R1.0 - Feed Safety Management Systems Requirements

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GMP+ International

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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

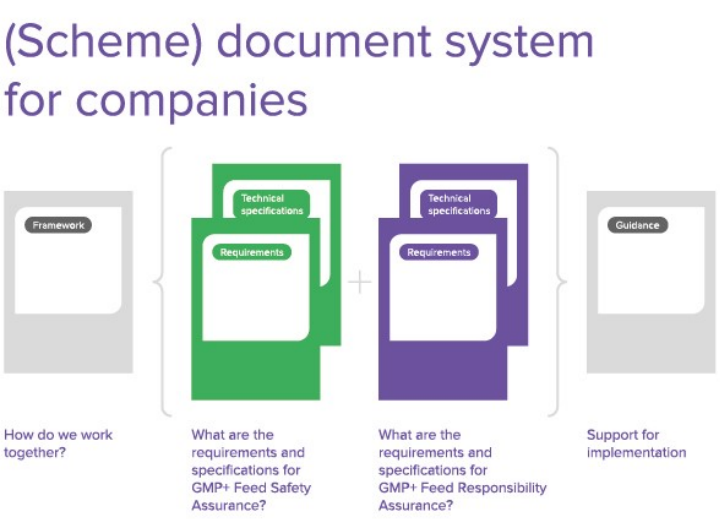
This document enables a company to achieve its feed safety objectives. It specifies requirements for a Feed Safety Management System (FSMS) which enables a company to provide safe feed products and feed services.

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.

When creating this standard use has been made of the ISO22000:2018 *Food safety management systems — Requirements for any organization in the food chain*, which specifies requirements and conditions for a food safety management system. To a certain extent, the same requirements and conditions also apply to a management system which feed companies can implement to ensure the safety of feed. The use of ISO22000 is expressed in the same structure, and for a number of requirements and conditions in the same wording and formulation of requirements and conditions. In this way, combining both standards is relatively easy.

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.


(Scheme) document system for companies
Framework
Technical specifications
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Technical specifications
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How do we work together?
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2. Normative references

Some of the requirements contained in this document (the Feed Safety Management Systems Requirements) refer to the GMP+ Technical Specifications (TS). These Technical Specifications explain in more detail a specific element of the Feed Safety Management Systems 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 Systems 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 the 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;~~
~~the needs of the relevant interested parties for the FSMS.~~

The certified company must safeguard that the delivered products and services comply with the applicable requirements of the GMP+ FC scheme and the needs from the relevant interested parties.

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

c) which of the activities, processes, products or services on those locations are subject to GMP+ certification;

   It is possible to exclude activities, processes, products or services related to the production, trade, storage and transport of feed from the scope of GMP+ certification.

d) other (feed and non-feed related) activities, processes, products or services as defined under c) 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. *See for more details TS 1.10 Operational Activities § 1.10 Separation.*

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 documented and updated.~~The scope must be available and updated as documented information.~~

Helpful tip:
This is complex matter. A great place to start reading about the scope of activities concerning GMP+ certification is the document: "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 individual 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. Commitment of the top managementLeadership and Commitment

The top management of a GMP+ certified company must safeguard that:Top management of a GMP+ certified company must demonstrate leadership and commitment with respect to the Feed Safety Management System (FSMS) by:

a) the feed safety policy and the objectives of the FSMS are recorded;ensuring that the feed safety policy and objectives of the FSMS are established;
b) the FSMS requirements are integrated with the company's processes;ensuring that FSMS requirements are integrated into the organisation's business processes;
c) resources are available to comply with the FSMS and to ensure its continuous improvement;ensuring that the resources are made available for compliance with FSMS;
d) the compliance with the FSMS and customer requirements are evaluated, maintained and communicated;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) persons are instructed and supported to take their responsibility to an effective FSMS.ensuring that the FSMS is evaluated and maintained to achieve its intended result(s);
directing and supporting persons to contribute to the effectiveness of the FSMS;
promoting continual improvement;
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. Feed safety policy contentEstablishment feed safety policy

