (TS 1.5 *Specific feed safety limits*).

8.5.1.3 Intended use

The intended use must be considered and must be maintained as documented information to the extent needed to conduct a risk assessment (see § 8.5.2.2). The following must be documented:

a) intended use
b) preparation instructions;
c) instruction for feeding (if applicable: including withdrawal periods);
d) storage conditions and shelf life;
e) conditions regarding transport and conditions for the place of delivery;
f) shelf life;
g) legally required information on the packaging and/or in accompanying documents;
h) reasonably expected incorrect handling or misuse of the product

Helpful tip:
An example of such misuse is giving sheep feed products with a high copper content intended for goats and other livestock.

Sheep will be poisoned if they consume feed with a high copper content. This is one of the most common causes of sheep poisoning.

8.5.1.4 Flow diagrams and description of Processes

The Feed Safety Team must establish, maintain and update flow diagrams and a floor plan as documented information for each feed (group), feed ingredient (group).
When conducting a hazard analysis, flow diagrams must be used as a tool for identifying and assessing feed safety hazards.

Helpful tip:
You are permitted to create product groups. When you create product groups, you should combine products with the same characteristics, produced using similar processes. Be sure not to overlook the specific risks of individual products when creating groups.

8.5.1.4.1 Preparing flow diagrams

Flow diagrams must be clear, accurate and detailed enough to facilitate a hazard analysis.
Flow diagrams must, as appropriate, include the following:

a) representation of all the individual steps in the process sequence (from purchasing to delivery), customer returns and waste which may be produced during the process;
b) any outsourced processes;
c) where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;
d) where reworking and recycling take place;
e) where end-products, intermediate products, by-products and waste are produced.

8.5.1.4.2 Preparing a floor plan

When relevant the whole infrastructure of the company location must be shown in a floor plan, including;

a) the production units, storage areas and personnel facilities;
b) machines and equipment;
c) the routing of feed and raw material through the organisation in order to make any cross-contamination points visible.

8.5.1.4.3 On-site conformation of Flow diagrams and Floor plan

The Feed Safety Team must confirm on-site the accuracy of the flow diagrams and the floor plan, update the flow diagrams and floor plan where appropriate and keep as documented information.
The Feed Safety Team can delegate this action to the Validation Team or another representative with knowledge of the process(es) and the HACCP system.

8.5.2 Hazard analysis

8.5.2.1 Hazard identification

The Feed Safety Team must identify and document all feed safety hazards which may have a negative effect on the safety of the product, type of process and process environment.
The identification must be based on:

a) the preliminary information and data collected in accordance with the previous HACCP steps (§ 8.5.1);
b) experience;
c) internal and external information including, as much as possible, epidemiological, scientific and other historical data;
d) information from the feed chain on feed safety hazards related to the safety of the end-products, intermediate products and the feed and food at the time of consumption;
e) statutory and regulatory requirements.
f) the generic risk assessment from the Feed Support Products (FSP);
g) the fact sheets of undesirable substances and products from the Feed Support Products (FSP).

Hazards must be analysed in sufficient detail to enable risk assessment and the selection of appropriate control measures.

The Feed Safety Team must identify step(s) at which each feed safety hazard can be present, be introduced, increase or persist. Examples of such steps include: receiving raw materials, processing, distribution and delivery.

When identifying hazards, the following must be considered:

h) the stages before and after in the feed chain;
i) all steps in the flow diagram;
j) the process equipment, utilities/services, process environment and persons.

For each hazard, the Feed Safety Team also establishes and records a feed safety limit whereby there is at least compliance with the statutory feed safety limits and those laid down in TS 1.5 *Specific feed safety limits*.

8.5.2.2 Risk Assessment

For each identified feed safety hazard, the Feed Safety Team must conduct a risk assessment to determine whether preventing or reducing the hazard to an acceptable level is essential for the processing of safe feed.

The certified company must evaluate each feed safety hazard with regard to:
a) the likelihood of occurrence in the end-product prior to application of control measures;
b) the severity of its adverse health effects in relation to the intended use.

The methodology used must be described, and the result of the risk assessment must be kept as documented information.

Helpful tip:
The Guideline HACCP (GMP+ D2.1 *Guidelines HACCP GMP+)* provides a useful example methodology for risk assessment. Certified companies may use this or a different methodology to do the risk assessment.

8.5.2.3 Establishing Critical Control Points (CCPs)

Based on the risk assessment, the Feed Safety Team must select an appropriate control measure or combination of control measures that will prevent or reduce the identified significant feed safety hazards to within defined feed safety limits.

For each control measure, the Feed Safety Team must establish whether this control measure is the final measure in the process of controlling this hazard. If so, then this is called a Critical Control Point (CCP). The reasons for setting up a Critical Control Point (CCP) must be documented.

