GMP+ International

Production, Trade and Services

GMP+ B 1

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GMP+ Feed Certification scheme

Feed Safety Worldwide

gmpplus.org

History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
/ 09-2010	Previous versions can be found in History		01-01-2011
/ 09-2011			01-01-2012
0.2 / 11-2012			01-03-2013
1.0 / 06-2014	Editorial changes: 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
	The requirements regarding the notification of contamination in feed towards customers and in the framework of the EWS has been updated.	6.6	01-01-2015
	Requirements for control of residues have been updated. Detailed requirements have been transferred into 1 new appendix, called GMP+ BA2 'Control of residues'.	6.7.1.5	01-10-2015
	Requirements for specification of the status of the feed product or service to be purchased has been updated.	7.10.2	01-10-2015
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2.0 / 11-2015	Definition domestic animals is changed. The FSP list is not applicable for feed for non-food producing animals.	Par. 7.2.1	01-04-2016
	Requirements for specification of the status of the feed product or service to be purchased has been amended.	Par. 7.10.2	01-04-2016
3.0 / 04-2017	Homogeneity requirements are tightened. Reference is made to the standards in the GMP + BA2. Some textual corrections	6.7.1.3 Entire document	01-07-2018
4.0 / 05-2018	Corrected reference	5.5.2 b	01.07.2018
	Requirements for internal transport are added	4.1	01.07.2019
	Link is added to the GMP+ B11 *Protocol for GMP+ registration for laboratories*	7.7.1	01-07-2019
	Reference is added to GMP+ BA7 *Specific requirements for by-products from Oil and Fat Industry*	7.2.1	01-01.2019

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.

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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.

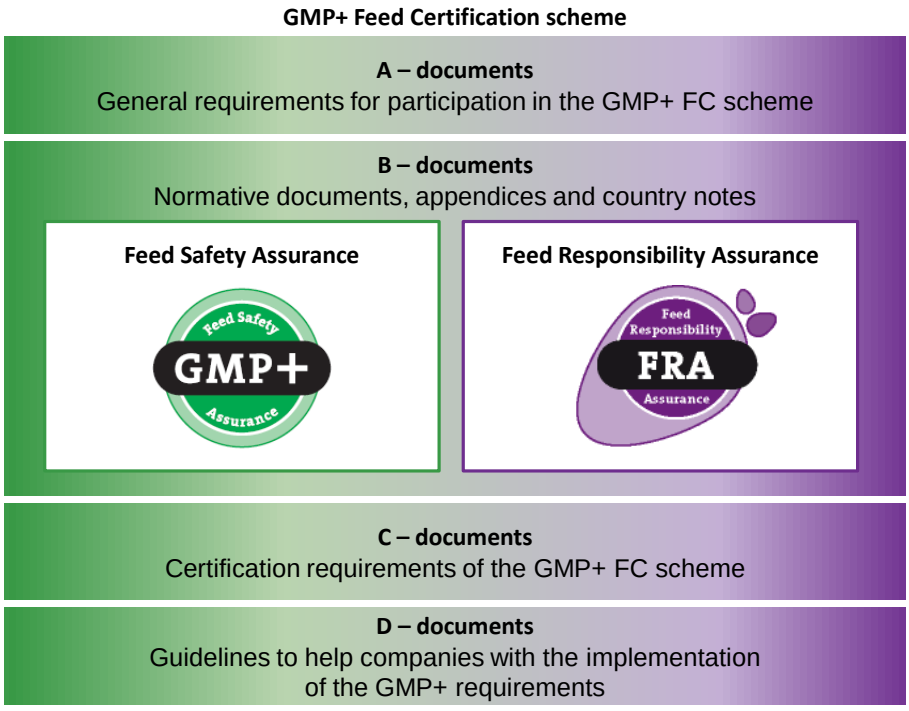
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and 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+ B1 *Production, Trade and Services* and is part of the GMP+ FSA module.

1.3 Scope and application of this standard

This standard gives the conditions and requirements for establishing a feed safety management system to assure:
a. production/processing of feed,
b. trade in feed;
c. storage and/or transhipment of feed

In most cases in this standard in the requirements for production or processing of feed the word ‘production’ is used. In some cases this may be taken to mean ‘processing’. The requirements relate to each form of physical action on or to feed. Examples of physical actions during the production or processing of feed are: collection, drying, cleaning, mixing, packaging, storing, transhipping.

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 describ7es as accurately as possible for activities or feeds 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 with feeds which are outside the scope of this standard, it may be necessary to apply another GMP+ standard instead of, or in addition to, this standard.

For exact details is referred to GMP+ C10 *Acceptance requirements and Procedure for Certification Bodies*, Annex 1.

The participant remains responsible at all times for the safety of the feeds 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 of his services or feeds 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

This standard is structured according to the latest version of the ISO 9001 standard. The requirements regarding the prerequisite programme are laid down in chapter 6. Requirements related to the application of HACCP are laid down in chapter 7. This standard is easy to combine with the ISO 9001, ISO 22000 standard or with any other GMP+ standard.

GMP+ Appendices (GMP+ BAxx), to which there are also references, are separate GMP+ documents within the B part. 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.

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 the 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

See GMP+ A2 *Definitions and Abreviations*.

4 Feed Safety Management System

4.1 Requirements for the feed safety management system

The participant must set up the feed safety management system so that it complies with the requirements of this GMP+ standard. The participant must document this, implement it and maintain it as well as continuously improve its effectiveness.

The participant must:

a. establish and record the scope of the feed safety management system. The scope must at least include the activities related to feed for which the participant is responsible:

1. The responsibility of the participant begins where the responsibility of the previous link (the supplier) ends, and ends where the responsibility of the following link (the customer) in the feed chain begins.

2. The participant must specify every feed which he puts on the market, processes, treats or trades.

3. All business locations and processes / process lines where production, treatment, processing, trade, storage & transhipment (wether at owned or hired sites), affreightment and transport of feed (wether packaged or un-packaged) are carried out, must be brought under the scope of the feed safety management system. This might mean application of other GMP+ standards as well. See also GMP+ A1 *General regulations* and the next subarticles 4.1.a.6 up to 4.1.a.8.

4. If an participant decides to outsource a process which influences ompliance with the requirements on the product, the participant must ensure that such processes also comply with the requirements of this GMP+ standard. The participant must at least comply with section 7.10.

5. All other activities, which means the activities which are not able to over under this or other GMP+ standards, must also be described by the participant. The participant must ensure that these activities do not have a negative influence on the safety of the feed.

<u>Possibilities for exclusions from scope of the feed safety management system:</u>

6. All activities related to pet foods may be excluded on the condition that they are produced, traded and/or transported as such separately and that they do not have an influence on the safety of feed which are covered under the feed safety system.

