GMP+ International

# Production of Feed Ingredients

## GMP+ B 2

Version EN: 1st of July 2018

**GMP+ Feed Certification scheme**

Feed Safety Worldwide

gmpplus.org

## History of the document

| Revision no. / Date of approval | Amendment | Concerns | Final implementation date |
|---|---|---|---|
| 0.0 / 09-2010 | Previous versions can be found in History | | 01-01-2011 |
| 0.1 / 09-2011 | | | 01-01-2012 |
| 0.2 / 11-2012 | | | 01-03-2013 |
| 1.0 / 06-2014 | Editorial changes:<br>All editorial changes are listed in a factsheet | Entire Document | 01-01-2015 |
| | Chapter 2 has been updated. Emphasized is that GMP+ FSA requires the implementation of a management system to assure the feed safety, as defined in applicable legislation and GMP+ FSA standards | 2 | 01-01-2015 |
| | Reference to the new appendix GMP+ BA2 *Control of residues* | 5.2.4.1 | 01-01-2015 |
| | The requirements regarding the notification of contamination in feed towards customers and in the framework of the EWS has been updated. | 5.5 | 01-01-2015 |
| | Requirements for specification of the status of the feed product or service to be purchased has been updated. | 7.1.2 | 1-10-2015 |
| | ~~Deleting the chapters 7.7.2.1 till 7.7.2.6 and replacing them by reference to GMP+ B4~~ | ~~7.7.2.1 till 7.7.2.6~~ | ~~01-01-2018~~ |
| 1.1 / 05-2015 | Editorial changes | Entire Document | 01-06-2015 |
| 2.0 / 11-2015 | Definition domestic animals is changed<br><br>The FSP list is not applicable for feed for non-food producing animals. | 6.2.1 | 01-04-2016 |
| | Requirements for specification of the status of the feed product or service to be purchased has been amended. | 7.1.2 | 01-04-2016 |
| | References to GMP+ B4.1, B4.2, B4.4. and B4.5 are deleted as these standards are abolished per 31-12-2015. | 7.7.3<br>7.7.5 | 01-04-2016 |
| 3.0 / 05-2018 | Reference is added to GMP+ BA7 *Specific requirements for by-products from Oil and Fat Industry* | 6.2.1 | 01-01-2019 |
| | Link is added to the GMP+ B11 *Protocol for GMP+ registration for laboratories* | 6.6 | 01-07-2019 |
| | Requirements for internal transport are added | 7.7.1 | 01-07-2019 |

**Editorial note:**
All changes in this version of the document are made visible. This is how you can recognize:
- New text
- ~~Old text~~
The changes must be implemented by the participant latest at the final implementation date.

## INDEX

# 1 Introduction

## 1.1 General

The GMP+ Feed Certification scheme was initiated and developed in 1992 by the Dutch feed industry in response to various more or less serious incidents involving contamination in feed materials. Although it started as a national scheme, it has developed to become an international scheme that is managed by GMP+ International in collaboration with various international stakeholders.

Even though the GMP+ Feed Certification scheme originated from a feed safety perspective, in 2013 the first feed responsibility standard has been published. For this purpose, two modules are created: GMP+ Feed Safety Assurance (focussed on feed safety) and GMP+ Feed Responsibility Assurance (focussed on responsible feed).

GMP+ Feed Safety Assurance is a complete module with standards for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA standards, such as requirements for a feed safety management system, for application of HACCP principles, for traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

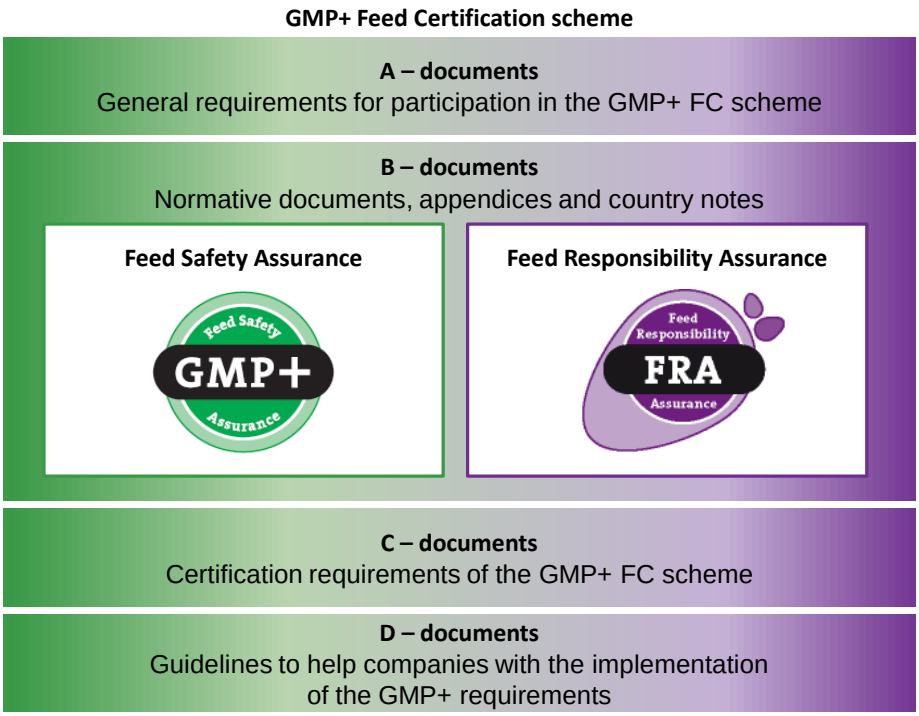
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance. GMP+ International facilitates via independent certification the demands from the market.

Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

## 1.2 Structure of the GMP+ Feed Certification scheme

The documents within the GMP+ Feed Certification scheme are subdivided into a number of series. The next page shows a schematic representation of the content of the GMP+ Feed Certification scheme:




All these documents are available via the website of GMP+ International (www.gmpplus.org).

This document is referred to as GMP+ B2 *Production of Feed Ingredients* and is part of the GMP+ FSA module.

### 1.3 Scope and application of this standard

This standard contains the conditions and requirements for the feed safety assurance of industrially-produced feed ingredients, including their storage and trading (sale).

The requirements of this standard apply to organisations, irrespective of their type or size, which carry out activities which are covered within the scope of this standard. It is not important whether a company carries out these activities on its own account or as a (sub)contractor ('service provider').

Each participant must establish the company-specific hazards relating to the safety of feeds and analyse and control them by applying HACCP principles. This standard describes as accurately as possible for activities or feed ingredients which are covered within the scope of this standard what the requirements are with respect to the various risks and what the associated control measures are. A participant may make these control measures part of a prerequisites programme or may implement them as specific measures for controlling a particular critical control point. This standard also provides requirements for inspections and audits.

If a participant carries out activities involving feeds which are outside the scope of this standard then it may be necessary to apply another GMP+ standard instead of, or in addition to, this standard.

For exact details is referred to GMP+ C1 *Production of Feed Ingredients*, Annex 1.

*Guidance:*
*For example, this standard does not include the collection, storage and the trading of feeds. Other standards are available for these activities.*

The participant remains responsible at all times for the safety of the feed ingredients and activities associated with them as well as for checking on compliance with the requirements. This must be done by the participant himself. By complying with the requirements of this standard and by being certified accordingly, the participant can demonstrate the safety and quality of his services or feed ingredients to third parties.

Irrespective of the obligations arising from this standard, the participant will only place on the market or offer services regarding feeds which are safe for animals and (indirectly) safe for the consumers of the animal products.

The participant may not introduce any feeds to the market which represent a danger to the health of consumers of animal products or animals or to the environment.

### 1.4 The structure of this standard

The feed safety system requirements are laid down in Chapter 4. Chapter 5 contains the requirements for a prerequisite programme. This programme is essential for establishing a basic level of hygiene. Chapter 6 provides the minimum HACCP requirements.

Additional requirements for the control of a number of operation activities are included in Chapter 7. Finally, the conditions and requirements for verification and improvement are to be found in Chapter 8.

*Guidance*
*Guidance has been included for a number of requirements in this standard. This guidance is in a separate blue box starting with the word 'Guidance'. The guidance does not include mandatory requirements or conditions but is intended only as an aid to the better understanding of the requirement. The box also often contains information which is useful for auditors. In order clearly to distinguish between the guidance boxes and the mandatory requirements, the guidance boxes will preferably make no use of the word 'must'. We did, however, not succeed to apply this in every box. Nevertheless, where the word 'must' is used in a guidance box, it must be read as guidance relating to the requirements set.*

The structure of this standard corresponds to that of a number of other GMP+ standards. The requirements in a number of general chapters in these standards are the same with respect to content as those in this standard although they are not described in such detail in all standards.
This depends on the scope of the standard. Because every standard is written for a specific target group, some of the wording used to describe the requirements in these general chapters may differ a little. This has been done to increase the link to the target group as much as possible.

*Guidance*
*The general chapters are chapters 4, 5, 6 and 8.*

*The structure of this GMP+ B2 standard is, for example, identical to that of the GMP+B3 Trade, Collection and Storage & Transshipment standard. The GMP+ B2 standard is intended for producers. The words 'production' and 'to produce' therefore occur regularly in this standard.*
*The GMP+ B3 Trade, Collection and Storage & Transshipment standard is intended for collectors, storage companies and traders. The words 'production' and 'to produce' are avoided as much as possible in this standard and words such as 'trade', 'storage' and 'collection' occur much more frequently.*

*A company which produces a feed material and also trades in feed materials (meaning feed materials which are produced by third parties) can apply both standards in combination. A combined application is quite simple to achieve because of the identical structures and because a number of chapters are identical with respect to content. This company should be alert to completeness in the application of a second standard or should check whether any extra measures are necessary for the second activity.*

GMP+ Appendices (GMP+ BAxx), to which there are also references, are separate GMP+ documents within the B segment. If there is a reference in this standard then it applies within the framework of this standard. See also Chapter 2.