The feed safety policy implemented and maintained by the top management must:Top management must establish, implement and maintain a feed safety policy that:

a) eensure the compliance with the relevant GMP+ documents, applicable (feed) legislation and customer requirementsnsures commitment to the requirements of this GMP+ FSA module;
b) fit the context and objective of the organisation;is appropriate to the purpose and context of the organisation;
c) include a structure to define and evaluate the objectives of the FSMS, as described in Chapter 6;provides a framework for setting and reviewing the objectives of the FSMS, as described in Chapter 6;
d) include the internal and external communications applicable to the FSMS;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) include the commitment to the continuous improvement of the FSMS and the necessary feed safety knowledge.~~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 be:

a) kept as documented information;~~be available and updated as documented information;~~
b) communicated and applied within the GMP+ certified company;~~be communicated, understood, and applied at all levels of the organisation;~~
c) available to interested parties.~~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 secure the responsibilities and authorities for the relevant roles are defined, communicated and understood within the company. ~~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~~ establish responsibilities and authority for:

a) safeguarding that the FSMS complies with the GMP+ requirements;~~ensuring that the FSMS conforms to the requirements as described in this document;~~
b) establishing 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;~~reporting on the performance and any need for improvement of the FSMS to Top management;~~
c) establishing the Validation Team(s) and the Validation Team leader(s).
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. If there is more than one Validation Team, a coordinator must be assigned;~~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;~~
~~c)~~d) nominating persons to start and document action(s).~~appointing the Validation Team(s) and the Validation Team leader(s). If there is more than one Validation Team, a coordinator must be assigned;~~
~~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~~ accountable for:

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

The Validation Team must clearly document the persons involved on the team and the activities which they carry out.~~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

Everybody within the GMP+ certified company must notify potential and actual issue(s) regarding the FSMS to the management.~~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. FSMS Objectives~~The Objectives of the FSMS and how to achieve them~~

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

The objectives of the FSMS must be:

a) in line with the feed safety policy and the applicable legal requirements as mentioned in Chapter 4;~~be consistent with the feed safety policy;~~
b) quantifiable;~~be measurable;~~
c) monitored and verified~~take into account applicable legal and regulatory feed safety requirements as mentioned in Chapter 4~~;
d) notified~~be monitored and verified~~;
e) maintained and revised as appropriate~~be communicated~~;
f) kept as documented information.~~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:

- the activities to be done;
- the resources needed;
- the responsible persons;
- the timeframe to achieve;
- the assessment of the results.
- ~~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. Changes on the FSMS~~Planning of changes~~

The certified company must take into consideration when changes are required on the FSMS:~~When the certified company determines that changes need to made relating to feed safety the certified company must consider:~~

a) the objective of the changes and their potential impacts;~~the purpose of the changes and their potential consequences;~~
b) the continued integrity of the FSMS;
c) the resources needed;~~the availability of resources;~~

d) the assigned roles and authorities.~~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 take into account the:~~The certified company must consider the:~~

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

Helpful tip:
By "resources" here ~~we~~ it is meant ~~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 personnel responsible for operating and maintaining an effective FSMS are competent. This competence must be kept as documented information.~~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.~~

When external personnel is hired to perform activities related to the FSMS, the certified company must keep documented information about the agreements or contracts that define their competency, responsibility and authority.~~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 to determine and maintain the infrastructure necessary to fulfil the requirements of the FSMS. ~~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 for more details TS 1.1 Prerequisite Programme, Chapter1 Infrastructure.

7.1.4. Work environment

The certified company must provide resources for a work environment necessary to comply with the requirements of the FSMS.~~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 is influenced by human and physical elements, for example, hygiene, temperature, humidity, natural light, air conditions and noise~~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 for more details TS 1.1 Prerequisite Programme, Chapter 2 Maintenance.

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 supplier(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*.

The certified company must keep documented information of the supplier assessment and any necessary actions related to it.~~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 support documents S 9.3 *Explanation of GMP+ feed chain* and S 9.7 *How to execute supplier assessments* are very useful and provide more information.