7. For a company which also carries out trading activities it is permissible to exempt the part of the trade in non – GMP+ certified feeds from the scope of the feed safety management system. This should however be available for checking. The participant will in his records make a clear and demonstrable distinction between the GMP+ assured feed materials and the non – GMP+ assured feed materials.

See GMP+ BA6 *Minimum requirements for labelling & delivery* for the specific requirements regarding the trade and labelling of non-GMP+ certified feeds.

Feed materials which are delivered to livestock farmers, irrespective of whether they participate or not in chain quality programmes, should always be covered by the GMP+ certificate.

8. Transport of packaged raw materials or feed
If a participant makes use of an external carrier for the transport of packaged raw materials of feed~~,~~ then this external carrier (and / or freight 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 feed 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.

9. 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.

b. determine the sequence and interactions of the processes; identify all critical items in the production process which influence the feed safety of the feed or the service (see section 7.4)

c. determine criteria and methods required to ensure that both the implementation and control of these processes are effective

d. ensure that resources and information are available as required for the implementation and monitoring of these processes

e. monitor, measure and analyse these processes

f. implement actions which are necessary to achieve planned results and continuous improvement of these processes.

These processes must be managed by the participant in accordance with the requirements of this GMP+ standard.

NOTE:
If at one location several companies carry out activities covered by a GMP+ standard, each of them must hold a certificate for these activities. See GMP+ A1 *General Regulation*.

4.2 Documentation

4.2.1 General

The participant must maintain a register of the documentation related to the production process and the controls.

The participant must have a documentation system for the description of the critical points in the production process and for the drawing up and implementation of a feed safety management system. He must keep the results of the controls. All these documents must be kept to be able to trace the production history of any batch of feed put on the market and in the event of complaints to be able to determine responsibility.

The documentation of the feed safety management system must include:
a. documented statements of the involvement of the management, the feed safety policy and feed safety objectives
b. a quality manual
c. documented procedures required by this GMP+ standard
d. documents with which the participant ensures the effective planning, implementation and control of the production processes
e. records required by this GMP+ standard (see section 4.2.4)
f. all relevant required permits, records and certificates under the applicable feed legislation.

4.2.2 Quality manual

The participant must set up and update a quality manual which includes:
a. the scope of the feed safety management system, including the details of and clear justification for any exclusions
b. the documented procedures as required as a minimum under the GMP+ standard(s) which have been established for the feed safety management system or a reference to them
c. a description of the interactions between the processes of the feed safety management system
d. the structure of the documentation.

4.2.3 Control of the documentation

Documents which are required by the feed safety management system must be controlled.

There is a documented procedure in which the authorities related to the approval, issue and control of documents and data are regulated. Controls are established in this as needed to:

a. approve documents with respect to suitability before they are issued;
b. review documents and update them if necessary and to re-approve them; as in the event of changes to applicable the feed legislation and/or the GMP+ standard;
c. know changes and the current revision status of the documents;
d. have the current versions available at workplaces where activities are carried out which are important for the implementation of feed safety;
e. keep documents legible and easily recognisable;
f. keep documents from an external source recognisable as such and controlling their distribution;
g. prevent of unintended use of lapsed documents and application (=using) of appropriate identification if they are retained for whatever reason.

Records must be controlled in accordance with the requirements in section 4.2.4.

4.2.4 Control of the records

Records must be established and maintained to provide evidence of compliance with the requirements and of the effective operation of the feed safety management system so that the feed safety of the feed is guaranteed.

Records must be legible, easily recognisable and retrievable. A well-documented procedure must be established to define the control required for the identification, storage, protection, retrieval, storage period and destruction of records.

The storage period for these records amounts to at least three years unless a longer storage period is required according to the applicable feed legislation or other regulations.

5 Management responsibility

5.1 Management commitment

Top management must demonstrate its involvement in the development and implementation of the feed safety management system and the continuous improvement of its effectiveness through:

a. making known within the organisation the importance of compliance with both the requirements of the customers and the applicable feed legislation;
b. establishing the feed safety policy (see section 5.2);
c. establishing a management statement;
d. establishing feed safety objectives (see section 5.3.1);
e. carrying out management reviews (see section 5.5);
f. ensuring the availability of resources (see section 5.4.4).

5.2 Feed safety policy

Top management must ensure that the feed safety policy:

a. is appropriate for the production and maintenance of safe feed;
b. is matched to the requirements of customers as established within the framework of chain programmes;
c. prescribe that the organisation works in accordance with the requirements of the feed safety management system;
d. offers a framework for the establishment and assessment of feed safety objectives;
e. is made known and is understood within the organisation, and;
f. is reviewed for continuing suitability and improvement.

5.3 Planning

5.3.1 Feed safety objectives

Top management must ensure that objectives related to the safe production of feed are established for relevant functions and levels within the organisation. The feed safety objectives must be measurable and consistent with the feed safety policy.

5.3.2 Planning of the feed safety management system

Top management must ensure that

a. the feed safety management system is implemented and maintained correctly in order to comply with both the requirements in section 4.1 and the feed safety objectives, and
b. the operation and cohesion of the feed safety management system is maintained when changes relating to the feed safety system are planned and implemented.

5.4 Responsibility, authority and communication on feed safety

5.4.1 Responsibility and authority

Top management must ensure that the responsibilities and competences are defined and made known in writing within the organisation. This applies in particular to the HACCP team (see section 5.4.2) and to the other functions which influence feed safety. The participant must record the responsibility structure in an organisational chart.

5.4.2 HACCP-Team

Top management must establish a HACCP team to set up and maintain the feed safety system.

Top management must show that the HACCP team has expertise in various disciplines, or can obtain this, if necessary for the establishing and maintenance of the feed safety system (see section 6.2.2a).

In the event of more than one HACCP team, there must be a coordinator who has responsibility for progress and for the proper establishment and maintenance of the feed safety system.

5.4.3 Management representative

Top management must appoint a management representative who, irrespective of other responsibilities, must have the responsibility and authority:

a. to establish a feed safety management system and to implement it and maintain it in accordance with this standard, and
b. to report to top management on the performance of the feed safety management system and any need for improvement, and
c. to ensure that the awareness of the requirements of chain stakeholders is promoted throughout the whole organisation.

5.4.4 Provision of resources

Management must determine which resources are needed and ensure that these resources are available

a. to implement and maintain the feed safety management system and continually to improve its effectiveness.
b. to improve feed safety through compliance with the requirements of the chain stakeholders as established in the GMP+ FSA module.

5.4.5 Internal communication

Top management must ensure that appropriate methods of communication are established within the organisation and that communication takes place with respect to the effectiveness of the feed safety management system in order to comply with the GMP+ standard.

