



*GMP+ Feed Safety Assurance scheme*

## **Production, Trade and Services**

### **GMP+ B1**

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## History of the document

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0.0 / 09-2010	Transfer of the document from PDV to GMP+ International	Entire document	01-01-2011
	Specification of appendices. Gives more clarity	7.2.1	01-01-2011
	Specification of appendix. Gives more clarity	7.4.1	01-01-2011
	Specification of appendix. Gives more clarity	7.7.1	01-01-2011
0.1 / 09-2011	Introduction has been updated. Reshuffling of requirements for defining scope of the feed safety system, including clarification of the requirements regarding (partial) certification of a location: Production must always been covered (except for petfood), parts of trade, storage or transport may be excluded. Transport of packaged products does not have to be certified.	1.1;1.2 4.1.a.	01-01-2012 01-01-2012
	The requirements regarding labelling of non-GMP+ certified feeds are moved to GMP+ BA6.	4.1	01-01-2012
	Also a reference is made in this document to the additional labeling requirements in GMP+ BA6	7.11.3	01-01-2012
	Amendment of the internal traceability-requirements.	6.5	01-01-2012
	Salmonella kill step must be applied when Salmonella-critical feed materials are processed.	6.7.1.4	01-01-2012
	Position description of loading inspector is added. Requirements for entry checks of LCI reports are better described.	7.10.3	01-01-2012
	The participant must provide the carrier with sufficient product information.	7.11.3	01-01-2012

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# 1 Introduction

## 1.1 General

The GMP+ Feed Safety Assurance Scheme (GMP+ FSA 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.

The GMP+ FSA scheme is a complete scheme 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 scheme can facilitate this excellently.

The basic principle of the GMP+ FSA scheme is that the feed chain is part of the food production chain. Proper quality assurance of feed safety throughout the feed chain has a high priority. It is important that companies take their responsibilities in this respect by responding in a proper and convincing way to the need for safe feed materials in the food production chain.

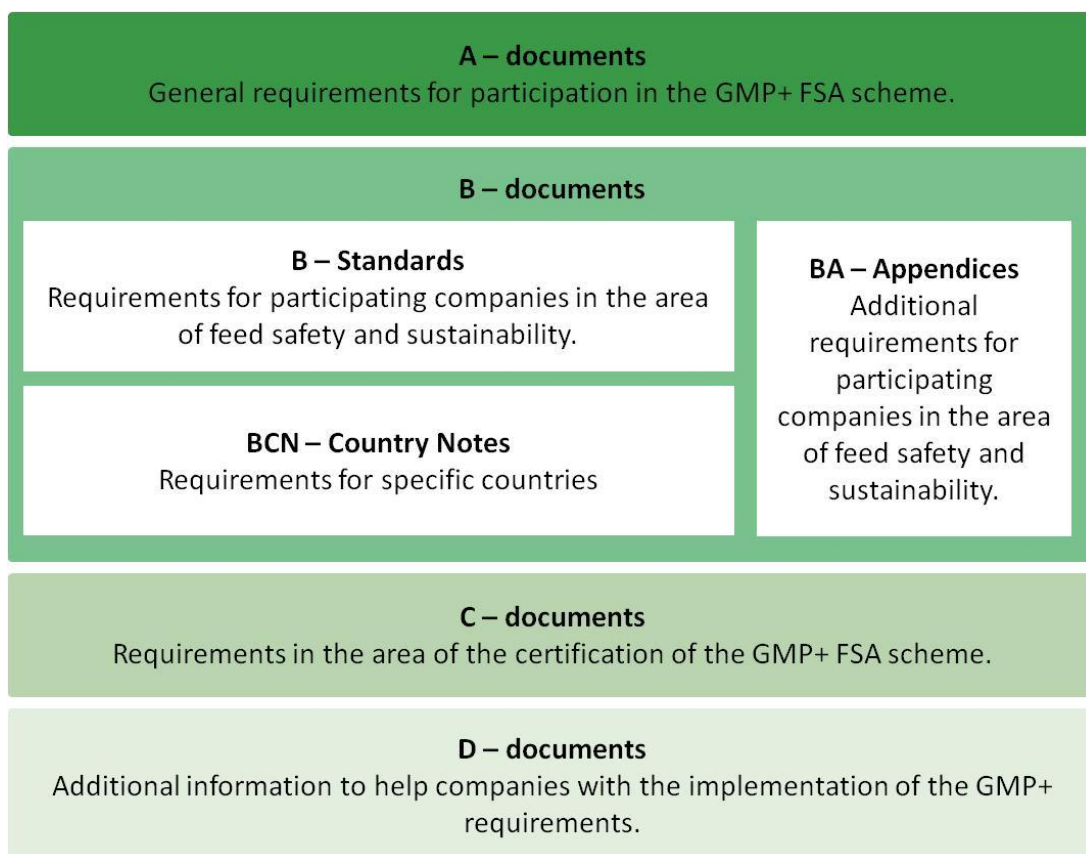
Based on needs in practice, multiple components have been integrated into the GMP+ FSA scheme, such as requirements for the quality management system (ISO 9001), HACCP, product standards, traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