### 1.5 Exclusion of requirements

It is possible that certain requirements do not apply to a participant. A participant may exclude these requirements. Exclusions must, however, be justified and recorded. The exclusions may in any event not lead to the participant supplying feeds or offering services which do not comply with feed safety as defined in the GMP+ FSA module.

No requirements may be excluded because the participant finds them to be not relevant such as because customers do not ask for them or because compliance with these requirements is not a legal obligation or because the company is small.

*Guidance*
*Smaller companies sometimes have trouble implementing certain requirements. A number of guidance boxes in this standard provide suggestions for how a small company can meet a requirement. The aim of the requirement remains in force.*

## 2 Feed Safety Management System Objective

Implementation of this standard aims to establish a management system to ensure the safety and quality of the feed products and feed services, as covered under de scope of this standard.

This standard is meant to be aligned with applicable feed legislation as well as feed safety principles and standards that are commonly accepted in the feed sector to be taken into account when producing and delivering safe feed.

The feed safety management system must ensure that the applicable legal requirements and sector requirements are met, as well as applicable statutory, regulatory and contractual arrangements.

Some remarks:

- Regarding the feed legislation, special attention was paid when drawing up this standard to include relevant requirements of applicable feed legislation. However, it remains the responsibilty of the participant to ensure full compliance with relevant feed legislation.
- Additionally, regarding the sector requirements, in some GMP+ appendices (coded as GMP+ BAxx), a number of sector specific feed safety standards and conditions have been laid down, which are worldwide to be considered as necessary to meet, in order to produce and deliver safe feed. When this standard makes a reference to such a GMP+appendix, it is expected that the participant ensures that the required feed safety management system is effective to meet these sector specific feed safety standards.
- However, both this standard and the appendices, may not cover all sector specific feed safety standards. Therefore, also related this item, it remains the responsibility of the participant to identify all relevant sector specific feed safety standards and to ensure the feed safety management system is able to control them.

Certification of the feed safety management system against the requirements of this standard, does not guarantee legal compliance nor compliance with the sector requirements, but demonstrates that the participant has a effective feed safety management system to achieve and maintain legal compliance as well as compliance with sector specific feed safety requirements.

The participant must also comply with the relevant requirements as recorded in the GMP+ A - documents.

These documents can be found on the GMP+ International’s website (www.gmp-plus.org)

# 3 Terms and definitions

For definitions and abbreviations see GMP+ A2 *Definitions and Abbreviations*. (www.gmpplus.org).

In addition, the following specific definitions apply to this standard:

**Feed ingredient**: A product that as such or in a mixture, makes up a feed, whether or not it has a nutritional value in the animal's diet. Ingredients may be of vegetable, animal or maritime origin and may concern organic or inorganic material. (derived from Codex definition).

*Guidance*
*This includes feed additives and feed materials as defined in GMP+ A2 Definitions and Abbreviations. This excludes compound feed, semi-finished products and premixtures, consisting of more than one feed ingredient, intended to be fed to animals or mixed in with compound feed, respectively.*

*In the definition of 'Feed additives' also preparations are mentioned. One can think of a feed additive and a carrier, which is put on the market and used as a feed additive.*
*Mixtures of feed additives should be considered as premixtures.*

**Raw material**: A product used for manufacturing or processing of a feed ingredient.

# 4 The Feed Safety Management System

## 4.1 Management: responsibility and involvement

Management must be aware of its responsibility for the safety of the feed. Feed is part of the food production chain.

Management must:
a. Make the organisation aware of the importance of feed safety and of compliance with both the requirements of the customer, of this GMP+-standard and the obligations of the feed legislation.
b. Demonstrate its responsibility and involvement in the development and introduction of the feed safety management system to achieve safe feed.
c. Establish a HACCP Team.
d. Ensure that resources are available. Management must determine what resources are required to realise safe feed and ensure that these resources are also available. At least, compliance with this standard is necessary.
e. Assess at least once per 12 months whether the feed safety management system is still suitable and effective. See for details about such a management review section 8.3.

*Guidance*
*Feed safety is mostly laid down in norms for undesirable substances. Refer to the applicable legislation and to GMP+ BA1 Specific feed safety limits.*

*By resources is meant, among other things, the infrastructure (buildings, work areas and facilities), personnel and other means which are required for a suitable feed safety system. See for this see Chapter 5.*

*For more details about the requirements of the customer refer to section 6.2.*

## 4.2 HACCP team

In order to establish a risk assessment system, the participant must appoint an HACCP Team to produce an effective HACCP Plan.

The HACCP Team must include personnel from all of the relevant operations and functions within the company and at least one member with demonstrably HACCP-knowledge and/or HACCP-experience.

The HACCP Team must carry out a hazard analysis with the object of identifying and controlling risks which could have a negative effect on feed safety. See for this Chapter 6.

The HACCP Team must have expertise in various disciplines or must be able to make use of expertise for the carrying out of the hazards analysis and the drawing up and maintenance of the required feed safety system.
The members of the HACCP Team must be recorded within the HACCP documentation.

It is acceptable for individual personnel to fulfil multiple roles in the HACCP Team or for the participant to utilise resources from outside of the company, provided that the role of the team remains effective.

*Guidance*
*To assist a company in identifying, evaluating and controlling hazards that are significant for food / feed safety, a so-called HACCP-Guideline was made. This guideline can be found on de website of GMP+ International (*http://www.gmp-plus.org*).*

*A HACCP Plan is a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food / feed safety.*

### 4.3 The feed safety management system

The participant must establish, document, implement and maintain a feed safety management system in accordance with the requirements of this standard. The feed safety management system must be adapted to regulatory and other safety related developments, as they occur.
The feed safe management system must ensure that all those activities that could impact on the safety of the feed ingredients produced / processed are consistently defined, implemented and maintained in the organisation.

The participant must determine and record the scope of the feed safety management system by identifying the (categories of) feed ingredients and production sites which are covered by the system and ensuring that the feed safety objectives are established. The scope must in any event include all feed ingredients and all activities related to the feed ingredients for which the participant is responsible.

The participant shall determine the following:
a. The part of the chain for which the participant is responsible. This begins where the responsibility for the previous link (the supplier) ends and ends where the responsibility for the following link in the feed chain begins.
b. All feed ingredients (in specifications) which are produced.
c. All activities related to the production of the feed ingredients, including activities which are outsourced.
d. All relevant locations whether these are the property of the company or not, including locations where relevant administrative activities are carried out.

If a participant decides to outsource an activity which may have an influence on feed safety then the participant must ensure that this activity is also carried out in accordance with the requirements of this GMP+ standard and is also certified as such. See GMP+ BA10 *Minimum Requirements for Purchasing*.

The participant must also describe all other activities and/or products which are not feed related. The participant must ensure that these activities do not have a negative influence on the safety of the feed ingredients.

*Guidance*
*The scope of the system should include at least:*
*a. The selection of suppliers and purchasing of raw materials*
*b. All transport and storage contracted or controlled by the participant*
*c. The process by which feed ingredients are produced*
*d. All other process steps which are purchased or controlled by the participant such as planning, purchasing, (interim) storage, internal transport, sales and packaging.*

*The structure of the feed safe management system may be specific to the organisation of the participant and include policies, requirements and documented procedures that maintain feed ingredient safety.*

*The description of all activities may result in the participant having to apply a second or perhaps a third standard in addition to this standard. The participant may also choose to apply the GMP+ B1 Production, Trade and Services standard instead of a number of target group standards. If in doubt, consult your certification body or the website of GMP+ International (*www.gmpplus.org*) for more information.*

*Concerning the last section: not feed related activities or products are for example storage of fuels, paint, agricultural vehicles, timber, etc.*

## 4.4 Documentation and registration

### 4.4.1 Quality documentation and manual

A participant must produce and implement procedures and instructions that incorporate the requirements of this standard.

The feed safe management system documentation must include, or refer to:
a. The documented Quality Policy, including feed safety objectives;
b. Description of the scope of the feed safety management system as required in section 4.3;
c. All relevant records or approvals in accordance with national and international legislation;
d. The HACCP documentation;
e. All procedures, instructions, registration forms, etc. required by this standard, and/or necessary for the operating of the feed safe management system;
f. All records of treatment, audits and inspections and all other records which are required under this standard. This register must be set up and maintained as evidence of compliance with the requirements and of the effective operation of the feed safety management system;

There must be a clear, unambiguous structure applied to these documents, instructions, forms, etc.

*Guidance:*
*Re. c) This may also include legal permits to produce or to export*

*Documented procedures may form part of a structured and certified feed safety and/or feed safety management system (for example ISO-9001), or be part of a national, industry or company scheme that delivers equivalent controls. Independently certified HACCP or quality systems are not a pre-requisite for certification against this standard.*
*It is allowed to control the documents digitally.*

*The lay out and structure of the quality documentation, which is necessary and required in this standard, like (documented) procedures, instructions, forms and documented data, may be geared to the nature of the assured activities, the size of the company and the training and knowledge level of the personnel.*

### 4.4.2 Control of documentation and data

The documents and (registration) data must be controlled.