5.5 Management review

5.5.1 General

Top management must review the feed safety management system at least once per year with regard to effectiveness and whether it is possible to comply with the requirements of this standard. This review must also include the assessment of opportunities for improvement as well as the need for changes in the feed safety management system, including feed safety policy and feed safety objectives.

Records of management reviews must be kept (see section 4.2.4).

5.5.2 Review input

The input to the management review must include information on:

a. results of the monitoring plan (section 7.7.1), the internal audits (section 8.2) and the verification (section 8.3)
b. the assessment and evaluation of the suppliers (sections ~~7.11.1~~ 7.10.1 and 8.3)
c. results of external audits
d. feedback from customers
e. the extent to which the processes and the feed comply with the requirements
f. status of preventive and corrective actions
g. follow-up measures from previous management reviews
h. changes which may influence the feed safety management system, and
i. recommendations for improvement.

5.5.3 Review output

The output of the management review must consist of the exclusions and measures with respect to:

a. improvement of the effectiveness of the feed safety management system
b. improvement of the feed with respect to the requirements of the stakeholders in the chain, and
c. requirement for resources.

6 Prerequisites Programme

6.1 General

In order to be able to apply the HACCP principles successfully, the participant must establish and apply a general prerequisites programme for parts of the business process as shown in the table. The participant may implement additional prerequisites.

The participant may exclude prerequisites as long as reasons are given. The requirements specified in section 1.5 Exclusion of Prerequisites also apply.

Summary table of GMP+ prerequisites

Section	Subject	Section	Subject
6.2	Personnel	6.3.2.4	Other facilities
6.2.1	General		Processing aids
6.2.2	Competence, awareness and training		Packaging material
6.3	Infrastructure		Water
6.3.1	Basic requirements	6.4	Working environment
6.3.2	Requirements for company layout, production areas, installations and other facilities	6.4.1	Maintenance
6.3.2.1	Business set-up	6.4.2	Cleaning
6.3.2.2	Production areas	6.4.3	Pest control
	General	6.4.4	Waste control
	Windows and other openings	6.5	Identification and traceability
	Disposal facilities		General
	Ceilings		Retained samples
	Water drainage	6.6	EWS and Recall
	Light	6.7	Production
	Access regulation	6.7.1	General (= control of production)
	Storage areas	6.7.1.1	Drying
	Physical separation	6.7.1.2	Dosage
	Silos	6.7.1.3	Mix
6.3.2.3	Installations	6.7.1.4	Pelletising/expansion/extruding
	Mixing installations	6.7.1.5	Control of residue norms
	Weighing / dosage installations		Carry-over
	Drying installations		Production sequence
	Measurement facilities on process equipment	6.7.1.6	Return flows
	Control of monitoring and measurement equipment		

6.2 Personnel

6.2.1 General

Personnel performing work affecting feed safety must be competent based on appropriate education, training, skills and experience. The participant must have personnel with the skills and qualifications which are required for the production of safe feed.

The production department must be led by a person who has the necessary qualifications.

Where relevant, a person with relevant qualifications, must be responsible for quality control.

An organisation chart must be drawn up. There must also be a description of the qualifications (for example diplomas, professional experience) and the responsibilities of the supervisory personnel which must be made available to the competent authorities who are responsible for inspection.

The personnel must be clearly informed in writing of the tasks, responsibilities and authority, especially in the event of changes, to obtain the desired feed safety.

The participant must ensure that the personnel take care of themselves with respect to feed safety. Protective clothing must be worn if the risk assessment shows that contamination of feed materials may occur.

There must be clear rules with respect to eating, drinking and smoking in the production areas which are aimed at avoiding contamination of feed.

6.2.2 Competence, awareness and training

The participant must:

a. determine the necessary skills for the personnel performing work which influences the achievement of safe feed. This also applies to the HACCP team
b. provide training or take other actions to satisfy these needs
c. evaluate the effectiveness of the actions taken
d. ensure that its personnel are aware of the importance of their activities with respect to feed safety and how they contribute to the achievement of feed safety objectives
e. maintain records of personnel education, training, skills and experience (see section 4.2.4).

6.3 Infrastructure

The participant must determine, provide and maintain the infrastructure needed to comply with the product requirements (see also section 7.4.2).

Infrastructure includes, as applicable:
a. buildings, workspace and associated facilities (such as tools and machines)
b. process equipment (both hardware and software), and
c. supporting services (such as transport or communication).

6.3.1 Basic requirements

Production 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.

Production buildings may not stand on or near places which clearly present a danger to feed safety such as contaminated sites, waste sites, etc. If the environment entails risks for feed safety the participant must show by way of a risk analysis that the risks are controlled.

6.3.2 Requirements for facilities, production areas, installations and other facilities

6.3.2.1 Facilities

The facilities must be such that:
a. the chance of errors is as small as possible and contamination, cross-contamination and general harmful effects on the safety and quality of the feed is avoided as much as possible
b. no confusion can occur between different products, the products are properly identified and no incorrect use of the products can take place
c. that a strict and complete physical and organisational separation is applied and maintained between on the one hand feed products and on the other hand products which must not be in feed[1].
   This separation is intended for the prevention of a mixing of feed and these products taking place with risks for feed safety. See section 6.4.4.

6.3.2.2 Production areas

Areas for the production, processing and storage of feed and also equipment, containers, boxes, vehicles and their immediate surroundings must be clean.

The lay-out design, construction and size of the production areas and equipment must:
a. be such that cleaning and/or desinfection and maintenance can be carried out in a proper fashion. This applies in particular to materials and surfaces which come into direct contact with feed materials
b. are in good technical condition
c. are appropriate for their intended use and function in accordance with their intended use
d. make good hygiene production and practices possible.

[1] *Examples are fertiliser, fuel, cleaning and disinfectant agents, glass, crop protection agents, waste.*

The production areas are designed and equipped in such a way that:

e. production can take place in a tidy and orderly fashion
f. the quality and safety of the feed can be guaranteed throughout the whole production process
g. areas or storage units for products which are not part of feed (section 6.3.2.1c) are clearly recognizable and/or marked. If applicable the areas or storage units must be closable to prevent undesirable contamination of feed
h. there is a good resistance to / protection against pest and other animals which may contaminate the feed.
   Windows and other openings must be proofed against pests. Doors must close-fitting and proofed against pests when closed.
   They must be closed as much as possible if the production activities permit this. Windows must be fitted with insect screens if necessary.
   Where closure is not (permanently) possible (for example ventilators, doors, dumping pit, bulk loading, etc.) measures must be taken (such as insect screens or plastic flaps) to restrict the entry of pest.
i. drainage facilities are appropriate for the intended purpose. They must be designed and constructed in such a way that any risk of contamination of the feed is prevented.
j. ceilings and overhead fixtures must where necessary be designed, constructed and finished in such a way that no dirt can accumulate and condensation, undesirable moulds and shedding of particles are reduced so that the safety and quality of the feed is not affected.
k. drains water, waste water and rain water is removed in such a way that the equipment and the safety and quality of the feed is not affected. Spoilage and dust must be kept under control in order to prevent the penetration of harmful organisms.
l. there is daylight and/or artificial light to guarantee the production of safe feed. Contamination of the feeds should be prevented in the event of lighting breakage.
m. the areas, including the company site around them, are only accessible for persons who have been given permission to do so by the participant. There is also an access arrangement for visitors.