Together with the GMP+ partners, GMP+ International transparently sets clear requirements so that feed safety is guaranteed and certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of its various databases, newsletters, Q&A lists and seminars.

## 1.2 Structure of the GMP+ Feed Safety Assurance scheme

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



All these documents are available via the website of GMP+ International ([www.gmpplus.org](http://www.gmpplus.org)) .

This document is referred to as GMP+ B1 *Production, Trade and Services* and is part of the GMP+ FSA scheme.

### 1.3 Scope and application of this standard

This standard contains the conditions and requirements for the feed safety assurance of:

- 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 stan-

standard describes 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+ C1 *Approval Requirements and Procedure for Certification Bodies*, Appendix 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+ B<sub>Axx</sub>), 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 scheme.

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 Normative references

### 2.1 GMP+ documents

In addition to the requirements listed in this GMP+ standard, the participant must also comply with the requirements included in the GMP+ Appendices (GMP+ BAxx) to which reference is made in this standard.

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.gmpplus.org](http://www.gmpplus.org))

### 2.2 Legal compliance

Special attention was paid when drawing up this standard to the inclusion of the relevant requirements in the applicable feed legislation. Compliance with this standard does not however guarantee that there is compliance with all the legal requirements or mean that feed legislation can then be ignored. It is the participant's own responsibility to comply with the relevant feed legislation.

In addition to the requirements of this standard the participant must also verify and ensure that his product activities and all the feeds that he produces and supplies are in accordance with the applicable legal requirements.

## 3 Terms and Definitions

See GMP+ A2 *Definitions and Abbreviations*.

## 4 Feed Safety System

### 4.1 Requirements for the feed safety system

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

The applicant must:

- a. establish and record the scope of the feed safety system. The scope must at least include the activities related to feed for which the applicant is responsible:
  1. The responsibility of the applicant 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 applicant 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 & transshipment (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 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 applicant decides to outsource a process which influences compliance with the requirements on the product, the applicant must ensure that such processes also comply with the requirements of this GMP+ standard. The applicant must at least comply with section 7.10.
  5. All other activities, which means the activities which are not able to cover under this or other GMP+ standards, must also be described by the applicant. The applicant must ensure that these activities do not have a negative influence on the safety of the feed.

#### Possibilities for exclusions from scope of the feed safety system:

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 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. In order to prevent confusion about the status of the feed, the status ('GMP+ certified' or 'non – GMP+ certified') must be speci-

fied in the sales contract or otherwise recorded in writing by delivery at the latest.

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

If a participant trades non-GMP+ certified feeds then the status of these must be reported to the customer in writing. This applies in the event of delivery to GMP+ certified customers or customers who are certified in another certification scheme which has been declared to be equivalent to the GMP+ scheme (see GMP+ BA10 *Minimum Requirements for Purchasing*). The sentence “The goods delivered do not have the GMP+ status as specified in the GMP+ FSA scheme” (or: “The goods delivered are non-GMP+ certified”) must be specified in the sales contract. If there is no sales contract then this must be specified in some other written form by the time of delivery at the latest.

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. If an applicant decides to outsource a process which influences compliance with the requirements on the product, the applicant must ensure that such processes also comply with the requirements of this GMP+ standard. The applicant must at least comply with section 7.11.

Separate standards have been established for the transport of animal feeds (GMP+ B4.1 Road Transport, GMP+ B4.2 Affreightment of Short Sea Shipping and Inland Waterway Transport, GMP+ B4.3 Inland Waterways transport, GMP+ B4.4 Sea Transport Affreightment and GMP+ B4.5 Rail Transport Affreightment). An applicant who is involved in these forms of transport must have the transport take place in accordance with the requirements of the GMP+ standards mentioned.