The decision-making process and results of the selection and categorization of the control measures must be kept as documented information.

Helpful tip:
Critical control points (CCPs) can also be set up with the help of a decision tree as explained in the Guideline HACCP (*Guidelines HACCP GMP+)*.

8.5.3 CCP control

8.5.3.1 Determine feed safety limits for CCPs

To determine whether a control measure works effectively, the Feed Safety Team will determine the following for each Critical Control Point (CCP):

a) which parameters must be measured, analysed or observed, and
b) which feed safety limits apply for these parameters.

When determining feed safety limits, the certified company must:

c) ensure that applicable statutory and regulatory requirements are identified;
d) ensure that applicable feed safety limits are identified as laid down in GMP+ FSA module (TS 1.5 *Specific feed safety limits*);
e) consider the intended use of end-products;
f) consider any other relevant information.

The reasoning behind why the certified company decided on specific Feed Safety Limits must be kept as documented information.

If there are no legal or GMP+ feed safety limits for a certain type of feed, certified companies are responsible for setting the feed safety limits in their HACCP study.
Research must be based on literature studies, information from the sector, etc.

If there is both a legal feed safety limit and a GMP+ feed safety limit for a certain type of feed, the most strict feed safety limit applies.

8.5.3.2 Monitoring CCPs

At each CCP, a monitoring plan must be set up for each control measure or combination of control measure(s) to detect any failure to remain within the feed safety limits. The system must include all scheduled measurements relative to the feed safety limits.

The monitoring plan must consist of documented information, including:

a) measurements or observations that provide results within an adequate time frame;
b) the methods of sampling;
c) the frequency of the sampling;
d) responsibility and authority related to sampling;
e) monitoring methods or equipment used;
f) calibration methods or equivalent methods for verification of reliable measurements or observations;

g) monitoring frequency;
h) monitoring results;
i) responsibility and authority related to monitoring;
j) responsibility and authority related to evaluation of monitoring results.

At each CCP, the monitoring method and frequency must be capable of detecting any failure to remain within feed safety limits as fast as possible, to allow quick isolation and evaluation of the product.

The certified company must ensure proper identification and storage of samples taken for monitoring during an appropriate time as stated in TS 1.6 *Sampling*. Retained samples must be kept available for the competent authority. The certified company can make written agreements with third parties on taking and storing of samples.

The monitoring plan must at least be in accordance with TS 1.7 *Monitoring*. The certified company must justify the structure of the monitoring plan.

The monitoring methods must be suitable to achieve planned results. If measurement and monitoring take
s place by the way of an analysis, this must be carried out by an approved laboratory. See TS 1.2 *Purchase*.

8.6 Validation & Verification

8.6.1 Validation

The Validation Team (see § 5.3.3) must validate the HACCP plan prior to its implementation and after any change are made. The purpose of validation is to ensure that the hazards which were established by the Feed Safety Team are complete and correct and that they are be effectively controlled using the proposed control measures, the monitoring plan and the corrective actions.

When the result of validation shows that the control measures(s) is (are) not capable of achieving the intended control, the Feed Safety Team must modify and re-assess the control measure(s) and/or combination(s) of control measure(s).

The Validation Team must keep the validation methodology -- and the evidence of capability of the control measure(s) to achieve the intended control -- as documented information.

Helpful tip:
It's useful to remember that "modifications" can also mean changes in control measures and/or changes in the manufacturing technologies for raw materials, end-product characteristics, methods of distribution and the intended use of the end-products.

8.6.2 Verification

8.6.2.1 Verification of the HACCP plan

The certified company must establish, implement and maintain verification activities. The verification planning must define the purpose, methods, frequencies and responsibilities for these verification activities.

Verification is carried out by the Feed Safety Team.

The verification activities must confirm that:
a) the hazard control plan is implemented and effective;
b) hazard levels are within identified acceptable levels;
c) input to the hazard analysis is updated;
d) other actions determined by the organisation are implemented and effective.

8.6.2.2 Analysing the results of Verification activities

If samples show nonconformity with the acceptable feed safety limit (see TS6 *Specific feed safety limits*) -- when verification is based on analysing of end-product samples or direct process samples -- the certified company must handle the affected batch(es) of feed as potentially unsafe and apply the corrective actions in accordance with § 8.7.1.

The Feed Safety Team must (at least once a year) conduct an analysis of the results of verification that must be used as an input to the performance evaluation of the Feed Safety Management System (see § 9.3).

8.7 Control of Product and Process nonconformities

8.7.1 Define corrections and Corrective actions

If feed safety limits are not met (nonconformities occur) the Feed Safety Team must specify corrections and corrective actions to be taken and must ensure that action is taken to remove the observed nonconformity that ensures:

a) the potentially unsafe products are not released;
b) the cause of the nonconformity is identified;
c) the parameter(s) controlled at the CCP is (are) returned within the feed safety limits;
d) recurrence is prevented (verification of corrective action).