With respect to storage areas the following also applies:

n. feeds are stored and transported in appropriate containers. They are stored in areas which are designed, equipped and maintained in order to ensure good storage conditions.
o. feeds can be stored and transported in such a way that they can easily be identified and confusion and cross-contamination are avoided and detoriation is prevented. A separate section of the storage area is intended for the storage of premixtures and feed additives. Veterinary medicines must also be kept in a locked room.
p. processed feed are kept separate from unprocessed feed materials and feed additives in order to avoid cross-contamination of the processed feed. If the participant stores multiple products in a storage area he must take measures to avoid undesired mixing. Untreated and treated products are, where necessary, separated to prevent microbiological cross-contamination.
q. if the participant stores products in silos he must prevent the build-up of material and the forming of condensation as much as possible.
r. the participant must record the release of silos clearly.
s. record of date of silo / tank empty report (minimum 1x per 3 months) [2].
(If this is not feasible in practice then a company may in certain situations use a lower frequency of silo empty reporting. The reasons for this should be given. The company should realise that any recall will be larger in size because the period of time between two silo empty reports will be longer.

6.3.2.3 Installations

The receptacles and equipment installations used for the transport, storage, internal transport, handling and weighing must be clean and in a clean and hygienic condition that they have no negative influence on the feeds which come in contact with them.

Mixing installations

All mixing installations which is used for the production of feed must be appropriate for the range of weights or volumes to be mixed in order to obtain homogenous mixtures and dilutions. The participant must demonstrate the effectiveness of the mixing installations with respect to homogeneity. See the requirements in section 6.7.1.3.

Weighing / dosage equipment

All scales and dosage devices installations 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.

[2] *For wet by-products from a continuous production process the date of silo empty reporting must be recorded. The time of silo empty reporting depends on the production process.*

The following must be clearly stated and recorded with respect to the installations:
a. the minimum and maximum weight permissible for the weighing equipment or dosage equipment;
b. the accuracy of the weighing or dosage installations.

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.

Driers / drying installations
In the event of direct drying the participant must show by way of a risk analysis that the drying process leads to feed which comply with the product standards. Special attention is required for the choice of fuel. Undesirable substances (such as dioxins and PAHs) must not be able to contaminate the feed possibly as a result of the drying process.

Measuring facilities on process equipment installations
Installations / equipment for heat treatment, chilling, freezer storage and freezing must be designed such that the required product temperatures can be reached and that the temperature can be kept low that the safety and soundness of the feed is maintained. The time and temperature must be registered.

If necessary, the equipment must be provided with effective resources for the control and recording of the humidity, air flow and other process parameters which may have a harmful influence on the safety and soundness of feeds.

Control of monitoring and measurement installation
The participant must determine before implementation of the monitoring plan which monitoring and measurement installations is required to demonstrate the feed safety of the feed. The monitoring and measurement equipment must be registered (see section 4.2.4).

The participant must establish processes to ensure that the monitoring and measurement can be carried out and that it is carried out in a way which matches the monitoring and measurement requirements.

The measurement installations must:
a. be calibrated or verified at specified intervals or prior to use in accordance with measurement standards which are derived from international or national measurement standards; if such standards do not exist the basis used for the calibration or verification must be recorded (see section 4.2.4) and inspections must be in accordance with standardised checklists;
b. adjusted or re-adjusted if necessary;
c. identified so that the calibration status can be determined;
d. secured against adjustment which would make the measurement result invalid;
e. protected against damage and deterioration during handling, maintenance and storage.

The participant must also assess and record the validity of the previous measurement results if it appears that the monitoring and measurement equipment does not function in accordance with the requirements. The participant must take appropriate measures with respect to the equipment and any product which is influenced by it. Records of the results of calibration and verification must be maintained (see section 4.2.4).

If computer software is used in the monitoring and measurement of specified requirements this software must be validated. This must be done before initial use and re-confirmed if necessary.

Control of monitoring and measurement installations (supplementary)
Installations which are used for the weighing/dosage of premixtures, feed additives and feed medicines must be calibrated at least twice a year according to a method established by the organisation and which achieves the objectives of the GMP+ FSA module.

All installations which are used for the dosing of - for example - feed materials must be calibrated at least once per year.

6.3.2.4 Other facilities

Processing aids
For the processing aids used in production it must be demonstrated that the unintentional but technically unavoidable presence of residues of these processing aids or their derivatives in the end product has no detrimental effects on animal health, human health or the environment and no technological effect at all on the end product.

Packaging material
The packaging material used must be sound. Materials used for packaging must provide suitable protection for the feeds so that pollution or contamination is minimised, damage is avoided and the materials can be provided with suitable labelling.

Packaging materials must not be toxic and may not form any threat to the safety and soundness of feeds under the conditions established and laid down for storage and use.
Reusable packaging should be sturdy, easy to clean and, if necessary, should be able to be disinfected. The participant must, if necessary, establish a cleaning regime on the basis of a hazards analysis. If applicable, special attention must be paid to the return of pallets and other reusable packaging material.

Water or steam
The water or steam used for the production (including cleaning activities) of feeds must be safe for animals. The participant must ensure that the feeds are not contaminated through the use of water of poor quality. Water supply lines must be of inert material.

6.4 Work environment

The participant must determine and manage the work environment needed to achieve conformity with feed safety requirements.

6.4.1 Maintenance

Production areas and equipment which are intended for use in storage and/or production must be properly and regularly checked in accordance with the procedures established in writing by the producer for feed.

The activities and findings must be recorded.

6.4.2 Cleaning

Dust, dirt and feed remains can form a major breeding ground for the growth of micro-organisms which can contaminate feed materials. The accumulation of dust, dirt and feed remains must therefore be avoided as much as possible.

The following applies to all areas:
a. Spoilage must be prevented as much as possible and kept under control in order to prevent pest invasion.
b. Where necessary the temperature must be kept as low as possible in order to prevent condensation or spoilage.

Cleaning programmes must be introduced. This must include responsibilities and methods, frequency and times of the cleaning.
The cleaning and decontamination agents require special attention. These must be appropriate for the purpose for which they are used. They must also not form any risk to feed safety.