This means that the documentation:
a. must be kept up to date;
b. approved, signed and dated, and must be assessed at least annually by a competent person. This assessment must at least consider any changes to the regulations or to the GMP+ FSA module;
c. always be accessible and understandable to those members of the personnel who implemented the requirements of the procedure
d. be revised and updated if the process undergoes a relevant change so that it is always up to date.

The participant must ensure that all documentation and data required under this standard are:
a. kept for a period of at least 3 years unless a longer retention period is prescribed by law;
b. stored in a way that any degradation in the condition of or damage to the documentation and data is prevented;
c. stored in such a way that the documentation and data is complete and easy to retrieve;
d. clearly legible.

*Guidance:*
*Documentation may also be made available in digital form, and may be controlled and stored in that way.*

*A participant should demonstrate that he has procedures in place that ensure he remains up-to-date with regulatory requirements and any food / feed safety issues relevant to the feed ingredients the participant produces.*

*Information relating to safety issues that may affect the operation of the organisation should be reliably and effectively transmitted to those personnel with responsibility for the areas involved. Any changes in practices or procedures necessitated by new information should be implemented effectively.*

# 5 Prerequisite programmes

In order to successfully apply the HACCP principles, the participant must determine a general programme of prerequisites for various operational issues and apply these in accordance with this chapter. The participant may implement additional prerequisites. The participant may exclude certain prerequisites provided that a valid motivation is given.

*Guidance*
*See also the GMP+ D2.1 Guideline HACCP GMP+, available from the website of GMP+ International.*

*Prerequisite programmes create the hygiene and environmental conditions for the production of safe feed ingredients. See also Codex Alimentarius.*

*The identified prerequisite programmes are part of the HACCP plan and are subsequently included in all internal auditing schemes established as part of the HACCP plan.*

## 5.1 Personnel

### 5.1.1 General

All personnel must be aware of their responsibility for feed safety.

There must be:
a. an organisational chart;
b. a description of the qualifications (for example diplomas, summary of professional experience) of (also temporary employed) personnel.
c. A description of the personnel's tasks, responsibilities and authorities.

All relevant personnel must be informed clearly in writing of their duties, responsibilities and powers with regards to the maintenance of safe raw materials and feed ingredients. This information must be updated in the event of any significant changes.

Protective clothing must be worn wherever contamination of feed ingredients by personnel is identified as a risk by the risk assessment study. All clothing and equipment must be maintained in hygienic condition.
Clear policies on smoking and eating / drinking on site must be made known to employees and visitors (including personnel from a third party) and must prohibit eating, drinking and smoking in areas where these activities may adversely affect feed ingredients. If necessary, separate facilities must be provided.

The participant must ensure that (technical) personnel from a third party working on site are controlled in such a way that maintenance and building works do not adversely affect either raw material or feed ingredient safety. There must be a procedure in place to ensure that appropriate cleaning and tidying has been completed prior to recommencing activities in that area.

#### 5.1.2 Competency and training

Personnel who carry out work which may influence feed safety must be competent. Their level of competency is based on suitable courses, training, skills and experience. The participant must have personnel with the skills and qualifications which are required for the production of safe feed ingredients.

The participant must:
a. Establish the necessary skills which the personnel must have if they carry out work which influences feed safety. This also applies to the HACCP Team.
b. Offer training or take other measures to meet these needs.
c. Maintain personnel records of courses, training, skills and experience.

The above also applies to temporary personnel.

### 5.2 Infrastructure

#### 5.2.1 Environment

The production of feed ingredients must be carried out in an environment where it is not possible for the presence of potentially hazardous substances to lead to an unacceptable level of those substances in feed ingredients.

If an environment presents a risk to feed safety then the participant must show by way of a hazard analysis that the risks are controlled.

*Guidance*
*Buildings where production takes place or where work is done on feed ingredients should not be at or near to places which present a clear hazard for feed safety. This includes contaminated ground, proximity of rubbish tips and suchlike.*

#### 5.2.2 Facilities and equipment

##### *5.2.2.1 General*

Facilities and equipment must be designed, constructed, maintained and managed to ensure that the safety of raw materials and feed ingredients is protected at all times. Consideration must be given to preventing both the malicious and accidental contamination of feed ingredients.

Facilities must be designed and constructed such that, where necessary:
a. accumulation of dirt is prevented;
b. condensation and undesired mould is prevented as much as possible;
c. falling particles and feed remainder are limited;
d. cleaning, disinfection and maintenance can be carried out properly;
e. that birds and other animals have the least possible chance of getting in.

The facilities must be such that:
a. the chance of errors is limited as much as possible and contamination, cross-contamination, carry-over and any other negative influence on the safety of feed ingredients is prevented as much as possible.

b. There can be no confusion among the various feed ingredients, the feed ingredients are properly identified and no incorrect use of the feed ingredients can take place.
c. That a strict and complete physical and organisational separation is imposed between the feed and products that may have an adverse effect on animal health, human health or the environment.
This separation is intended with respect to feed safety to prevent feed ingredients coming into contact or being mixed with other products.

The facilities must be provided with proper natural and/or artificial lighting to ensure that cleaning, processing and other activities important to raw material and feed ingredient safety can be undertaken effectively.

Ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of moulds and the shedding of particles that may adversely affect the safety of raw materials or feed ingredients.

Sewer, waste, rain and melt water must be discharged in such a way that the equipment and the safety of the feed ingredients in not influenced.

Spilled feed and dust must be controlled to prevent pest.

Drainage facilities are suitable for the intended purpose. They must be designed and constructed in such a way that any risk of contamination of the feed ingredients is prevented.

*Guidance*
*Examples of products that may have an adverse effect on animal health, human health or the environment are: fertiliser, fuel, lubricants, cleaning and disinfectant agents, glass, crop protection agents, waste.*

*A physical and organisational separation can be constructed as the participant chooses, but should prevent mixture of feed and products that may have an adverse effect on animal health, human health or the environment.*

### *5.2.2.2 Intake and loading facilities*

Proper areas must be provided for reception, loading and unloading of feed ingredients and potentially hazardous products (such as cleaning agents, lubricants, fuels, etc.).

During reception or loading and unloading the participant must do everything which is reasonably possible to create such conditions that the risk of contamination is avoided and that, for example, bad weather cannot have an influence on the feed ingredients to be loaded.

*Guidance*
*During loading, unloading and storage the penetration of for example rain water and contaminated water should be prevented.*

#### *5.2.2.3 Storage facilities*

Facilities for storage of feed ingredients and potentially hazardous products (e.g. cleaning materials, lubricants, fuels, etc.) must be provided.

In the case of a storage area care must be taken that mud, snow and other potential contaminants which may be transferred by vehicles are not able to exert any negative influence on the stored feed ingredients.

There must be hardened ground (for example a concrete floor) at the entrance to the storage area so that water and mud are not able to penetrate the storage area.

#### *5.2.2.4 Equipment*

All equipment used for producing or processing feed ingredients must be fit for the purpose for which it is used.

Equipment coming into contact with feed ingredients must be designed and constructed to ensure that, where necessary, it can be cleaned, disinfected and maintained to avoid the contamination of the feed ingredients.

Where mechanical drying is undertaken, procedures must ensure that any adverse effect on the feed ingredients being dried is minimised.

Where drying operations result in combustion gases coming into contact with raw materials or feed ingredients, a participant must be able to demonstrate that the levels of undesirable substances are not exceeded beyond the maximum levels prescribed for feed ingredients in the regulations of the country of production and the countries where the participant will place feed ingredients onto the market.

Magnets and / or metal detectors must be included in production systems where indicated as necessary by the risk assessment study.

Critical sieves, screens, filters, separators, magnets and metal detectors must be regularly checked to ensure that they are not damaged and that they continue to operate effectively.

All scales and metering devices which are used in the production of feed must be appropriate for the range of weights or volumes to be weighed or dosed, and their accuracy must be checked regularly. The dosage capacity must also be matched to the quantity of product to be disseminated. The following must be clearly stated and recorded with respect to the weighing equipment:

a. the minimum and maximum weight permissible for the weighing equipment or dosage equipment;
b. the accuracy of the weighing or dosage equipment.

Security must be applied such that the participant is sure that the weighed and/or dosed quantity of component is actually put into the feed (batch) for which it is intended.
If the participant makes use during production of dosage silos when filling these silos a proper locking system must be used.

Where screenings (materials separated from the primary production stream by sieves, screens, filters, separators, etc) are reclaimed or reprocessed for inclusion in feed ingredients, the risk assessment study must consider the potential hazards resulting from such practices.

*Guidance*
*Where undesirable or unwanted materials are removed from a primary product and concentrated into a by-product supplied as a feed ingredient, a risk assessment study must consider the potential hazards resulting from such practices. Any necessary precautions should be implemented.*

### 5.2.3 Access regulation

Access arrangements must be established for the production areas. Anyone who is not an employee may only be given access to the production areas under the supervision of or with the permission of an authorised person.

### 5.2.4 Other items

#### *5.2.4.1 Cross/contamination*

Technical or organisational measures must be taken to prevent or minimise cross-contamination or errors, including contamination by means of carry-over

Equipment and procedures must be designed and operated to ensure that cross-contamination between different types of feed (or other) materials is minimised.

The processed feed ingredients must be kept separate from the untreated feed ingredients to prevent cross-contamination.