7.2. Competence

To ensure the feed safety and the effectiveness of the FSMS, the certified company must:~~The certified company must:~~

a) clearly describe how it organises its personnel~~ in relation to FSMS~~;
b) determine the needed competence of the personnel - own and external;~~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 all personnel are competent by education, training, and/or experience;~~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 expertise and experience in implementing the FSMS. This includes (but is not limited to) the company's products, processes, equipment and feed safety hazards within the scope of the FSMS;~~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, obtain the necessary competence, and assess the effectiveness of the actions taken;~~where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;~~
f) keep the evidence of competence as documented information.~~keep appropriate documented information as evidence of 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.

7.3. Awareness

The certified company must ensure that personnel – own and external - related to the FSMS must be aware of:~~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 activities~~task(s)~~;
c) their influence on the effectiveness of the FSMS;~~their individual contribution to the effectiveness of the FSMS, including the benefits of improved feed safety performance~~;

d) the consequences of not complying with the FSMS requirements.~~the implications of not conforming with the FSMS requirements.~~

7.4. Communication

7.4.1. General

When determining the internal and external communications relevant to the FSMS, the certified company must specify the information to be communicated, the timeframe of communication, the responsible persons, the communication methodology and the receiver of the communication.~~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 personnel - own and external - related to the FSMS comprehends the need of effective communication.~~he certified company must ensure that the requirement of 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 keep effective communications about feed safety with:~~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 and customers about:~~suppliers of products and services, contractors and customers in relation to:~~
   1) product information to enable the proper handling, storage, distribution and use of the product within the feed chain;~~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 on the products/ services that have to be controlled by other companies in the feed chain;~~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) relevant legal competent authorities;~~statutory and regulatory authorities;~~

c) other organisations that are relevant to the FSMS.~~other organisations that have an impact on, or will be affected by, the effectiveness or updating of the FSMS.~~

The certified company must keep any external communication relevant to the FSMS as documented information.~~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.

7.4.3. Internal communication

The certified company must implement an effective communication system to inform about feed safety issues within the organization, particularly to the Feed Safety Team.~~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 include the relevant information when updating the FSMS (§ 4.4 and § 10.3).~~The Feed Safety Team must ensure that this information is included when updating the FSMS (§ 4.4 and § 10.3).~~

Top management must include the relevant information as input to the management review (§ 9.3).~~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 must include the documented information in the FSMS, concerning the:~~The certified company's Feed Safety Management System must include:~~

a) feed safety policy and feed safety objectives;~~documented information concerning the feed safety policy and feed safety objectives;~~
b) requirements by the GMP+ scheme;~~documented information required by the GMP+ standard;~~
c) measurement for the effectiveness of the FSMS;~~documented information determined by the certified company as being necessary for the effectiveness of the FSMS;~~
d) required information by national and international legislation and customers;~~all relevant documented information required by national and international legislation and customers;~~

e) scope of the FSMS (Chapter 4).~~documented information concerning the scope of the FSMS (Chapter 4).~~

Helpful tip:
Several factors can impact the quantity of documented information in the FSMS kept by certified companies, for example:
- the size of company
- type and complexity of activities, processes, products and services;
- the competence of personnel.

~~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

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

a) be identified (e.g. a title, date, author, or reference number);~~identification (e.g. a title, date, author, or reference number);~~
b) have an appropriate format (e.g. language, software version, graphics) and media (e.g. paper, electronic);~~format (e.g. language, software version, graphics) and media (e.g. paper, electronic);~~
c) have suitable and adequate information.~~review and approval for suitability and adequacy of the information.~~

7.5.3. Control of documented information

The certified company must have the documented information required by the FSMS available, suitable for use and protected (e.g. from loss of confidentiality, improper use, or loss of integrity).~~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 address the following, as applicable:

~~c)~~a) distribution, access, retrieval and use;
~~d)~~b) storage and preservation, including preservation of legibility;
~~e)~~c) control of changes (e.g. version control);

~~f)~~d) 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 used for the planning and operation of the FSMS – must be identified and controlled.~~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 demonstrate that the processes have been carried out as planned.~~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 unintentional changes, mitigating any negative effects.~~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 certified company must establish Prerequisite programmes (PRPs) that are:~~The Prerequisite programmes (PRPs) must be:~~

a) suitable to the organisation and its context concerning feed safety;~~appropriate to the organisation and its context with regard to feed safety;~~
b) suitable to the size and type of the operation and the nature of the products being produced, stored and/or transported;~~appropriate to the size and type of the operation and the nature of the products being produced, stored and/or transported;~~
c) implemented within the organisation according to the FSMS scope;~~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.
~~d)~~e) complying with applicable feed safety regulations and customer needs (see Chapter 4).