The residues of cleaning and disinfecting agents must be kept as small as possible.

Machinery which come into contact with dry feed must be dried after wet cleaning or must be dry when they are to be used again.

The cleaning programme, carried out, must be recorded by the participant (section 4.2.4), so that it is clear that the programme was correctly carried out.

6.4.3 Pest control

The participant must ensure that a level of cleanliness and tidiness is achieved in every stage of production that no pest are attracted. The purpose of this is to prevent the feed material being contaminated.

Effective programmes must be used for combating harmful organisms. Everything which is reasonably possible and effective must be done to keep birds, pets and pest away from the production areas and to prevent their presence. Acceptable and permitted pest control methods and resources must be used taking into consideration the safety of the employees and the safety of the animal feed.

Pest control is done by persons who are qualified to do so. The pest control programme carried out, must be recorded by the participant (section 4.2.4) so that it is clear that the programme was correctly carried out.

6.4.4 Waste control

Waste and material that is not appropriate as feed must be identified as such and kept separate. If such materials contain hazardous concentrations of feed medicines, contaminants or other hazards, they must be removed in a proper fashion and may not be used as feed (see section 6.3.2.1.c).

Waste must be collected and stored in clearly designated bins or containers. Places where waste is collected and stored must be included in the cleaning and disinfestation programmes.

The participant must make clear how waste and its removal is controlled and must be able to show that the waste does not and can not get into the feed chain.

6.5 Identification and traceability

Products (as defined in GMP+ A2 *Definitions and Abbreviations*) must be traceable in all stages of production, processing and distribution so that, where necessary, they can immediately be withdrawn from the market specifically and precisely and/or the users of these products can be properly informed. The participant must, for this purpose, set up and describe an internal traceability procedure.

The participant must take appropriate measures to ensure that the feed produced can be traced effectively during all the stages specified above for which the participant is responsible (also refer to section 4.1). The participant must maintain a register with the relevant details with respect to purchase, production and sale which can be used to trace the products from reception to delivery (including export to the final destination). The required information must be available within four hours unless the authorities determine a shorter time

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

The participant must record the following details for 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. This can also be designated as a manufacturer's batch number, a reference number, a batch number or a lot number.
f. transport/ distribution details (if the participant is responsible for transport)

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

Retained samples:
In addition, within the framework of traceability, samples of the ingredients and of each batch of feed manufactured and put into circulation or of each specific portion of production in the case of continuous production must be taken in sufficient quantity by a procedure pre-established by the participant and be retained. [3] This applies in any event if the participant receives and processes a feed so that this feed is sent out being no longer as it was received.

These samples must be sealed and labelled in such a way that they are easily identifiable. They must be stored in such a way that any change to the composition or any deterioration of the sample is excluded. They must be kept available for the competent authorities for a period which has been matched to the use for which the animal feeds were put on the market.

In the case of animal feed for animals which are not intended for human consumption the participant must only keep samples of the manufactured animal feed (end product).

The participant may enter into written agreements with third parties on the taking and storing of samples. This may, for example, be applicable when the participant is not the manufacturer or the recipient of the product.

GMP+ BA13 *Minimum Requirements for Sampling* includes guidelines for sampling.

6.6 EWS and Recall

The participant has a documented procedure for the (early) signalling and treatment of signals which indicate that the safety of an animal feed might not match the statutory norms or the norms laid down in the GMP+ FSA module and which might lead to damage to subsequent links in the chain. Signals will be assessed on this basis.

When an animal feed is discovered which does not comply with:
a. the statutory provisions with respect to safety, or
b. usual trading quality, or
c. the essential requirements of the GMP+ FSA module.

then the participant will 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

[3] *This is a legal requirement, derived from the feed hygiene regulation (Regulation (EC) No 183/2005 laying down requirements for feed hygiene). GMP is consistent with this.*

b. immediately block the animal feed or have it blocked, and
c. recall the animal feed and make sure that it stays outside the animal feed and livestock farming sectors,

unless the participant can demonstrate that the non-conformity is without harmful consequences for the health of animals or humans and that the statutory norms are not exceeded.

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 draw up a recall procedure for the above actions. After the establishment of the recall procedure then a recall simulation must be carried out within three months. The recall simulation must be repeated every year after this. The experience gained during this recall simulation should be recorded.

6.7 Production

6.7.1 Control of production

The participant must plan production and implement it under controlled circumstances.

There must be supervision on the presence of feed, undesirable substances and other contaminants which are harmful to the health of humans or animals and proper control strategies must be available to make the risk as small as possible.

Controlled circumstances must, where applicable, consist of:
a. the availability of information describing the characteristics of the feed (see section 7.2.3);
b. ensure that production activities by the participant are carried out in accordance with written instructions and procedures in order to control the critical points in the production process (see section 4.2.1);
c. the use of appropriate equipment (see section 6.3);
d. appropriate resources must be available to carry out the controls during the production process (see section 5.4.4);
e. the implementation of monitoring and measurement (see section 7.7), and
f. the implementation of activities in the area of release, delivery and after-sales.

6.7.1.1 Drying

In the event of direct drying (= drying where the combustion gases come in direct contact with the animal feed) the participant selects on the basis of a risk assessment only those fuels who do not form a danger to the safety of the animal feed. He will in any event ensure that no use is made of prohibited fuels as specified in GMP+ BA3 *Minimum Requirements Negative List*.

6.7.1.2 Dosage

Technical and organisational measures must be taken to prevent cross-contamination and errors or to limit them as much as possible.

The participant must ensure that the right feed materials, feed additives, feed medicines and other products are processed in the right dosage and in the right feed.

Premixtures with coccidiostatica and histomonostatica[4] and feed medicines must be added to the main flow of the compound feed as close as possible to or in the mixer but after the hammer mill or milling process.

The participant must keep a record of which raw materials are used in the feed to guarantee traceability. This data must be kept available for the competent authorities for a period which has been matched to the use for which the feed were put on the market.

6.7.1.3 Mixing

The participant must ensure that feed materials and feed additives and feed medicines are mixed uniformly through the feed using the mixing equipment. He must ensure that:

a. the rate of feed of the mixer lies between established minimum and maximum volume values;
b. the mixing time amounts to an established and recorded minimum time;
c. the mixing time must begin once all the ingredients in the mixer have been dosed. The participant must provide the reasons for the chosen mixing time and rate of feed.
d. the dry mixtures produced comply with the conditions regarding homogeneity established in GMP+ BA2 *Control of residues*.

Guidance
After mixing, the ingredients in the mixtures should remain homogenously mixed.The homogeneity of mixtures can change when there are differences in the characteristics of the present ingredients in mixtures. Most important here are the differences in particle size or particle weight of the individual ingredients.