8. If a participant makes use of an external carrier for the transport of packaged feed (including sealed loading units), 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. The loading compartment should be completely emptied and free of load remains and odour from previous loads.

9. The participant should control all his own storage and transshipment activities using his own feed safety system in accordance with the requirements of this standard. This applies to storage and/or transshipment at both own and hired sites, and both packaged and unpackaged feeds

- 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 applicant 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 *Regulation*.

## **4.2 Documentation**

### **4.2.1 General**

The applicant must maintain a register of the documentation relating to the production process and the controls.

The applicant 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 quality management plan. 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 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 applicant 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 applicant must set up and update a quality manual which includes:

- a. the scope of the feed safety 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 system or a reference to them

- c. a description of the interactions between the processes of the feed safety system
- d. the structure of the documentation.

#### 4.2.3 Control of the documentation

Documents which are required by the feed safety 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 of appropriate identification if is the 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 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 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 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 system

Top management must ensure that the feed safety system is implemented and maintained correctly in order to comply with both the requirements in section 4.1 and the feed safety objectives, and the operation and cohesion of the feed safety 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 applicant 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 sufficient 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 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 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 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 scheme.

### **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 system in order to comply with the GMP+ standard.

## **5.5 Management review**

### **5.5.1 General**

Top management must review the feed safety 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 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 7.8.1), the internal audits (section 8.2) and the verification (section 8.3)
- b. the assessment and evaluation of the suppliers (sections 7.11.1 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 measures
- g. follow-up measures from previous management reviews
- h. changes which may influence the feed safety 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 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 various parts of the business process as shown in the table. If this is not sufficient then the participant must detail and implement additional prerequisites.

The participant may exclude prerequisites as long as reasons are given. The requirements specified in section 1.2 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 applicant must have sufficient 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 designated with 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 applicant 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 applicant 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 applicant 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 applicant must show by way of a risk analysis that the risks are sufficiently 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<sup>1</sup>.

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 decontamination 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.

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.

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<sup>1</sup> *Examples are fertiliser, fuel, cleaning and disinfectant agents, glass, crop protection agents, waste.*

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 sufficient 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 applicant. 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 deterioration is prevented. A separate section of the storage area is intended for the storage of premixes 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 applicant 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 applicant stores products in silos he must prevent the build-up of material and the forming of condensation as much as possible.
- r. the applicant must record the release of silos clearly.
- s. record of date of silo / tank empty report (minimum 1x per 3 months) <sup>2</sup>.  
(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 sufficiently clean and hygienic condition that they have no negative influence on the feeds which come in contact with them.

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<sup>2</sup> 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.

### 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 applicant 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 metering 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.

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 applicant 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 applicant 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 applicant 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 sufficiently 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 applicant 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 applicant 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 applicant 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 applicant 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 premixes, feed additives and feed medicines must be calibrated at least twice a year according to a method established by the organisation and which is sufficient to achieve the objectives of the GMP+ FSA scheme.

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 sufficiently 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 applicant 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 bacteria 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 applicant 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 vermin 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 applicant (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 disinfection programmes.

The applicant 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 applicant 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 applicant 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* (specifically Appendix IV) 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, sufficient 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. 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 scheme 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 scheme.

then the participant will undertake the following actions:

- a. immediately inform the customer, and
- 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.

If there is a potential hazard which can not be controlled by the participant in question and which may also cause damage to others, then the participant is obliged to inform GMP+ International properly and adequately. This should be done in accordance with GMP+ BA5 *Minimum Requirements EWS*.

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 applicant must plan production and implement it under controlled circumstances.

There must be supervision of 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 7.3.3);
- b. ensure that production activities by the applicant 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 6.1);
- d. sufficient appropriate resources must be available to carry out the controls during the production process (see section 7.8.2);
- e. the implementation of monitoring and measurement (see section 7.8), 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 applicant 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.

Premixes with coccidiostatica and histomonostatica 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 applicant 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 applicant 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 applicant must provide the reasons for the chosen mixing time and rate of feed.

#### 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 applicant 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 *Control of residue standards*

##### Carry-over

The applicant must determine based 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 to another through carry-over may lead to an unsafe feed or to an feed which does not comply with the standards.

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

The measurement frequency of carry-over in production and transport lines depends on the (feed with) feed additives and feed medicines which the applicant processes and whether he processes feed for which a residue standard has been established. See GMP+ BA1 *Product Standards* for this.

The applicant must measure this carry-over by means of a testing procedure established by GMP+ International. See GMP+ BA4 *Minimum Requirements for Sampling and Analysis* for this. The carry-over must be re-established in the above situations in the event of major changes to the installation.