The participant must determine based on a risk assessment whether the degree of carry-over for his equipment must be determined. A major item for attention in this is the risk that substances or products can get from one feed ingredient to another through carry-over and may lead to an unsafe feed ingredient.

In any event the carry-over must be known for production and transport lines in an installation on which (feed with) feed additives are processed, produced and/or transported, that may have an adverse effect on animal or human health (due to residue build-up).

The measurement frequency of carry-over in production and transport lines depends on the (feed with) feed additives which the participant processes and whether he processes feed ingredients for which a residue standard has been established. See GMP+ BA2 *Control of Residues* for this.

The participant must measure this carry-over by means of a testing procedure established by GMP+ International. See BA2 *Control of Residues* for this.

The carry-over must be re-established in the above situations in the event of major changes to the installation.

*Guidance*
*Carry-over: see GMP+ A2 Definitions and Abbreviations.*

#### *5.2.4.2 Air movement*

In cases where air is used for conveying or cooling, the participant must evaluate the risk of this becoming a vehicle for pathogens and take any necessary precautions.

#### *5.2.4.3 Water and steam*

The participant must be sure that the water or the steam which is used during the cleaning or in the production of the feed ingredients is safe for animals. The participant must ensure that the feed ingredients are not contaminated by the use of water of poor quality.
Special attention must be paid to processing aids such as anti-corrosion agents.

#### *5.2.4.4 Processing Aids and Technological Additives*

The participant must ensure that the use of processing aids or (technological) additives does not adversely affect the feed safety.

Where processing aids are used during production, a risk assessment must show that the unintentional but technological unavoidable presence of residues of the substance or its derivatives in the feed ingredient do not have any adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed.

A participant must ensure that control systems provide the correct and effective dosing levels for processing aids and technological additives at all times.

Dosing systems for processing aids and technological additives must be calibrated by a competent person and calibration records maintained.

#### *5.2.4.5 Packaging*

The packaging of the feed ingredients must be suitable for the kind of feed and the chosen method of delivery or transport. The packaging must be designed for the protection of the feed ingredient during normal storage, treatment and delivery conditions.

Reusable packaging should be sturdy, easy to clean and, if necessary, should be able to be disinfected. The participant should establish a cleaning regime on the basis of a hazard analysis.
If applicable, special attention should be paid to the recovery from livestock farms of pallets and other reusable packaging material.

### 5.3 Maintenance and hygiene management

#### 5.3.1 Maintenance

A (written) programme of planned maintenance must be drawn up and implemented for all relevant areas and equipment so that safe and hygienic operations are ensured.

Records of the maintenance activities must show that there is compliance with the requirements.

The participant should record the maintenance which is carried out on all equipment which is critical for the processing of and/or operations with feed ingredients.

*Guidance*
*The maintenance programme should contain at least the following elements:*
a. *The (production) areas and production halls;*
b. *Equipment and (internal) transport systems;*
c. *Personnel involved (own personnel or hired personnel);*
d. *Frequencies;*
e. *Other aspects. Maintenance activities may not form any risk at all for feed safety*

#### 5.3.2 Maintenance of measuring equipment

All inspection, measuring and test equipment used to confirm that feed ingredients meet specified feed safety requirements must be calibrated at intervals not exceeding 12 months.

Records of the results of calibration and verification must be maintained.

*Guidance*
*The participant should ensure that:*
a. *Calibration acceptance criteria are defined.*
b. *Calibrated equipment is traceable to national standards or when this is not possible that the basis of the calibration is defined.*
c. *All relevant equipment is uniquely identified and traceable to calibration records.*
d. *The calibration frequency is defined.*

*If equipment is found to be performing outside acceptable calibration limits the participant should investigate the effect this will have on the conformity of any feed ingredients and take appropriate corrective action to recalibrate the equipment. Depending on the severity of the discrepancy and the nature of the test, the participant should be able to demonstrate that appropriate action has been taken (for example feed ingredient recall).*

### 5.3.3 Cleaning and sanitizing

A participant must ensure that at all relevant stages of the production, storage or handling of raw materials and feed ingredients, standards of cleanliness are operated such that exposure to pests and pathogens is minimised.
A cleaning programme must be documented and ensure that feed ingredient production, storage and transport facilities are cleaned to maintain feed ingredient safety at all times.

Cleaning and disinfection programmes must be monitored for their suitability and effectiveness. An authorised person must carry out inspections of cleaning and a record of all inspections must be kept.

Cleaning and disinfection / sanitising chemicals must be stored, if required by legislation, separately in clearly identified containers to avoid the risk of (malicious or accidental) contamination.

Machines or components which come into contact with dry feeds must be dried after wet cleaning or must be dry before they are used again.

*Guidance*
*Cleaning should remove residues and dirt that may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the business and may include disinfection / sanitising.*
*Only food-/feed compatible cleaning and disinfectant / sanitising agents may be allowed to come into contact with feed ingredients and should be used in accordance with manufacturers recommendations and safety data sheet requirements.*
*Where cleaning agents and disinfectants / sanitizers come into contact with feed ingredients, the participant should ensure that control systems provide the correct and effective dilution levels at all times. The participant can make use of the information in the user instructions for the cleaning agent or disinfectant used.*

*The cleaning programme should contain at least the following elements:*
a. *(production) areas and production halls*
b. *equipment and (internal) transport systems*
c. *involved positions / personnel*
d. *frequency of cleaning*
e. *the cleaning agents used should be recorded and should be suitable for purpose.*

*These activities may not form any risk at all for feed safety. Make sure that remains of cleaning and disinfectant agents don't unnecessarily stay behind on cleaned equipment, facilities, etc.*

### 5.3.4 Pest prevention and -control

Everything which is reasonably possible must be done to keep birds, pets and pest away from the production areas and to prevent their presence. The participant must take measures to counter pest and set up, implement and document a pest control programme.
Personnel must be appropriately qualified and trained to carry out any control treatment required.

Activities within the framework of pest control must be planned, carried out and recorded. Records of the control activities must show that there is compliance with the requirements.

*Guidance*
*Consider the following:*
a. *Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites.*
b. *Doors should be kept closed whenever possible and should be close-fitting and proofed against pests when closed.*
c. *Holes, drains and other places where pests are likely to gain access should be kept sealed wherever possible. Where sealing is not possible measures such as wire mesh screens should be in place to reduce the possibility of pest entry.*
d. *Animals should, wherever possible, be excluded from the grounds of factories, and the area surrounding stores and production plants. Where the presence of pigeons, seagulls and other pests is unavoidable, procedures should be implemented to protect raw materials and feed ingredients from potential contamination.*
e. *In cases where shooting is undertaken as part of the pest control programme lead, or other toxic ammunition, should not be used.*
f. *All bait containers should be fixed in their intended position unless there is a specific reason why this is not appropriate.*
g. *Open bait containers and loose baits should not be positioned in areas where their use may result in a hazard to raw materials or feed ingredients.*

*Pest control procedures should be documented and should ensure that no materials designed to kill or deter pests can contaminate raw materials or feed ingredients. Pest control records should include:*
a. *Details of any poisons used including safety data sheets.*
b. *Qualifications of personnel involved in pest control activities.*
c. *Map(s) indicating the location of any bait stations and the type of bait which is used.*
d. *Records of any pests found (species and numbers).*
e. *Details of corrective actions implemented.*

### 5.3.5 Waste management

All materials which are considered to be waste must be visually designated as such and protected in such way that the chance of errors or unintended use is eliminated.

The waste must be collected and stored in separate bins or containers. These must be easily identifiable and must be covered to prevent pest.

### 5.3.6 Glass and breakable materials

The participant must ensure that glass and breakable materials do not form any hazard to the feed ingredients. All reasonable efforts must be made to minimise the risk of glass breakage and to ensure that no contamination of feed ingredients can take place in the event of glass breakage.

## 5.4 Identification and traceability / sampling

### 5.4.1 Identification and traceability

Products (as defined in GMP+ A2 *Definitions and Abbreviations*) must be traceable at all stages of production, processing and distribution, in order to allow for immediate, targeted and accurate recall of these products if necessary, and/or to allow for adequate information to the users of these products. The participant must, for this purpose, set up and describe an internal traceability procedure.

The participant must take suitable measures to ensure that the products can be traced effectively during each of the stages referred to above for which the participant is responsible. He must maintain a register with the relevant details with respect to the purchase, production and sale which can be used to trace the products from reception to delivery.
The participant must have the necessary information available within 4 hours unless the competent authorities have established a shorter time.

See D2.4 Guideline for Traceability for more information about setting up a internal traceability procedure.

The participant must record at least the following details of all products and services:
a. name and address details of suppliers and customers;
b. date of delivery;
c. type of product or service;
d. product quantity;
e. batch number, where appropriate.
f. transport/ distribution details (if the participant is responsible for transport)

The participant should himself determine whether the recording of other details is necessary.

*Guidance*
*The Food-/Feed Law requires that feed ingredients and all other substances which are intended to be processed in a feed or for which it may be expected that they will be processed in a feed, must be traceable in every stage of production, processing and distribution so that, in applicable cases, they can immediately be withdrawn from the market in a specific and precise way and/or the users of these products can be properly informed.*

*The batch number can also be designated as a producer's batch number, a reference number, a batch number or a lot number.*

5.4.2 Sampling

In addition, within the framework of traceability samples must be taken from incoming raw materials and/or outgoing feed ingredients. To do this a previously-determined procedure must be followed by the participant.