~~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).~~

The certified company must take into account the following items when establishing Prerequisite programmes (PRPs):~~When establishing Prerequisite programmes (PRPs) the certified company must consider:~~

~~e)~~f) structure, layout of buildings including employee facilities;~~construction, layout of buildings and associated utilities;~~
~~f)~~g) supplies of air, water, energy and other utilities;~~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) equipment suitability and its cleaning and maintenance;~~the suitability of equipment and its accessibility for cleaning and maintenance;~~
j) cross-contamination prevention;~~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.

The certified company must have documented information regarding the implementation, monitoring and verification of the Prerequisite programmes (PRPs).~~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 identify incoming material from the suppliers to delivery of the end product.~~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 for more details TS 1.1 Prerequisite Programme, Chapter 10 Traceability system.

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 support document S 9.8 *How to develop traceability systems* document, 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. Incident management~~Emergency Preparedness and Response~~

8.4.1. General

Top management must ensure procedures to respond to potential incidents that can have an impact on feed safety or to the role of the certified company in the feed chain.~~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.~~

The certified company must keep documented information to manage these incidents.~~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 incidents by~~respond to actual emergency situations and incidents by~~:
   1) identifying the applicable legal requirements;~~ensuring applicable statutory and regulatory requirements are identified;~~
   2) communicating within the company;~~communicating internally;~~
   3) communicating to interested parties (e.g. suppliers, customers, relevant authorities, media);~~communicating externally (e.g. suppliers, customers, appropriate authorities, media);~~
b) mitigate the consequences of the incident (see § 8.9.4);~~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~~incidents related to feed safety are:~~that can affect feed safety and/or production are~~ natural catastrophes, workplace accidents, public health emergencies and disruption of essential services like water, electricity or refrigeration.~~: 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. Preparation for hazard analysis~~Preliminary steps to enable hazard analysis~~

8.5.1.1. Description of ingredients~~Characteristics of ingredients~~

The GMP+ certified company must keep documented information up-to-date about 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:~~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~~ origin (e.g. animal, mineral, vegetable, fermentation etc.);
d) place of origin (provenance);
e) ~~method of~~ production method;
f) packaging;
~~f)~~g) method of delivery;
~~g)~~h) storage conditions and shelf life;
~~h)~~i) preparation and/or handling before use or processing;
~~i)~~j) feed safety limits for feed ingredients, feed additives and processing aids (TS 1.5 *Specific Feed Safety Limits*);
~~j)~~k) legal requirements (see § 4.1);
~~k)~~l) product name or similar identification.

8.5.1.2. Description of end-products~~Characteristics of end-products~~

The certified company must keep documented information up-to-date about the end-products to the extent needed to conduct a risk assessment (see § 8.5.2.2). The following must be documented:~~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;
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 detailed enough to conduct a hazard analysis. Flow diagrams must include:~~Flow diagrams must be clear, accurate and detailed enough to conduct 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, rework recycling and waste which may be produced during the process;~~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)~~d) where end-products, intermediate products~~,~~ and 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. ***Validation of the Flow diagrams and Floor Plan*** ~~***On-site conformation of Flow diagrams and Floor Plan***~~

The Feed Safety Team must validate on-site the accuracy of the flow diagrams and the floor plan, update where appropriate and keep as documented information.~~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 information and data collected in the previous HACCP steps (§ 8.5.1);~~the preliminary information and data collected in accordance with the previous HACCP steps (§ 8.5.1);~~
b) experience;
c) relevant internal and external information including epidemiological, scientific and other historical data;~~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) legal requirements;~~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 which hazard can be present, be introduced, increased or remain at each process step.~~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.~~

The certified company must identify the hazards of:~~When identifying hazards, the following must be considered:~~
h) the links before and after in the feed chain;~~the stages before and after in the feed chain;~~
i) all steps in the flow diagram;
~~j)~~ the process equipment, infrastructure~~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

The Feed Safety Team must conduct a risk assessment for each identified feed safety hazard, to determine whether preventing or reducing the hazard to an acceptable level is critical for the processing of safe feed.~~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 determine for each feed safety hazard:~~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 feed safety effects.~~adverse health effects in relation to the intended use~~.