### Production order

The applicant must draw up and make use of a production order whereby the feed (end products) comply with the residue standards in GMP+ BA1 *Product Standards*. The production order to be used must be laid down in an instruction. The applicant 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<sup>3</sup> must be known. The applicant 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 scheme or other regulations.

Return flows of premixes may only be added to premixes 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.

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<sup>3</sup> This refers to external return flows which have not been taken back under a recall

## 7 Process control

### 7.1 Planning of the realisation of a safe feed

The applicant 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 applicant must determine:

- a. the relevant requirements set in the GMP+ FSA scheme (see GMP+ BA1 *Product Standards* 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 applicant and which relate to feed safety.

If the applicant produces a feed material

- a. for which there is no generic risk assessment in the Database Risk Assessments of Feed Materials 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 applicant 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 domestic animals.

#### 7.2.2 Review of feed requirements

The applicant must review the feed requirements. This review (for example: that there is compliance with the standards in GMP+ BA1 *Product standards* and GMP+ BA3 *Minimum Requirements Negative List* must be carried out before the applicant 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 applicant 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 applicant 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 premixes) 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 applicant 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 applicant 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 applicant 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 sufficient 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 Database Risk Assessments of Feeds Materials (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 scheme (GMP+ BA1 *Product Standards*).

### 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 applicant 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 scheme. 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 applicant may possibly make use of that which has been determined in section 7.3.

In addition to compliance with the adopted product standards (GMP+ BA1 *Product Standards*) the applicant must comply with the residue levels of feed additives and feed medicines. GMP+ BA1 *Product Standards* 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 premixes. To control the residue standards the applicant 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 7.12.

## 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 7.7) 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 scheme (GMP+ BA4 *Minimum requirements for Sampling and Analysis*). The applicant 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 applicant must ensure proper identification and storage of the samples taken for monitoring during an appropriate period of time. The applicant must make the results available on request to GMP+ International.

Each applicant must, within the framework of the feed safety system, be able to have available a laboratory with sufficient personnel and equipment.

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.

If no laboratory is GMP+ B10 *Laboratory testing* certified for this analysis the applicant must at any rate have this analysis carried out by a laboratory which is GMP+ B10 *Laboratory testing* certified for other analyses. The applicant 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 applicant 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 applicant 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 7.12.1 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 7.9 for this.

## 7.8 Corrective actions

The applicant 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 applicant 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 and measures-

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

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

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

- a. The applicant 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 applicant may also take products or services from suppliers which are certified based on a standard approved in the GMP+ FSA scheme;
- 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.

Prior to the purchase of other products (other than feed) or services<sup>4</sup> (other than storage and transshipment, transport or laboratory) the applicant must carry out its own risk assessment based on HACCP principles. Based on this risk assessment and also the quality assurance, which is applied by the supplier, the applicant must make a selection of suppliers and must adjust his (entry) check accordingly.

From each type of feed material be purchased or received, there must be a generic risk assessment in the Database Risk Assessments of Feed Materials.

If it is a feed material for which there is no risk assessment in the ~~Database Risk Assessments of Feed Materials~~ ~~Feed Safety Database~~ of GMP+ International, the applicant 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 or additive 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).

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<sup>4</sup> Which may (can) not be covered under a GMP+ standard because, for example, no GMP+ standard has been established.

### 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 system (see section 4.1).

The applicant 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 7.3).

### 7.10.3 Verification of the purchased product or service

The applicant 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 applicant or his customer desires verification to be carried out at the supplier then the applicant 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 quality 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 applicant 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 applicant must be careful with the property of the customer when it is under the control of or used by the applicant.

The applicant 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 inappropriate for use this must be reported to the customer and records must be kept of this (see section 4.2.4).

The applicant 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 applicant 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 loading and delivery

When the participant is responsible for the transport he must provide the carrier with sufficient 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 ~~the principle~~ 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 applicant 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 system meets the requirements, and
- c. continuously to improve the effectiveness of the feed safety system.

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

### **8.2 Internal audit**

The applicant must carry out internal audits at planned intervals to determine whether the feed safety system:

- a. conforms to the requirements of this GMP+ standard and to the requirements of the feed safety system established by the applicant, 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 applicant must also record the verification results.

### **8.3 Verification of the feed safety system**

The applicant 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 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 7.3.)
- 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 applicant 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 applicant 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 not 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 Preventative action**

The applicant 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.