These samples must:
a. Be sealed in such a manner that re-sealing after opening is not possible.
b. Be labelled in order to ensure that samples are easy to identify.
c. be stored in such a way that any change to the composition or any deterioration of the sample is excluded.
d. be kept available for the competent authorities for a period which has been matched to the use for which the feed ingredients were placed on the market.

See for this GMP+ BA13 *Minimum Requirements for Sampling*.

The participant may enter into written agreements with third parties (for example the producer or supplier) on the taking and storing of samples.

*Guidance*
*Within the framework of the GMP+ FSA module all participants who actually physically process, produce or import products must have samples taken. In all other companies the obligation to take samples can be made dependent on the interpretation of the feed legislation by the competent authorities in question.*

## 5.5 EWS and Recall

The participant has a documented procedure for warning at an early stage and for handling these signals which warn that the safety of feed ingredients may not comply with the legal standards the standards set in the GMP+ FSA module or merchantable trading quality, and may lead to damage in subsequent links in the chain. The signals must be assessed on this basis.

If a feed ingredient is found to not comply with:
a. legal requirements relating to safety, or
b. the usual merchantable quality, or
c. the essential requirements of the GMP+ FSA module,

then the participant shall undertake the following actions:
a. inform the customers:
   - In case of exceeding the maximum permitted level(s) of undesirable substances in feed as mentioned in legislation or/and GMP+ BA1 *Specific feed safety limits*, the customers must be informed within 12 hours after confirmation of the contamination.
   - In case of all other perceived non-conformities and irregularities (others than complaints, see GMP+ BA5) not controlled by the participant, which could have consequences for the customers, the customers must be informed, and
b. immediate suspension of the sale of the relevant feed, and
c. recall of the feed ingredient and ensuring that the feed ingredient does not enter the feed and cattle farm sector,

unless the participant can demonstrate that the non-conformity does not have any harmful consequences to animal and human health and that the product is still in compliance with legal requirements.

The participant needs to notify GMP+ International and the Certification Body in accordance with GMP+ BA5 *Minimum Requirements EWS*. If it is a legal obligation, the participant also needs to notify the non-conformity to the competent authority in the country or region of residence.

The participant must prepare a recall procedure for the above actions. After determining the recall procedure, a recall simulation must be carried out within three months. Subsequently, the recall simulation must be repeated annually. The experiences of these recall simulations must be recorded.

*Guidance*
*On the website of GMP+ International a guidance is published with information about recall and how to establish and implement a procedure for recall*

*As part of the recall procedure, all relevant contacts must be listed and kept up-to-date. Contacts listed must include the Competent Authorities to be notified in the following circumstances:*
a. *In the event of a serious safety risk.*
b. *When legal limits are exceeded and national legislation requires notification.*

*Recall procedures must include systems for:*
a. *Identifying the non-conforming feed ingredient batch / lot, including consequences to other feed ingredients, batches / lots or raw materials.*
b. *Ensuring that where recall of a non-feed product is required, recall of feed ingredients is also considered and, if necessary, implemented;*
c. *Identifying the location of affected batches / lots.*
d. *Management of returned feed ingredients, including segregation from other products.*
e. *Recording the destination of any recalled products.*

# 6 HACCP

## 6.1 Planning of the realization of a safe feed

The participant must ensure the introduction, implementation and maintenance of one or more written procedures which are based on the HACCP principles.

These principles are:
a. Conduct a hazard analysis
b. Determine Critical Control Points (CCP's)
c. Determine standards for CCP's
d. Set up and implement a monitoring plan for CCP's
e. Define corrective actions
f. Validate and verify the HACCP plan
g. Document and register the HACCP plan

To apply these principles successfully, the participant must first comply with a number of other requirements which are laid in other chapters and sections of this standard:
a. Establishing a HACCP-Team (section 4.2);
b. Description of product and process, including the intended use (section 6.2)
c. Establishing and implementing a prerequisite program (chapter 5)

*Guidance*
*Refer to the HACCP Manual on the GMP+ International website (www.gmp-plus.org) for a description of a step-by-step approach to the application of the HACCP principles*

*The results of the application of the HACCP-principles can be recorded in a so-called HACCP Plan, being a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food / feed safety in the sector of the feed chain under consideration.*

## 6.2 Description of product and process

### 6.2.1 Determination of requirements

The participant must determine all (safety) requirements with respect to the feed ingredients to be produced, including storage and/or transport:
a. legal requirements for the feed ingredients, including requirements for storage and transport, and
b. all additional feed safety requirements, including those necessary for the specified or intended use, if known.

Communication with (potential) customers may result in determining:
a. customer requirements relating to the safety of feed ingredients, and/or
b. any other special customer requirements. If the customer participates in a certain feed safety programme, the participant must ensure he understands, determines and complies with the specific programme requirements, including, for example, any specific storage or transport conditions.

Each type of *feed material* that is produced must be listed (with its generic risk assessment) in GMP+ International's Feed Support Products. If the participant produces a *feed material*
a. of which no risk assessment is listed in the Feed Support Products; or
b. using a manufacturing method that is not in accordance with one of the risk assessments already included in the Feed Support Products.

then the participant must guarantee that the risk assessment is listed in the Feed Support Products. The above does not apply to feed materials produced exclusively for purposes of feed for non-food producing animals.

In Appendix GMP+ BA7 *Specific requirements for by-products from Oil and Fat* for specific by-products from the oil and fat industry (from certain origins) additional requirements have been laid down. These requirements focus on purchase of raw materials, shipment, transport, monitoring, and labelling. If applicable, the participant needs to comply with these requirements.

*Guidance*
*See for the relevant requirements in the context of the GMP + Feed Safety Assurance Module (FSA) mainly:*
a. *GMP+ BA1 Specific feed safety limits;*
b. *GMP+ BA3 Minimum Requirements Negative List;*
c. *GMP+ BA4 Minimum Requirements for Sampling and Analysis;*
d. *GMP+ BA10 Minimum Requirements for Purchasing.*

*See the GMP+ International website for the procedure how to send in a risk assessment for publication in the Feed Support Products.*
*A generic risk assessment of a feed additive or a non-protein nitrogenous product does not have to be listed in the Feed Support Products.*

### 6.2.2 Specification of feed ingredients

The participant must determine and specify all (safety) requirements relating to the feed ingredients to be produced. For each feed ingredient, a description must be available based on the above-mentioned requirements.
The scope of this specification must include the products used, ranging from the products used in the manufacturing process (feed materials, processing aids and/or (technological) additives) through distribution.

If requirements are modified, the participant must ensure that the relevant specification is updated and that the relevant personnel is aware of these changes. This specification must be kept up to date.

The specification must at least – if applicable - include:
a. Characteristics of the feed ingredient
    1. General details (name, code, origin, creation/manufacturing model etc.);
    2. Composition (chemical, physical, microbiological)
    3. Used raw materials and processing aids (including any additives and processing aids);
    4. Requirements (feed legislation; agreements with buyers) and tolerances; Within the GMP+ FSA module, the feed ingredients must at least comply with the relevant product standards as determined in the GMP+ BA1 *Specific feed safety limit.*

5. Other characteristics (including storage, packaging).

b. Characteristics of use:
1. Intended use;
2. Preparation instructions;
3. Instructions for feeding to animals
4. Storage conditions;
5. Shelf life;
6. Conditions and agreements relating to transport and place of delivery;
7. Legally required information on the packaging and any accompanying documents.

*Guidance*
*The GMP+ FSA module is dedicated to assurance of feed safety. A specification at least contains information relating to safety aspects. Specifications of the finished product offer an initial indication of possible hazards. In addition to the ingredients used in the feed ingredient (raw materials, additives, processing aids), other elements are included that may affect food and feed safety. This may concern chemical, physical and microbiological characteristics (for example polluting or undesirable substances), or the desired conditions for production, storage and transport.*

*This is based on the conditions and standards included in the various Appendices of the GMP+ standard and these are, if necessary, included in the specification.*

*Please note: A producer is not always able to fully specify all components. This especially applies to the components listed under b).*

*Due to considerations of effectiveness, the participant may choose to form groups of feed ingredients. In this respect, the following is important:*
*a. Specific differences between the separate feed ingredients to be produced must be critically reviewed;*
*b. The production and storage conditions must be equivalent;*
*No major issues relating to product safety may be missed.*

### 6.2.3 Process description

The HACCP Team must draw up a description of the production process for each feed ingredient in the form of flow diagrams and a floor plan which enables the organisation to identify and assess hazards.
The flow diagrams and the layout must be verified by the HACCP Team, and must be kept up-to-date.

The flow diagrams must comply with at least the following requirements :
a. Representation of all the individual steps in the process (from purchasing through to delivery), including any work outsourced as well as the description of all products used and also any by-products, customer returns and waste which may be produced during the process.
b. Clear, accurate and detailed in order to establish possible hazards

The whole infrastructure of the establishment must be shown in a floor plan, including:
a. the production units, storage areas and personnel facilities
b. the routing of products
c. the areas/rooms where cross-contamination or incidental contacts are possible between raw materials and auxiliary substances, lubricants and cooling agents, semi-produced and other feed ingredients (end products), packaging, pallets, etc.

*Guidance*
*See the HACCP Manual on the GMP+ International website for an overview of the useful symbols with which a process can be described schematically.*

## 6.3 Hazard analysis

### 6.3.1 Hazard identification

The HACCP Team must identify and record systematically all potential hazards which may have a negative effect on feed safety.