The Feed Safety Team must make corrections in accordance with § 10.1. See also § 8.7.2. regarding (potentially) unsafe products.

8.7.2 Handling of potentially unsafe products

8.7.2.1 General

The certified company must take action(s) to prevent potentially unsafe products from entering the feed and/or food chain, unless the certified company can demonstrate that the specific feed safety hazard(s) is (are) reduced to defined feed safety limits § 8.5.3.1.

8.7.2.2 Evaluation of potentially unsafe products

Each lot of products affected by the nonconformity must be evaluated, to determine if the products are safe or unsafe. Products must be considered as unsafe if;

a) the feed safety limit(s) of undesirable substances in feed are exceeded, as mentioned in legislation or/and TS 1.5 *Specific feed safety limits*,
b) the certified company has determined that the nonconformity or irregularity related to feed safety aspects are not controlled and can have consequences for other companies, even if there is no legislation and/or under TS 1.5 *Specific feed safety limits*.

Products that are under the control of the certified company and that have been determined as unsafe must be handled in accordance with § 8.7.1.

The controls, evaluation for release of products, and related responses from relevant interested parties and authorisation for dealing with potentially unsafe products must be kept as documented information.

If a product is determined unsafe, the certified company must notify relevant interested parties. If products have left the control of the certified company, the certified company must also notify relevant customers and initiate a withdrawal/recall (see 8.7.2.4).

If the certified company is the owner of the goods, the certified company must then also notify GMP+ International and the Certification Body within 12 hours of detection or confirmation. GMP+ International must be notified via the EWS notification form which is available on the GMP+ International website.

The certified company must establish and maintain documented information for notifying GMP+ International, the Certification Body and other relevant interested parties.

Note: Interested parties can, for example, be statutory and regulatory authorities, customers and/or suppliers. If the certified company assesses the situation as being under control, the 12-hour notification deadline may be extended.

8.7.2.3 Disposition of nonconforming products

Products that are not acceptable for release must be:

a) reprocessed or further processed within or outside the organisation to ensure that the feed safety hazard is reduced to within feed safety limits; or
b) redirected for other use as long as feed safety is not affected; or
c) destroyed and/or disposed as waste.

Documented information on the disposition of nonconforming products, including the identification of the person(s) with approving authority must be kept.

8.7.2.4 Withdrawal / Recall

The certified company must have a documented procedure that demonstrates that the certified company is able to ensure the timely withdrawal/recall of products that have been identified as unsafe
(§ 8.7.2.2).

The certified company must establish and maintain documented information for:

a) notifying to relevant interested parties;
b) handling withdrawn/recalled products;
c) performing the sequence of actions to be taken.

Withdrawn/recalled products must be secured or held under the control of the certified company until they are managed in accordance with § 8.7.2.3.

The cause, extent and result of a withdrawal/recall must be kept as documented information and reported to top management as input for the management review (see § 9.3).

The certified company must verify the implementation and effectiveness of withdrawals/recalls procedure and keep documented information at least once a year.

For more information see GMP+D2.3 *Guidelines recall*.

9 Performance evaluation of Feed Safety Management System

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

The certified company must evaluate the performance and effectiveness of the Feed Safety Management System. This includes taking into account:

a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;
c) when the monitoring and measuring must be performed;
d) when the results from monitoring and measurement must be analysed and evaluated;
e) who must analyse and evaluate the results from monitoring and measurement;

The certified company must keep appropriate documented information as evidence of the results.

9.1.2 Analysis and Evaluation

The certified company must analyse and evaluate appropriate data and information arising from monitoring and measurement. This must at least include the results of verification activities related to PRPs and the hazard control plan (§ 8.6.2), as well as internal audits (§ 9.2) and external audits.

The analysis must be carried out in order to:

a) confirm that the overall performance of the system meets the planned arrangements, and that the FSMS is effective and performs according to the FSMS requirements as established by the certified company;
b) identify the need for updating or improving the FSMS;
c) identify trends which indicate a higher incidence of potentially unsafe products or process failures;
d) collect information for planning the internal audit programme (concerning the status and importance of the areas which are to be audited);
e) provide evidence that any corrections and corrective actions are effective.

The results of the analysis and any resulting activities must be kept as documented information and must be reported to top management and used as input for the management review (§ 9.3) and updating the FSMS (§ 10.3).

Note: Methods to analyse data can include statistical techniques.

9.2 Internal audit

The certified company must conduct internal audits at planned intervals to provide information on whether the FSMS:

a) conforms to:
   1) the certified company's own requirements for its FSMS;
   2) the requirements of this GMP+ standard;
b) is effectively implemented and maintained.