[4] *These additives are included in Group E of EU Regulation 1831/2003, Article 6, paragraph 1*

6.7.1.4 Pelletising / Expansion / Extruding

In pelletising / expansion / extrusion the conditions must be attuned to the stability of the processed feed additives and feed medicines, in accordance with the processing advice as provided by the supplier.

If the participant produces poultry feed, in which Salmonella-critical feed materials have been processed, a Salmonella kill step must be applied. See GMP+ BA4 *Minimum Requirements for Sampling and Analysis* with additional requirements for the use of Salmonella-critical feed materials.

6.7.1.5 Cross contamination

Based on a risk assessment, the participant must implement procedures to control the cross-contamination in order to meet the quality and safety standards. Special attention must be paid to control (legally) defined residue levels of substances.

Knowledge of the carry-over is necessary as part of Good Manufacturing Practices, and also to establish procedures for controlling cross-contamination.
Accepted methods to measure the carry-over are laid down in GMP+ BA2 *Control of residues*

Guidance
A company must know the carry-over of his production facilities in order to decide if and how cross-contamination may influence the quality and safety of the produced feed.
As a result of carry-over, a part of the produced feed may end up in the next batch, thus introducing a risk that this next feed does not comply with quality and safety standards.

Especially when residue limits have been established by law or elsewhere

Specific attention must be paid to the implementation of procedures to control residues levels of feed additives and feed medicines.
Specified residue standards and specific requirements, laid down in GMP+ BA2 *Control of residues,* must be met. The residue standards of feed additives and feed medicines, which are laid down in this appendix may not be exceeded. Next to this the participant must assure that all control measures must be validated and their effectiveness must be verified with an appropriate frequency.

In any event the carry-over must be known for production and transport lines in an installation on which (feed with) coccidiostats or histomonostats or feed medicines are processed, produced and/or transported.

The participant must record the production order used for production and transport lines.

NOTE: The production order relates to the whole production process from the receipt of the raw materials up to and including delivery of the feed and is particularly important for common transport routes and storage bunkers and silos.

6.7.1.6 Returns

The production process is set up in such a way that internal returns are limited as far as possible.

If there are internal returns these must be fed back into the batch or run from which they originated. If this is not possible a record must be kept of in which storage locations these returns must be stored.

The quality (specifications) of external returns[5] must be known. The participant must have information which shows whether mixing or cross-contamination has taken place at the external company. A procedure must be established for the recall of external returns.

There must be an instruction which records which return products may be included in which products and in what percentage this may take place.
This must in any event not be in conflict with the requirements of this GMP+ FSA module or other regulations.

Return flows of premixtures may only be added to premixtures destined for target animals.

Daily record-keeping must make it possible to derive how much returned product has been processed and in what batch (for each feed type).

NOTE: Examples of return products are waste, the first quantities of a batch or powdered meal from filters in the pneumatic systems of an installation.

[5] *This refers to external return flows which have not been taken back under a recall*

7 Process control

7.1 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. to identify any hazards that must be prevented, eliminated or reduced to acceptable levels (see section 7.4);
b. to identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels (see section 7.5);
c. to establish critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards (see section 7.6);
d. to establish and implement effective monitoring procedures at critical control points (see section 7.7);
e. to establish corrective action when monitoring indicates that a critical control point is not under control (see section 7.8);
f. to establish procedures to verify that the measures outlined in subparagraphs (a) to (e) are complete and working effectively. Verification procedures shall be carried out regularly (see section 7.9 and 8.3);
g. to establish documents and records commensurate with the nature and size of the feed businesses to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f) (see section 4.2.1).

7.2 Requirements for the feed

7.2.1 Determination of feed requirements

With respect to the requirements set for feed, the participant must determine:
a. the relevant requirements set in the GMP+ FSA module (see GMP+ BA1 *Specific feed safety limits* and GMP+ BA3 *Minimum Requirements Negative List*), including the requirements for delivery and after-care and special customer requirements;
b. requirements not established in consultation with the stakeholders in the chain but which are necessary for the specified or intended use, where known;
c. feed legislation requirements related to the feed and process, and
d. any additional requirements determined by the participant and which relate to feed safety.

If the participant produces a feed material
a. for which there is no generic risk assessment in the Feed Support Products (FSP) of GMP+ International, or
b. using a method of production which does not correspond to a risk assessment which has already been included for the feed material

the participant must ensure that a risk assessment is included in the database in question. The above does not apply to feed materials which are only processed in feeds for non-food producing animals.

In appendix GMP+ BA7 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.

7.2.2 Review of feed requirements

The participant must review the feed requirements. This review (for example: that there is compliance with the standards in GMP+ BA1*. Specific feed safety limits* and GMP+ BA3 *Minimum Requirements Negative List* must be carried out before the participant agrees to deliver a feed to a customer and must ensure that :

a. the feed requirements have been established;
b. a solution is found for requirements from the contract or from orders which deviate from requirements which were made earlier, and;
c. the participant has the ability to meet the established requirements.

Records of the results of the review and actions arising from the review must be maintained (see section 4.2.4).

Where animal feed requirements are changed, the participant shall ensure that the relevant documents are amended and that the relevant personnel are made aware of the changed requirements.

7.2.3 Description of the feed based on requirements (specifications)

The participant must describe the feed (end products) based on the requirements which have been established to the degree necessary for proper identification and risk assessment.

There must be a description for each feed. The scope of the description of the feed must stretch from the ingredients used during production (for example feed materials, feed additives and premixtures) up to and including distribution.

The specifications must at least include the following:

a. features of the feed:
    1. general details (name, code, origin, method of creation/production, etc.)
    2. composition (chemical, physical, microbiological);
    3. raw materials and auxiliary substances used (including feed additives and processing aids);
    4. standards / requirements (feed legislation, agreements with clients) and tolerances;
    5. other features (including storage, packaging).
b. characteristics for use:
    1. intended use;
    2. processing instructions;
    3. instructions for use to animals (incl. any waiting periods);
    4. storage conditions;
    5. conditions and agreements with respect to transport and the place of delivery;
    6. storage life;
    7. the legal information on the packaging or the accompanying documents.

NOTE: It may be decided for reasons of effectiveness to form feed groups. It is important that:
a. specific differences between the individual feed to be produced (end products) are examined critically;
b. the production and storage conditions are equivalent;
c. no major aspects relating to product safety are forgotten.

7.2.4 Communication with the customer

The participant must establish and implement effective measures for communication with customers with respect to:
a. information about the feed;
b. enquiries, contracts or order handling including amendments, and;
c. customer feedback, including customer complaints.
The participant must have a system in place for the recording and handling of complaints.