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

Helpful tip:
The support document S 9.4 *Applying HACCP assessment* document, 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)

The Feed Safety Team must determine appropriate control measure(s) that will prevent or reduce the feed safety hazards within defined feed safety limits.~~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 outcome of the determination of the control measures 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 S 9.4 *Applying HACCP assessment* document.

8.5.3. CCP control

8.5.3.1. ~~Determine~~ Determination of feed safety limits for CCPs

To determine whether a control measure works effectively, the Feed Safety Team must 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

A monitoring plan must be established for each control measure at each CCP to identify any failure to remain within the feed safety limits. The monitoring plan must include all analyses relative to the feed safety limits.~~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) analyses or observations that deliver results within an adequate time frame;~~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~~ analysis 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.

The monitoring method and frequency at each CCP must be capable of detecting as fast as possible any failure to comply with the feed safety limits.~~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 takes 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.

The Feed Safety Team must modify and re-assess the control measure(s) and/or combination(s) of control measure(s) when they are not capable of preventing or reducing the feed safety risk.~~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 as documented information the validation methodology and the evidence that the control measure(s) are effective to prevent or reduce the feed safety risk(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~~modify" can also mean changes in control measures and/or changes in the production technologies for raw materials, end-product ~~characteristics~~descriptions, 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 implement and maintain verification activities. The verification preparation must define the objective, methods, frequencies and responsibilities.~~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.~~

The v~~V~~erification ~~is~~ must be carried out by the Feed Safety Team and ~~.~~

must demonstrate that:~~The verification activities must confirm that:~~

a) the HACCP plan is effective and up-to-date;~~the hazard control plan is implemented and effective;~~
b) hazard levels are within identified acceptable levels;
c) c) other actions regarding the HACCP plan are implemented and effective.~~input to the hazard analysis is updated;~~
~~other actions determined by the organisation are implemented and effective.~~

8.6.2.2. Analysing the results of verification activities

The certified company must implement the corrective actions in accordance with § 8.7.1 if samples of the end-products or direct process samples are not complying with the acceptable feed safety limits (see TS 1.5 Specific feed safety limits).~~If samples show nonconformity with the acceptable feed safety limit (see TS 1.5 *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 analyse the verification results at least once per year and use this as input for the Management review (see § 9.3).~~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 non-conform products and processes~~Control of Product and Process nonconformities~~

8.7.1. Corrections and Corrective actions~~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

The certified company must evaluate each nonconform batch of products to determine if the products are safe or unsafe. Products must be considered as unsafe if:~~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. Non-conform products disposal~~Disposition of nonconforming products~~

The certified company must handle the nonconform products according to one of the following options:~~Products that are not acceptable for release must be:~~

a) reprocessing or further processing to secure that the products comply with the relevant feed safety limits; or~~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) destining to another use different than feed; or~~redirected for other use as long as feed safety is not affected; or~~
c) destroying and/or disposing as waste.~~destroyed and/or disposed as waste.~~

The certified company must keep documented information on the destruction / disposition of non-conform products, including the approval of the authorizing person(s).~~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 to withdraw/recall unsafe products as quick as possible (§ 8.7.2.2). ~~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 keep documented information about:~~The certified company must establish and maintain documented information for:~~

a) the notification of relevant interested parties;~~notifying to relevant interested parties;~~
b) the handling of withdrawn/recalled products;~~handling withdrawn/recalled products;~~
c) the actions taken.~~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~~according to § 8.7.2.3.