The hazard identification is based on:
a. raw materials and auxiliary substances;
b. the specification of the feed ingredient;
c. the business layout and resources used;
d. the process diagram drawn up;
e. the lay-out drawn up;
f. experience, expertise, research and other sources of information (internal/external);
g. the generic risk assessment from the Feed Support Products (if applicable).

For each hazard the HACCP Team also records an acceptable level of presence in the feed whereby there is at least compliance with the statutory norms and those laid down in the GMP+ FSA module. See GMP+ BA1 *Specific feed safety limits*.

### 6.3.2 Risk assessment

The HACCP Team carries out a risk assessment for each identified hazard. This is also done systematically, and with the purpose to establish whether a hazard is of such a nature that elimination or reduction to an acceptable level is essential for the production of safe feed ingredients.

## 6.4 Establishing control measures and critical control points (CCP's)

### 6.4.1 Establishing control measures

The HACCP Team must establish, record and implement the measures to control any risk for which it has been established (based on the hazards analysis) that this risk may have a negative effect on feed safety.

More than one control measure may be necessary to control a risk and more than one risk may be controlled by a single control measure.

6.4.2 Establishing critical control points (CCP's)

The HACCP Team must then determine whether this control measure is the last measure in the process for controlling the risk. If this is the case then there is a critical control point (CCP). The reasons for why there is a critical control point (CCP) must be recorded.

### 6.5 Establishing critical limits

In order to establish whether a specific control measure is effective, the HACCP Team must establish for each Critical Control Point (CCP)
a. which parameters must be measured, analysed or observed, and
b. which product standards (action and rejection limits) apply for these parameters.

In establishing the product standards (action and rejection limits) there must be compliance with the relevant feed legislation and the product standards established under this GMP+ FSA module. These product standards must be considered to be (contractual) obligations.

*Guidance*
*In establishing the critical limits or product standards the participant should make use of what has been determined in section 6.2.*

*In addition to compliance with the adopted product standards (GMP+ BA1 Specific feed safety limits) the participant should comply with the residue levels of feed additives and technological additives. GMP+ BA1. Specific feed safety limits contains the maximum residue standards for (critical) feed additives. These product standards in some cases also apply to feed ingredients.*
*To control the residue standards the participant should, among other things, measure the carry-over for the installations and based on the results obtained from this establish the production order. See for this section 5.2.4.1.*

### 6.6 Monitoring

A monitoring plan must be drawn up in writing and implemented which includes in particular the control of critical points in the production process.

The plan includes all planned measurements, analyses and observations of features which indicate that the critical control points are controlled and applies to processed materials up to and including the produced feed (end products).

The monitoring plan must at least be in accordance with the inspections established in this GMP+ FSA module (GMP+ BA4 *Minimum Requirements for Sampling and Analysis*). The participant must provide the reasoning for the structure of the monitoring plan.

The results of the monitoring must be recorded.

The monitoring plan includes:
a. the procedures for and the frequency of the sampling;
b. the (analysis) methods and equipment to be used. These methods must be suitable to achieve planned results;
c. the laboratories that are selected for the analysis concerned;
d. the frequencies of the analyses, checks and inspections;
e. the compliance with the specifications – and the use, in the event of non-compliance with the specifications;
f. all planned inspections and checks and analyses;
g. the instructions for the carrying out of inspections and checks;
h. the personnel responsible for the carrying out of the monitoring;
i. the personnel responsible for the assessment of the monitoring results;
j. the personnel responsible for releasing the feed ingredients.

*Guidance*
*The participant should –as the occasion arises- check that the established residue standards for feed additives and feed medicines are not exceeded. This should be done at least after the measurement of the carry-over and the setting up of the production order, and – if there is reason to do so - at other moments.*

The participant must ensure proper identification and storage of the samples taken for monitoring during an appropriate period of time. See GMP+ BA13 *Minimum Requirements for Sampling*. The participant must make the results available on request to GMP+ International.

If measurement and monitoring takes place by way of an analysis this must ~~– preferably -~~be carried out by a laboratory ~~that is accepted~~ approved for this ~~within~~ under the GMP+ FSA module. ~~The analysis carried out by this laboratory should also be accredited.~~ See GMP+ BA10 *Minimum Requirements for Purchasing*.

~~*Guidance*~~
~~*ISO 17025-accreditated laboratories are accepted within the GMP+ FSA module. It is important to verify that the analysis concerned, is covered under the scope of the accreditation.*~~

~~*Preferably: If it is not reasonably possible to make use of a laboratory with ISO-17025 accreditation for the analysis in question then a participant can also make use of an*~~
~~*a. ISO-17025 laboratory which is accredited for other analyses*~~
~~*b. ISO-9001(2008)-certified laboratory.*~~
~~*If a laboratory does not comply with the above then it is in any event important that the laboratory produces results in a reliable fashion and that an independent third party has assessed this positively*~~

### 6.7 Corrective actions

The participant must ensure that non-conformities (in the feed ingredient or the process) to the requirements in this standard are recorded and controlled in order to prevent unintentional use or delivery of the product. The controls and associated responsibilities and competences for dealing with non-conformities must be defined in a documented procedure.

The participant must deal with non-conforming feed ingredient in one or more of the following manners:
a. by taking measures to remove the observed non-conformities;
b. by permitting use, release or acceptance with the approval of a competent authority;
c. by taking measures to exclude the originally-intended use or application If products are no longer appropriate for feed they must be transported to a destination that is in accordance with the provisions in the applicable feed legislation.

Records of the nature of non-conformities and any measures taken later, including approvals obtained, must be maintained (see section 4.4).
If a non-conformity is corrected it must be verified again to show that it complies with the requirements.

*Guidance*
*This control should provide for identification, documentation, evaluation, segregation (when practical), and disposal of non-conforming feed ingredients and for notification to the involved stakeholders, both internal and external.*

## 6.8 Validation and verification

### 6.8.1 Validation

An independent validation of the HACCP plan must be carried out. Management must establish a validation team in order to avoid undue influence. The members of the HACCP team can be members of the validation team but the validation team must have independent members. If this is not possible for the participant then he may deviate from this as long as his reasons are given.

The composition of the validation team and the activities they carry out must be clearly laid down.

*Guidance*
*The purpose of validation is to establish beforehand independently that the hazards which were originally established by the HACCP team are complete and correct and that they will be effectively controlled using the HACCP-plan.*

*It is apparent from the requirements that validation cannot be carried out by the HACCP Team itself as independence would not be guaranteed. If a participant has no possibility to establish a separate team then he may deviate from this. The reasoning does have to be provided.*
*Independent persons are, for example, members of production who were not directly involved in the drawing up of the HACCP Plan.*

*Collecting and assessing objective evidence (like results of analysis) may give a clear understanding of the way the HACCP-plan is working. See for this section 8.3.*

### 6.8.2 Verification

Once the HACCP plan has been drawn up, a periodic (at least yearly) verification of (elements of) the system must take place. Verification is carried out and documented by the HACCP team. See also section 8.3.

*Guidance*
*Verification is the use of additional information to check if the system is still effective and whether it is being used as intended.*

*The verification of the HACCP plan is often carried out as part of a general review of the management system. Other requirements for a complete assessment have for these reasons been laid down in section 8.3 'Assessment of the management system and improvements'.*

# 7 Control of operational activities

## 7.1 Purchase

### 7.1.1 General

The participant must ensure that the purchasing of raw materials (including processing aids, etc.), services and feed ingredients are in accordance with the GMP+ requirements. The purchase of all raw materials, services and feed ingredients must be clearly recorded.

A documented procedure must be drawn up for the whole purchase process. Specifications must be documented and must be part of the purchase documents and contracts.

*Guidance:*
*The purchasing process as such is a process of major importance that must be controlled in order to be able to guarantee safety of the feed ingredients.*

### 7.1.2 Purchasing

The participant must ensure that any purchased products as well as services are in compliance with the specified purchasing requirements.

If the participant wants to purchase an assured product or service (GMP+ assured or equivalent), it is his responsibility to demonstrably communicate this with the supplier. This is –of course- not applicable when an accepted gatekeeper option for purchasing is applied. See for this GMP+ BA10 *Minimum requirements for Purchasing*

The participant must select and assess its (potential) suppliers, choosing suppliers that are capable of delivering products and/or services that comply with the specified requirements.

At least the following requirements must be met with respect to the above.

If the participant purchases feed (to which feed ingredients belong) or certain services, the participant must make sure that these feed ingredients or services are:

a. from suppliers who are GMP+ certified at the moment of delivery, or
b. from suppliers which are certified based on a standard approved in the GMP+ FSA module;
c. certain feed ingredients and services may also be bought without one of the above certificates (i.e. from a non-certified supplier). Separate requirements have been established for this.

In GMP+ BA10 *Minimum Requirements for Purchasing* there are more details of the specific feed and services concerned, and further details of the above options.

d. Prior to the purchase of products or services that differ from the above meant the participant must carry out its own risk assessment based on HACCP principles. Based on this risk assessment and the quality assurance, which is applied by the supplier, the participant must make a selection of suppliers and must adjust his (entry) check accordingly.