7.3 Process information

The HACCP team must draw up a description of the production process for each feed or feed group in the form of flow diagrams and a layout which enables the organisation to identify and assess hazards.The flow diagrams and the layout must be verified by the HACCP team.

If an feed undergoes any change through treatment and processing or a stage of production, treatment and processing, storage or distribution the participant must review the procedure and modify it where necessary. The steps in sections 7.4 to 7.7 must be gone through. The verification must be established in a plan.

7.3.1 Flow diagrams of the process

The flow diagrams must comply with at least the following requirements :
a. representation of all the individual steps in the process order (purchasing to delivery), including any work outsourced as well as the description of all, raw materials and processing aids, used and also any by-products, customer returns and waste which may be produced during the process.
b. clear, accurate and ent detail in order
    1. to establish possible hazards
    2. to distinguish control measures used.

7.3.2 Diagram of the organisation

The whole infrastructure of the establishment must be shown in a diagram of the organisation, such as;
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 (end products), packaging, pallets, etc.

7.4 Hazard analysis

The HACCP team identifies and assesses based on flow diagrams all potential hazards which can have a negative influence on feed safety. This is done systematically for each process step in each process flow diagram and on every change in the process which can have a negative effect on feed safety. The prerequisites programmes are part of the hazards analyses.

7.4.1 Identification of hazards

The HACCP team must identify and record 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 animal feed;
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 (FSP) (if applicable).

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

7.4.2 Risk assessment

The HACCP team carries out a risk assessment for each identified hazard. The purpose is 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.

The carrying out of a risk assessment determines which possible hazards are actually a risk and where control by way of control measures is therefore necessary

The assessment is also based on practical experience, experimental data, literature, etc. The participant must document the data used and the conclusions.

The carrying out of the risk assessment can also be done using a decision-making tree including the risk estimate (‘chance x seriousness’) from the HACCP manual or in a way which is equivalent to this.

7.5 Establishment of Critical Control Points (CCP's)

7.5.1 Determination of control measures

The HACCP team must establish record and implement the measures to control any risk for which it has been established on the basis of the risk assessment in section 7.5 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.

7.5.2 Establishment of Critical Control Points (CCP's)

The HACCP team must then establish, for each control measure which is drawn up for a risk which may have a negative influence on feed safety, whether this control measure is the last measure in the process of controlling this risk in question. In the event of a positive decision then this is a critical control point (CCP). The reason for there being a critical control point (CCP) must be laid down.

The establishment of critical control points (CCPs) can also be done with the aid of a decision tree from the HACCP manual.

Control measures which are associated with critical control points (CCP) are designated as specific control measures. The participant must monitor each specific control measure. In addition, specific control measures must be provided with corrective actions and these specific control measures must be validated and verified.

Control measures which are not associated with critical control points (CCP) are designated as general control measures. General control measures are actions or activities. General control measures must also be validated and verified to demonstrate their correct functioning for the individual organisation.

7.6 Standards

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.

The derivation of the product standards must also be established.

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.

A appropriate method of working has therefore been established and maintained with respect to the management and application of the relevant product standards.

NOTE: In establishing the product standards the participant may possibly make use of that which has been determined in section 7.2.

In addition to compliance with the adopted product standards (GMP+ BA1 *Specific feed safety limits*) the participant must comply with the residue levels of feed additives and feed medicines. GMP+ BA2 *Control of residues* contains the maximum residue standards for (critical) feed additives and feed medicines. These product standards apply to compound feed, semi-finished products, feed materials and premixtures.
To control the residue standards the participant must, among other things, measure the carry-over for the installations and based on the results obtained from this establish the production order. See the requirements in section 6.7.1.5.

7.7 Monitoring and measuring

7.7.1 Monitoring plan

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 (section 7.5) 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 demonstrate the capacity of the processes to achieve planned results.
c. the frequencies of the analyses, checks and inspections
d. the compliance with the specifications – and the use in the event of non-compliance with the specifications
e. all planned inspections and checks and analyses
f. the instructions for the carrying out of inspections and checks
g. the personnel responsible for the carrying out of the monitoring
h. the personnel responsible for the assessment of the monitoring results
i. the personnel responsible for releasing the feed.

The participant must ensure proper identification and storage of the samples taken for monitoring during an appropriate period of time. 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 be carried out by a laboratory ~~certified in accordance with GMP+ B10 *Laboratory testing*, which is certified for this analysis.~~ approved for this under the GMP+ FSA module. See GMP+ BA10 *Minimum Requirements for Purchasing*.

~~If no laboratory is GMP+ B10 *Laboratory testing* certified for this analysis the participant must at any rate have this analysis carried out by a laboratory which is GMP+ B10 *Laboratory testing* certified for other analyses. The participant must obtain guarantees that the carrying out of this analysis is subject to the same guarantees as the carrying out of certified analyses.~~

~~NOTE: A participant can also have analyses carried out by a laboratory which is certified in accordance with a standard which has been declared to be equivalent to the GMP+ B10 Laboratory testing standard. See GMP+ BA10 *Minimum Requirements for Purchasing*.~~

7.7.2 Monitoring plan (supplementary for processing of feed additives / feed medicines

The participant must check that the established residue standards for feed additives and feed medicines are not exceeded. This must be done at least after the measurement of the carry-over and the setting up of the production order in accordance with section 6.7.1.5 and - if there is reason to do so - at other moments.

If the residue standards are exceeded then
a. the instructions and procedures must be adjusted, and
b. the feed materials in question must be considered to be non-standard products. See section 7.8 for this.

7.8 Corrective actions

The participant must ensure that non-conformities (in the feed or 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 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 4.2.4). If a non-conformity is corrected it must be verified again to show that it complies with the requirements.

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

7.9 Validation of the HACCP plan

The purpose of validation is to ensure that the hazards which were originally established by the HACCP team are complete and correct and that they must be effectively controlled using the proposed general and specific control measures, the monitoring plan and the corrective actions.

Top management must set up a validation team to ensure absence of bias. Members of the HACCP team may be members of the validation team but the validation team must also have members who are independent. The composition of the validation team and the activities they carry out must be clearly established.

Corrective actions are satisfactory and must prevent an unsafe feed from being released and provide proof that the situation can be immediately corrected.

The participant must ensure that all documents with the procedures developed in accordance with sections 7.1 to 7.10 are always up to date.

7.10 Purchasing

7.10.1 Purchasing process

The participant must ensure that purchased feed and services comply with the specified purchasing requirements. This is established in a documented procedure. The method of control which is used on the purchased product and the supplier must be dependent on the effect of the purchased product on subsequent product realisation or on the feed (end product).

The participant must assess suppliers and choose those suppliers who are able to deliver a product which complies with the requirements of the participant.