The certified company must keep documented information regarding the cause, size and the result of a withdrawal/recall must be used as input for the management review (see § 9.3).~~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 withdrawals/recalls procedure at least once a year and keep documented information about it.~~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 the support document S 9.9 *Executing a successful recall.*

9. Assessment of the FSMS performance~~Performance evaluation of the FSMS~~

9.1. Monitoring, Measurement, Analysis and Assessment~~Evaluation~~

9.1.1. General

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

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 Assessment~~Evaluation~~

The certified company must analyse and assess monitoring and analyses results, including at least 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 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 assessment must:~~The analysis must be carried out in order to:~~

a) demonstrate that the performance of the FSMS is according to the requirements established by the certified company;~~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) establish the necessity of updating or improving the FSMS;~~identify the need for updating or improving the FSMS;~~
c) identify the tendency of potentially unsafe products or process failures;~~identify trends which indicate a higher incidence of potentially unsafe products or process failures;~~
d) gather information for planning the internal audit programme;~~collect information for planning the internal audit programme (concerning the status and importance of the areas which are to be audited);~~
e) demonstrate that corrections and corrective actions are effective.~~provide evidence that corrections and corrective actions are effective.~~

The certified company must keep as documented information the results of the analysis and any resulting activities and must use it as input for the management review (§ 9.3) and updating the FSMS (§ 10.3).~~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: Statistical techniques can be used as methods to analyse data.~~*Note: Methods to analyse data can include statistical techniques.*~~

9.2. Internal audit

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

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

The certified company must:

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

   1) scope and audit criteria;
   2) an audit frequency of at least once per year;~~a frequency of at least once per 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 monitoring results and previous audits;~~the results of monitoring, measurement and previous audits;~~
   4) the selection of competent auditors to secure the objectivity and the impartiality of the audit process;~~the selection of competent auditors who conduct audits which ensure objectivity and the impartiality of the audit process;~~
   5) that audits results are reported to the Feed Safety Team and relevant management;~~that the results of the audits must be reported to the Feed Safety Team and relevant management;~~
   6) to keep documented information of the audit program and the audit results;~~that documented information is kept as evidence of the implementation of the audit program and the audit results;~~
   7) that corrections and corrective actions are taken within a defined deadline;~~that necessary correction and corrective action must be taken within a determined time frame;~~
   8) that the FSMS meets the intent of the feed safety policy (§ 5.2), and objectives of the FSMS (§ 6.1).~~whether the FSMS meets the intent of the feed safety policy (§ 5.2), and objectives of the FSMS (§ 6.1).~~

The certified company must verify the actions taken and report the verification results.~~Follow-up activities by the certified company must include the verification of the actions taken~~

~~and reporting the verification results.~~

9.3. Management review

9.3.1. General

The minimum frequency of the management review of the FSMS done by the top management is at least once per year to keep the FSMS suitable, adequate and effective.~~Top management must review the certified company's FSMS at planned intervals of at least once per year to ensure its continuing suitability, adequacy and effectiveness.~~

9.3.2. Management review input

The management review must include ~~consideration of~~:

a) the progress of actions from previous management reviews;~~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~~regarding:
   1) the compliance with legislation and regulations (§ 4.1);
   2) the FSMS updates (§ 4.4 and § 10.3);~~the results of system updating activities (§ 4.4 and § 10.3);~~
   3) monitoring and ~~measurement~~ analysis results;
   4) results of verification activities related to PRPs and the HACCP Plan (Chapter 8);~~analysis of the results of verification activities related to PRPs and the hazard control plan (Chapter 8);~~
   5) nonconformities and corrective actions;
   6) results of internal and external audits;~~audit results (internal and external);~~
   7) inspections (e.g. legal, customer);~~(e.g. regulatory, customer);~~
   8) performance of external suppliers;
   9) achievement of the objectives of the FSMS.~~the extent to which objectives of the FSMS have been met.~~
d) the suitability of resources (e.g. personnel, equipment);~~the adequacy of resources (e.g. personnel, equipment);~~
e) occurrence of any early warnings, incident (§ 8.4.2) or withdrawal/recall (§ 8.7.2.4);~~any emergency situation, early warnings, incident (§ 8.4.2) or withdrawal/recall (§ 8.7.2.4) that occurred;~~
f) relevant information related to feed safety, including requests and complaints, from interested parties (e.g. customers and suppliers) (§ 7.4.2 and § 7.4.3);~~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 continuous ~~continual~~ improvement.