*Guidance*
*The specified purchasing requirements are based on the requirements applicable to the feed ingredients to be produced (finished product; see section 6.2).*

*Above, the purchasing requirements as included in the GMP+ FSA module are listed. Not all requirements are relevant to producers of feed ingredients (feed materials or additives), as these producers produce, rather than purchase, feed ingredients. A producer of feed ingredients is often the first link in the GMP+ chain. The requirement that the suppliers of the raw materials must also be GMP+ certified is in those cases often not applicable.*

*The key requirements are listed under c and d, together with the annexes 2 through 4 of GMP+ BA10 Minimum Requirements for Purchasing. For the requirements relating to purchasing additives and unprocessed agricultural products, see the mentioned annexes in GMP+ BA10 Minimum Requirements for Purchasing.*

*If a participant – for whichever reason – purchases feed ingredients, these feed ingredients may exclusively be purchased from companies that are at that time certified for GMP+ or for a different assurance scheme approved as equivalent. Please refer to GMP+ BA10 'Minimum Requirements for Purchasing' in this respect.*

*Within the framework of the GMP+ FSA module, certification of the following services is possible: transport, storage, transshipment and laboratory services. If a participant buys one of these services, the participant must ensure that these services are certified for GMP+ or for a different standard approved as equivalent. Please refer to GMP+ BA10 Minimum Requirements for Purchasing in this respect:*
*a. A number of special exceptions apply relating to outsourcing storage and transport, in particular outside the Netherlands. Please refer to the relevant sections in this respect.*
*b. Production phases such as drying or packaging to third parties can be outsourced exclusively to certified companies. Please refer to GMP+ BA10 Minimum Requirements for Purchasing in this respect.*
*c. If a participant purchases any other types of services, for example cleaning silos, pest control, maintenance of installations et cetera, a certificate is not required. This only requires compliance with the conditions listed under d.*

### 7.1.3 Assessment of suppliers

The participant must assess all its suppliers on an annual basis. This requires determining criteria for selection, assessment, approval and evaluation. The participant must demonstrate that all suppliers always comply with these requirements.

*Guidance*
*Relating to this issue, please refer to document 'The Supplier under the spotlight – a guide for supplier assessment'. This document is available as a GMP+ D-document on the GMP+ International's website.*

### 7.2 Verification of received products

There must be a procedure for the acceptance of receiving of all products. This procedure must prescribe criteria for the proper acceptance of the products including criteria for the approval of transport.
Each incoming delivery must be verified on the basis of the specifications. During the entry check all incoming feed ingredients must be released before they can be stored and/or further processed. For the requirements with respect to sampling see section 5.4.

The products must comply with the specifications. Checking on compliance with specification is a major issue. The participant must also verify if the transport complies with the agreed requirements.
Note: If any kind of feed is received, the transport to the participant must be GMP+ certified. The participant must then include in his entry check as a minimum: a check on the correct GMP+ certification of the carrier, compliance with the requirements with respect to loading sequence, previous loads and implementation of the necessary cleaning regimes. The LCI reports for all received sea transport, short sea shipping, inland waterway transports or rail transport should be available or retrievable.

In the case of doubt the specifications must be verified by way of analysis. The frequency of this may differ for the various parameters. In addition, batches from 'new' suppliers must be checked at a higher intensity.

The received products must not be accepted if they do not comply with the specifications unless they are treated to ensure that the batch does comply with the safety specifications.

*Guidance*

*Inspections should include, as appropriate, assessment of:*
*a. Colour;*
*b. Physical form;*
*c. Odour;*
*d. Contamination by insect pests, droppings and other extraneous matter;*
*e. Moisture/Mould;*
*f. Excessive damage;*
*g. Compliance with specification.*

*With regard to transport, the participant should check, if applicable:*
*a. Proper certification of transporter/carrier?*
*b. Is the mean of transport acceptable? Leakage of oil!*
*c. Are the previous loads acceptable?*
*d. Has proper cleaning been carried out?*
*e. Has a load compartment inspection taken place?*

*In most situations a producer of a feed ingredient is to be considered the first link in the feed chain. Therefore, the transport of the raw materials to his plant does not have to be GMP+ certified. Verification should be focussed on compliance of the carrier with the agreed conditions.*

*If however – for any reason – the producer receives feed products under GMP+-certification, the entry check should include verification of the relevant GMP+ transport requirements.*
*A hazard analysis can provide information with which the intensity and the size of the entry checks could be established.*

## 7.3 Storage

### 7.3.1 General

The participant must control all storage activities with his own feed safety management system, in accordance with the requirements of this standard. This applies to storage
a. at both own and hired sites, and
b. both packaged and unpackaged feed ingredients or raw materials

Control measures for the storage must be documented.

Feed ingredients and raw materials must be transported (internally) and stored in such a way they are and remain easily identifiable. This is to avoid confusion, (cross-) contamination and degradation of the quality.

All products produced or stored in the same premises by the participant but not intended for feed use must be clearly segregated from feed ingredients and identified as such during all stages of production, packing, storage, despatch and supply, unless the hazard analysis demonstrates that non-separated storage does not entail any risks to the feed ingredient.

Where applicable, temperatures must be kept as low as possible in order to prevent condensation and spoiling. The presence of (storage) fungus may be detected based on discoloration and a musty smell. The responsible person should examine the batch for the presence of storage fungi (by means of using his senses).

The participant may only use stock protection agents if:
a. they are approved by the competent authorities, and
b. they are in accordance with the user instructions, and
c. they are applied by qualified persons, (persons who have permission to use the stock protection agent) .

The responsible person must document which agent is used, when it is used and for which feed ingredients. It is then important that the prescribed waiting times are taken into consideration.

Alternatively, storage may be outsourced to a GMP+ certified company, or a company certified for a different scheme approved as equivalent to the GMP+ FSA module. In some specific situations, storage may also be outsourced to a non-certified company. For more details and to look up acceptable storage certificates, please refer to GMP+ BA10 *Minimum Requirements for Purchasing*.

*Guidance*
*Decay is influenced by the duration, temperature and relative moisture content during storage. In storage conditions which are too damp and/or too hot there is a risk of decay through microbes, fungus and the creation of mycotoxins. The correct conditions should be controlled.*
*Non-separated storage is possibly not necessary if foodstuffs are stored in the same space.*

## 7.4 Production

### 7.4.1 General

All activities must be carried out in conformity with this standard.

Production must be planned, scheduled and controlled by a designated and competent person, to ensure compliance with documented feed ingredient specifications and documented parameters for critical processes.
There must be suitable checks during the activities. All process controls relevant to the safety of the feed ingredients being produced must be demonstrably effective and managed in accordance with formal HACCP principles.

Procedures must include corrective actions to be taken in the event of critical process parameters being breached.

Where production processes contain an effective ‘kill step’ that is critical in maintaining the acceptable micro-organism count in feed ingredients, the participant must ensure that controls are in place to prevent feed ingredients becoming re-contaminated with pathogens at subsequent process stages. The participant must pay particular attention to areas where condensation may occur or where material is allowed to bypass the kill step and rejoin the finished goods stream.

Where mixing forms an essential part of the process, tests must be carried out to establish initial effectiveness of equipment and, on a subsequent frequency determined by risk analysis, to ensure that no loss of efficiency occurs through the effects of wear and tear. Records must be kept of such tests.

In situations where breakdown or other unforeseen circumstances result in the production of feed ingredients that do not meet the specification, the resulting products must be treated in accordance with Non-Conforming Product procedures.

7.4.2 Non-conforming products

The participant must establish a documented procedure for dealing with raw materials and feed ingredients that do not comply with specifications.

This procedure must include:
a. Identification of batches / lots affected.
b. Documentation for managing and recording non-conforming products.
c. Evaluation of the cause of the non-conformance.
d. Segregation of batches / lots affected.
e. Communication with relevant parties.
f. Preventive or corrective action to avoid repetition of the non-conformance.

Responsibility for review and disposal of non-conforming products must be defined. All incidences of non-conforming raw materials or feed ingredients must be recorded and decisions regarding actions to be taken must only be made by authorised personnel.

Non-conforming feed ingredients must be dealt with in one of the following ways:
a. Sent to waste or used as biomass;
b. Reworked;
c. Accepted by concession (if agreed in writing by the client);
d. Downgraded (if meeting the specification of another feed ingredient).

Requirements for reprocessing non-conforming feed ingredients must be documented and any affected feed ingredients must be re-evaluated on completion to ensure that the batch / lot concerned subsequently meets specified requirements.

The approval and use of reworks (e.g. from quality rejects, customer returns or spillage) must be considered within the HACCP Plan. Those that are not approved must become waste and be disposed of accordingly.

Feed ingredients that do not fully meet a customer specification must only be supplied if the customer is notified of the problem in writing and confirms in writing that he is prepared to accept them.

## 7.5 Sale and contracts

Feed ingredient specifications must be agreed between the participant and the purchaser and confirmed in the contract. The participant must ensure that all feed ingredients supplied meet the agreed specifications.

The sale of feed ingredients must be clearly recorded.

*Guidance*
*Feed ingredients specifications are related to feed safety: see section 6.2.2.*

### 7.6 Labelling and delivery requirements

The participant must provide his customer with the necessary information with respect to the feed ingredients supplied so that his customer (the next link in the chain) can carry out his own proper hazard analysis.

See GMP+ BA6 Minimum requirements for labelling & delivery for additional labelling requirements.

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|---|
| On delivery the batch must be accompanied by the legally-required product information. The documentation with respect to delivery must be clear.<br><br>The participant must ensure that the feed ingredients which are supplied by him comply with the applicable requirements for both the country in which it was produced or treated and, if applicable, the country in which it is placed on the market. |

### 7.7 Transport

#### 7.7.1 General

Transport may not lead to undesired contamination of the feed. To control the risks of contamination of feed ingredients during transport the participant must at least apply the relevant requirements and prescribed working methods specified in section *Procedures GMP+ International* published on the IDTF website.