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

a. The participant purchases products or services for which there is a GMP+ standard only from suppliers who are GMP+ certified at the moment of delivery;
b. Contrary to paragraph a., the participant may also purchase products or services from suppliers which are certified based on a standard approved in the GMP+ FSA module;
c. Contrary to paragraph a., certain products and services may also be bought without one of the above certificates. Separate requirements have been established for this.

In GMP+ BA10 *Minimum Requirements for Purchasing* there are details of the above options.

d. Prior to the purchase of other products (other than feed) or services[6] (other than storage and transhipment, transport or laboratory) the participant must carry out its own risk assessment based on HACCP principles. Based on this risk assessment and also the feed safety assurance, which is applied by the supplier, the participant must make a selection of suppliers and must adjust his (entry) check accordingly.

[6] *Which may (can) not be covered under a GMP+ standard because, for example, no GMP+ standard has been established.*

From each type of feed material be purchased or received, there must be a generic risk assessment in the Feed Support Products (FSP).

If it is a feed material for which there is no risk assessment in the Feed Support Products (FSP), the participant must first offer a risk assessment to GMP+ International for inclusion in the database referred to. Only after inclusion in the database may the feed material be sold or received.

Criteria for selection, assessment and reassessment must be established. Records of the results of the review and any required actions arising from the review must be maintained (see section 4.2.4).

7.10.2 Purchasing data

Purchasing data must describe the product or service to be purchased. This includes in any event and where applicable a description of:

a. requirements for approval of the product, procedures, processes and equipment;
b. requirements for the qualifications of personnel (see section 6.2), and
c. requirements of the feed safety management system (see section 4.1).
d. required status of the product or service. 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 guarantee the suitability of the specified purchasing requirements before making these known to the supplier.

NOTE: the specified purchasing requirements are based on the requirements which are set for the feed to be produced (end product, see section 7.2).

7.10.3 Verification of the purchased product or service

The participant must establish and implement the inspection or other activities which are required in order to ensure that the purchased products and services comply with the specified purchasing requirements.

If the participant or his customer desires verification to be carried out at the supplier then the participant must state the proposed verification requirements and the method of product release in the purchasing information.

On reception of the products the participant will carry out an entry inspection. He will verify that the products received comply with the requirements (specifications).

The participant must also check that the transport complies with the stated requirements (as a minimum a check on: the GMP+ certification of the carrier, compliance with the requirements with respect to loading sequence, previous loads and implementation of the necessary cleaning regimes). If the result of the inspection is positive then the loading compartment is approved for the transportation of feed.

This inspection must be carried out by a loading inspector. A 'loading inspector' is a position which is specified in the feed safety management system of the participant. This role is fulfilled by an employee who, on the basis of training and experience, has the knowledge and skills required for the inspection of a loading compartment for its suitability for the loading of feed.

The LCI reports for all received sea transport, short sea shipping, inland waterway transports or rail transport should be available or retrievable.

The participant will ensure that veterinary medical products are received and processed in accordance with the statutory provisions.

7.11 Production

7.11.1 Customer property

The participant must be careful with the property of the customer when it is under the control of or used by the participant.

The participant must establish, verify, protect and store the property of the customer when it is delivered for use or is part of the product. If any customer property is lost, damaged or is otherwise considered to be unappropriate for use this must be reported to the customer and records must be kept of this (see section 4.2.4).

The participant must control, handle, assess and secure the property of the customer throughout the production process in the same way as its own products (in accordance with the requirements of this GMP+ standard).

7.11.2 Maintenance of the product

The participant must ensure during internal processing and delivery to the proposed destination that the feed continues to comply with the requirements set. This maintenance must include identification, handling, packaging, storage and protection.

7.11.3 Labelling and delivery

When the participant is responsible for the transport he 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.

When the customer is responsible for the transport and the loading compartment is not clean, free from load remains or the odour of previous loads then the participant will submit this to the customer for assessment before allowing loading to start. A record is maintained of the judgement of the customer.

The mandatory statutory information must be provided on delivery to the customer.

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

8 Measurement, analysis and improvement

8.1 General

The participant must plan and implement the required monitoring, measurement, analysis and improvement processes in order to:
a. demonstrate that the feed meets the requirements;
b. ensure that the feed safety management system meets the requirements, and
c. continuously to improve the effectiveness of the feed safety management system.

This must include establishment of the methods used including statistical techniques and establishment of their degree of use.

8.2 Internal audit

The participant must carry out internal audits at planned intervals to determine whether the feed safety managementsystem:
a. conforms to the requirements of this GMP+ standard and to the requirements of the feed safety system established by the participant, and
b. is effectively implemented and maintained.

An annual (which means a minimum audit frequency of 1x per 12 months) audit programme must be planned and implemented in which all parts of the process must be addressed. Account must be taken of the results of the previous audits. The audit criteria, scope, frequency and methods must be established. Selection of the auditors and the conduct of audits must ensure the objectivity and impartiality of the audits. Auditors must not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see section 4.2.4), must be recorded in a documented procedure.

The management responsible for the area being audited must ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities must include the verification of the actions taken. The participant must also record the verification results.

8.3 Verification of the feed safety management system

The participant must determine, collect and analyse appropriate data at least once per year (which means with a minimum frequency of 1x per 12 months) to demonstrate the suitability and effectiveness of the feed safety system and to evaluate whether continuous improvement in the effectiveness of the feed safety management system is feasible. Verification of (elements of) the HACCP system is part of this assessment.

This must include monitoring and measurement data from other relevant sources (including monitoring, internal/external audits, complaints, records, evaluations). The analysis of the data must provide information with respect to:
a. compliance with feed requirements (see section 7.2)
b. characteristics and trends of processes and products including opportunities for preventive measures, and
c. the suppliers

NOTE: The output of this analysis partly forms the input for the management review (section 5.5.2)

8.4 Improvement

8.4.1 Continual improvement

The participant must continually improve the effectiveness of the feed safety system through the use of the feed safety policy, feed safety objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.4.2 Corrective action

The participant must take action to eliminate the cause of non-conformities in order to prevent recurrence. Corrective actions must be appropriate to the effects of the non-conformities encountered.

A documented procedure must be established to record requirements for:
a. reviewing non-conformities (including customer complaints);
b. determining the causes of these non-conformities;
c. evaluating the need for action to ensure that non-conformities do nor recur;
d. determining and implementing action needed;
e. records of the results of action taken (see section 4.2.4), and
f. reviewing corrective action taken.

8.4.3 Preventive action

The participant must determine measures to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions must be appropriate to the effects of the potential problems.

A documented procedure must be established to record requirements for:
a. determining potential non-conformities and their causes;
b. evaluating the need for action to prevent non-conformities;
c. determining and implementing action needed;
d. records of the results of action taken (see section 4.2.4), and;
e. reviewing preventive action taken.

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