9.3.3. Management review output

The results of the management review must include:~~The outputs of the management review must include:~~

a) decisions and actions related to continuous improvement;~~decisions and actions related to continual improvement opportunities;~~
b) any need for updates and changes to the FSMS.~~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~~ Deviations and Corrective actions

The certified company must immediately:~~When a nonconformity occurs, the certified company must immediately:~~

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

b) assess if action(s) to eliminate the cause(s) of the deviation -- once the deviation is under control – to avoid recurrence, by:~~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~~deviation;
   2) defining the root cause of the deviation;~~determining the causes of the nonconformity;~~
   3) analysing if similar deviation exist, or could occur;~~determining if similar nonconformities exist, or could potentially occur;~~
c) implement any action needed;
d) review the effectiveness of any corrective action taken;
e) update the FSMS~~make changes to the FSMS~~, if necessary.

Corrective actions must solve the root cause(s) of the deviation.~~Corrective actions must be appropriate to the effects of the nonconformities encountered.~~

The certified company must keep documented information regarding:~~The certified company must keep documented information as evidence of:~~

f) the description of the deviation and any actions taken;~~the nature of the nonconformities and any subsequent actions taken;~~
g) the results of any corrective action.

10.2. Continuous ~~Continual~~ improvement

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

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

a) establishing feed safety policy and objectives (Chapter 4)~~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 FSMS

Top management must ensure that the FSMS is ~~continually~~ continuously updated. 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:~~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) internal and external communication, (§ 7.4);~~input from communication, external as well as internal (§ 7.4);~~
b) other information concerning the FSMS;~~input from other information concerning the suitability, adequacy and effectiveness of the FSMS;~~
c) output of the FSMS verification (§ 9.1.2);~~output from the analysis of results of verification activities (§ 9.1.2);~~
d) output from management review (§ 9.3).

The certified company must keep as documented information the FSMS updating activities and must use it as input to the management review (§ 9.3).~~System updating activities must be kept as documented information and reported as input to the management review (§ 9.3).~~

Feed Support Products

That was a lot of information to digest and one might ask, what is the next step? Luckily we can offer support for the GMP+ Community when doing this. We provide support by means of various tools and guidances but as each company has a shared responsibility to feed safety, and therefor tailor-made solutions cannot be offered. However, we do help by explaining requirements and provide background information about the requirements.

We have developed various supporting materials for the GMP+ Community. These include various tools, ranging from Frequently Asked Questions (FAQ) lists to webinars and events.

Supporting materials related to this document (Guidelines and FAQ's)
We have made documents available which give guidance to the GMP+ requirements as laid down in the module GMP+ FSA and GMP+ FRA. These documents give examples, answers to frequently asked questions or background information.

Feed Fraud
Even when all feed safety requirements are applied things can go wrong. Did you even thought of the possibility that fraud could have been committed? There is information available that helps you in getting insights on fraud which effects your company, focussed on the prevention of feed fraud.

Early Warning System (EWS)
When you detect (possibly) unsafe feed, you have to report this to GMP+ International. Together we can prevent consequential damage to your company and the feed chain (as much as possible). Safe feed is, and remains, a joint responsibility. How this works is explained on our website.

Feed Support Products (FSP)
Feed Support Products (FSP) provides valuable and up-to-date information about potentially high-risk feed. The products vary from flow charts of production processes including the risks (Risk Assessments) and studies on undesirable substances (fact sheets).

Where to find more about the GMP+ International Feed Support Products

Guidelines
More information: https://gmpplus.org/en/feed-certification-scheme-2020/gmp-fsa-fra-certification/support/

Feed Fraud
More information: https://gmpplus.org/en/feed-certification-scheme-2020/gmp-fsa-fra-certification/support/

Early Warning System (EWS)
More information: https://www.gmpplus.org/en/services/early-warning-system/

FAQ
More information: https://gmpplus.org/en/feed-certification-scheme-2020/gmp-fsa-fra-certification/support/

Feed Support Products (FSP)
More information: https://portal.gmpplus.org/en-US/tools/fsp/

At GMP+ International, we believe everybody, no matter who they are or where they live, should have access to safe food.

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