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|---|
| All means of transport (whether by ship, barge, road vehicle, rail, container or other transport system) whether owned or contracted by the participant to carry either raw materials or feed ingredients, whether in bulk or packed, must be appropriate and controlled with specific regard to hygiene and potential contamination. Cargoes being carried concurrently with raw materials and feed ingredients must not adversely affect the safety of the raw materials and feed ingredients.<br><br>Where transport is used to carry raw materials and feed ingredients, the individual load compartments used must be recorded. For road / rail vehicles this may be the trailer / car number or, where load compartments are split into sections, the individual section must be recorded. For water transport, where load compartments are split into holds, the individual hold numbers must be recorded.<br><br>When the participant is responsible for arranging transport of feed ingredients to purchasers operating under a certified assurance programme, he must ensure that the specific transport requirements of that programme are met.<br><br>In any event the participant must provide the carrier with information with respect to the nature of the product and of the specific product characteristics including its (chemical) composition, to enable the carrier to determine a correct cleaning regime.<br><br>When the participant is not responsible for the transport and is instructed by a buyer to load a batch in a means of transport which does not comply with the requirements then the participant must consult with the buyer for further instructions before loading. The results of this consultation must be demonstrable. |

Internal transport
Internal transport (see GMP+ A2 *Definitions and Abbreviation*), whether carried out by own means or by a subcontractor, must comply with corresponding sections of GMP+ B4. This internal transport must as such be covered under the scope of certification. However, a scope Transport (in case of own internal transport) or hiring certified transport company (in case of subcontracting) is not necessary

*Guidance*
*For transport of feed ingredients in general it applies that before loading, load compartments should be empty, clean, dry and free from any remnants and odours of previous cargoes, in order to prevent load contamination. This includes:*
a. *Free of possible "agribulk-unfriendly elements", such as residues of preceding cargo and/or cleansing activities.*
b. *Free of pest, in the broadest sense of the word (insects and pest, dead or alive).*

*In order to comply with this, it may be necessary to clean the load compartment (before loading of the feed ingredients). If cleaning is necessary, this should be done in relation to the nature of the previous cargoes. See for this section Procedures GMP+ International published on the IDTF website*

*After this cleansing, the load compartment should be inspected for cleanness.*

*Furthermore, the load compartment should be shielded to protect the transported cargo against influence from other transported goods and be provided with resources to cover the cargo during transport.*

### 7.7.2 Road transport with own means of transport

#### *7.7.2.1 General*

The road transport of feed ingredients must meet the requirements in the GMP+ B4 Transport and be certified as such.

*Guidance*
*If the participant is not responsible for the transport then a limited number of requirements are still set (section 7.7.4).*

### 7.7.3 Road transport, carried out by subcontractors

Road transport is carried out by a GMP+ B4 *Transport* certified transporter, or by a transporter with an equivalent certificate. See for this GMP+ BA10 *Minimum Requirements for Purchasing*.

For some countries it is also possible to make use of non-certified carriers. In this case, the participant must apply the conditions from GMP+ BA10 *Minimum Requirements for Purchasing*, Annex 9.

Transport of packaged raw materials or feed ingredients

If a participant makes use of an external carrier for the transport of packaged raw materials or feed ingredients then this external carrier and / or fright broker does not have to be GMP+ certified or equivalent. Risk assessments must consider any potential hazards and ensure that controls effectively preclude any serious risk of contamination. Transport of packaged raw materials or feed ingredients must take place in a clean and dry loading compartment.

*Sealed loading units*
Under certain conditions sealed loading units are considered to be packaged products and therefore non-certified external carriers can be used. This is allowed when non-certified external carrier has no influence on the transported raw materials or feed ingredients. The carrier just positions this sealed loading unit on a chassis and brings it to the customer. Additionally to the above requirements this means practically that:

a) Management of cleaning and inspection of the loading unit is the responsibility of participant.
b) The loading unit must be closed and sealed on the responsibility of the participant immediately after loading. The seal may only be broken at the customer.
c) The carrier may not use own loading / unloading equipment (pipes, hoses etc.) unless the participant has agreed this with the customer.

### 7.7.4 Road transport, contracted by third parties (participant is not responsible for transport

Where a third party is responsible for the transport, the participant must take reasonable precautions to avoid potential hazards.

Where feed ingredients are to be loaded into transport contracted by the purchaser of the feed ingredients, the participant must ensure that any transport offered is suitable to receive the feed ingredients supplied and cleaned.

Should the participant be instructed by a purchaser to load transport that is considered unsuitable by the participant, he must inform the purchaser of any concerns and obtain written confirmation of such instructions from the purchaser, prior to loading. Copies of associated correspondence must be retained.

*Guidance*
*A hazard analysis can provide information with which the intensity and the size of the checks could be established.*

7.7.5 Transport via inland waterway, by sea and by rail

a. inland waterway transport to GMP+ B1-certified companies

If the affreightment of inland waterways transport takes place on the responsibility of the participant, he must be GMP+ B4 certified. If a third party is responsible, then this third party must be GMP+ B4 certified.

For the activities below no certification for GMP+ B4 is required, but the participant must demonstrably comply with corresponding sections of GMP+ B4. The participant must guarantee these activities in the feed safety system.

| | |
|---|---|
| Giving the order for affreightment: | demonstrable compliance with GMP+ B4 section 7.2.1 and 7.2.2 and guaranteed activity in the feed safety management system. |
| Approval of the ship before loading: | demonstrable compliance with GMP+ B4 section 7.2.1 and 7.2.2 and guaranteed activity in the feed safety management system. |
| Giving the order for LCI: | demonstrable compliance with GMP+ B4 section 7.2.3 to 7.2.5 and guaranteed activity in the feed safety management system. |

The carriage (= the actual transportation by inland waterway vessel) must be GMP+ B4.3 *Inland Waterway Transport* certified.

b. sea transport and rail transport to GMP+ B1-certified companies

Transport by sea or by rail should comply with the requirements of GMP+ B4 Transport (*Road & rail transport and affreightment)* The principal for the sea transport or rail transport should be certified as such.

c. inland waterway transport, sea transport and rail transport to other GMP+-certified companies

In the event of transport via inland waterway, sea transport and transport per rail, an inspection should take place to check the cleanliness of the loading compartments (LCI = Loading Compartment Inspection) before loading is started. The loading process should also be controlled to be able to guarantee feed safety.

The participant who himself acts as the affreightment party cannot carry out an LCI.
The inspection must be carried out by an inspection agency at EN 17020 level which is specialized in, and is accredited for, feed / grains or liquid agri-bulk and operates internationally on the basis of a certified quality system such as ISO 9001 or equivalent

If the participant does not act as the affreightment party, he can carry out the inspection by himself. This can be done by a loading inspector from the company. The 'load inspector' is a function specified in the quality system of the company and must be performed by an employee who - on the basis of training and experience - has the knowledge and skill to assess loading compartments on their suitability for use with feed ingredients.

In the event of the transport of GMP+-assured feed ingredients and non-GMP+-assured feed ingredients there must be a strict physical separation of these feed ingredients.

# 8 Verification and improvement

## 8.1 Complaints

The participant must document his procedure for handling complaints from customers. This procedure must in any event describe the registration of relevant aspects of the complaint and the measures taken.

A procedure for recording and handling complaints must at least consist of:
a. The registration of complaints
b. The examination of the sources of complaints
c. Registration of the measures which were taken as a result of the complaint
d. Registration of communication with the customer in question.

## 8.2 Internal audit

The participant must have a documented procedure for internal auditing.

Internal auditing procedures must require the participant to carry out a programme of planned audits to check that internal systems are operating as intended and are also effective. Such internal audits must encompass:
a. Compliance with the requirements of this standard.
b. Compliance with the requirements of the participant's HACCP Plan.
c. Compliance with the participant's formal procedures.
d. Compliance with legislation pertaining to feed ingredient safety and quality.
e. Satisfaction of specified customer requirements.

The programme of internal audits must ensure that all relevant activities are audited at least once a year (= every 12 months).

All personnel carrying out internal audits must be competent for this by training or education (internal or external), or experience.

Internal audits must be formally reported to those with responsibility for the area audited and record any aspects where the operations are not in compliance with operational requirements. Such areas of non-compliance must be corrected and audit report records signed off by an authorised person to indicate that problems have been corrected satisfactorily.

## 8.3 Management and review and improvement

The participant must establish, collect and analyse suitable data at least once per year
a. in order to show that the feed safety system is suitable and effective, and
b. to assess whether continuous improvement in the effectiveness of the feed safety system is possible

A documented procedure must be established up for this.

Verification of (elements of) the HACCP plan is part of this review.

This must be part of the management review (see section 4.1)

The input for such a review should in any event contain information on:
a. Assessment of the prerequisites programme
b. Assessment of analysis results for products
c. Verification of the hazards analysis.
d. Assessment of the level of knowledge of the personnel
e. the results of the supplier evaluation
f. feedback / complaints from customers
g. Assessment of the implementation of legislation and regulations
h. the results of internal and external audits
i. Changes which have an influence on the feed safety management system.

This review should in any event contain information about:
a. the extent to which the feed safety system must or can be modified
b. the possibilities and chances of improving the feed safety management system

The results of the management review must be recorded

*Guidance*
*See for details on the verification of the HACCP plan, the HACCP Manual.*

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