The certified company must:

c) plan, establish, implement and maintain an audit program(s) including:

   1) scope and audit criteria;
   2) a frequency of at least once a year;
   3) methods;
   4) responsibilities;
   5) planning requirements and reporting.

d) during the development of the audit program(s) take into consideration:

   1) the importance of the processes concerned;
   2) changes in the FSMS;
   3) the results of monitoring, measurement and previous audits;
   4) the selection of competent auditors who conduct audits which ensure objectivity and the impartiality of the audit process;
   5) that the results of the audits must be reported to the Feed Safety Team and relevant management;
   6) that documented information is kept as evidence of the implementation of the audit program and the audit results;
   7) that necessary correction and corrective action must be taken within a determined time frame;
   8) whether the FSMS meets the intent of the feed safety policy (§ 5.2), and objectives of the FSMS (§ 6.1).

Follow-up activities by the certified company must include the verification of the actions taken and reporting the verification results. For more information the audit checklist of GMP+ International can be used during the internal audit (www.gmpplus.org).

9.3 Management review

9.3.1 General

Top management must review the certified company's FSMS at planned intervals of at least once a year to ensure its continuing suitability, adequacy and effectiveness.

9.3.2 Management review input

The management review must include consideration of:
a) the status of actions from previous management reviews;
b) changes in the organisation relevant to the FSMS;
c) information on the performance and the effectiveness of the FSMS, including trends in:
    1) the compliance with legislation and regulations (§ 4.1);
    2) the results of system updating activities (§ 4.4 and § 10.3);
    3) monitoring and measurement results;
    4) analysis of the results of verification activities related to PRPs and the hazard control plan (Chapter 8);
    5) nonconformities and corrective actions;
    6) audit results (internal and external);
    7) inspections (e.g. regulatory, customer);
    8) performance of external suppliers;
    9) the extent to which objectives of the FSMS have been met.
d) the adequacy of resources (e.g. personnel, equipment);
e) any emergency situation, early warnings, incident (§ 8.4.2) or withdrawal/recall (§ 8.7.2.4) that occurred;
f) relevant information obtained through external (§ 7.4.2) and internal (§ 7.4.3) communication, including requests and complaints related to feed safety from interested parties (e.g. customers and suppliers);
g) opportunities for continual improvement.

9.3.3 Management review output

The outputs of the management review must include:
a) decisions and actions related to continual improvement opportunities;
b) any need for updates and changes to the FSMS, including resource needs and revision of the feed safety policy and objectives of the FSMS.

The certified company must keep documented information as evidence of the results of management reviews.

10 Improvement

10.1 Nonconformity and Corrective action

When a nonconformity occurs, the certified company must immediately:

a) react to the nonconformity and, as applicable:
   1) take action to control and correct it;
   2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity -- once the nonconformity is under control -- in order that it does not recur or occur elsewhere, by:
   1) reviewing the nonconformity;
   2) determining the causes of the nonconformity;
   3) determining if similar nonconformities exist, or could potentially occur;
c) implement any action needed;
d) review the effectiveness of any corrective action taken;
e) make changes to the FSMS, if necessary.

Corrective actions must be appropriate to the effects of the nonconformities encountered.

The certified company must keep documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;
b) the results of any corrective action.

10.2 Continual improvement

The certified company must continually improve the suitability, adequacy and effectiveness of the FSMS.

Top management must ensure that the organisation continually improves the effectiveness of the FSMS through the use of at least:

a) feed safety policy and objectives (Chapter 4);
b) communication (§ 7.4);
c) management reviews (§ 9.3);
d) audit results (internal and external) (§ 9.2);
e) analysis of results of verification activities (§ 8.6.2);
f) validation of control measure(s) and combination(s) of control measure(s) (§ 8.6.1);
g) corrective actions (§ 8.7.1) and
h) FSMS updating (§ 10.3).

10.3 Update of the Feed Safety Management System

Top management must ensure that the FSMS is continually updated. To achieve this, the Feed Safety Team must evaluate the FSMS at planned intervals. The Feed Safety Team must consider whether it is necessary to review the hazard analysis (§ 8.5.2), the established hazard control plan (§ 8.5.3) and the established Prerequisite Programmes PRPS (§ 8.2). The updating activities must be based on:

a) input from communication, external as well as internal (§ 7.4);
b) input from other information concerning the suitability, adequacy and effectiveness of the FSMS;
c) output from the analysis of results of verification activities (§ 9.1.2);
d) output from management review (§ 9.3).

System updating activities must be kept as documented information and reported as input to the management review (§ 9.3).

Annex 1: Cross reference between FSMR and FSA standards B1, B2, B3 and B4

In progress

This Annex will become eventually a separate guidance.

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