

GMP+ Feed Safety Assurance scheme

Trade

GMP+ B3

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Stadhoudersplantsoen 12
2517 JL The Hague
The Netherlands

Tel: +31 (0)70 370 86 70
Fax: +31 (0)70 370 86 71

info@gmplus.org
www.gmplus.org

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1 Introduction

1.1 General

The GMP+ Feed Safety Assurance scheme (GMP+ FSA) has been developed since 1992. It was managed from 1992 up until 2009 by the Product Board Animal Feed, The Hague, The Netherlands. Since 2010, this scheme is managed by GMP+ International.

It is a scheme for assuring feed safety in all the links in the feed chain. It is also an international scheme, applicable worldwide.

The establishment and development of the scheme was primarily the result of demand from the subsequent links in the animal production chain for better control of feed safety. Another contributory factor was the damage caused by more and less serious contamination incidents.

In the initial phase the demand arose for better differentiation in an increasingly saturated European sales market for animal products. Since 1999, feed & food safety has been a top issue internationally both politically and commercially, because of serious incidents in the feed sector. Because of this, demonstrable assurance of feed safety has become a sales prerequisite.

The basic principle of the GMP+ FSA scheme is that the feed chain is part of the food production chain. Proper assurance of feed safety worldwide is a high priority. Companies must live up to their responsibilities and respond properly and convincingly to the needs of animal production. The GMP+ Feed Safety Assurance scheme is an aid to realise this.

1.2 Structure of the GMP+ Feed Safety Assurance Scheme

The documents within the GMP+ FSA scheme are subdivided into a number of series. A description follows of these:

A
General (framework) documents

These documents contain the requirements for participation in the certification scheme for companies and certification bodies (framework regulation, the use of logo's, etc.). This series also includes a general list of definitions and abbreviations.

B
Normative documents.

These documents contain the international standards and additional country notes for use by companies with respect to the various feed products and production phases including cultivation and industrial production, treatment and processing, collection, trade, means of transport, storage and transshipment.

These documents are divided in several groups, with a code and a name

| document | code | name |
|-----------------|-------------|---------------------------|
| ⇒ Standard | GMP+ Bxx | e.g. GMP+ B3 <i>Trade</i> |
| ⇒ Appendix | GMP+ BAxx | |
| ⇒ Country Note | GMP+ BCNxx | |

C
Certification requirements

These documents contain the Rules of Certification including those for the approval of certification bodies and auditors, the frequency of audits, minimum audit time, assessment criteria, checklists, etc. There is also an explanation of how the supervision by certification bodies is implemented and of how GMP+ International supervises the certification process.

D
Interpretations and accompanying texts

In addition to the above-mentioned normative documents, there are also supporting documents in the D series including a list of frequently-asked questions, manuals and guidances with additional information.

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

The document in the present case is referred to as standard GMP+ B3 *Trade* 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 all kind of trade in feed

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.

Each participant must establish the company-specific hazards relating to the safety of feeds and analyse and control them by applying HACCP principles. This standard describes as accurately as possible for activities or 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 then it may be necessary to apply another GMP+ standard instead of, or in addition to, this standard.

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 and quality 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 Structure of this standard

This standard is structured after the latest version of the ISO9001-standard. This standard is easy to combine with the ISO9001-standard, or with other GMP+ standards.

GMP+ Appendices (GMP+ BAxx), to which there are also references, are separate GMP+ documents within the B series which are not attached to this standard. If there is a reference 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 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 website (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 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.

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 all the feed which he trades.
 - 3 All business locations and processes / process lines where production, treatment or processing, trade, storage or transshipment, affreightment or transport of animal feeds are carried out must be brought by the participant under the scope of the feed safety system.
 - 4 All other activities, which means the activities which do or are not able to not fall 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.
 - 5 All activities related to pet foods may be excepted 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 do fall under the feed safety system.
 - 6 For a company which also carries out trading activities it is permissible to exempt the part of the trade in non-GMP+-certified animal 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 specified in the sales contract or otherwise recorded in writing by delivery at the latest.

If a participant trades non-GMP+ certified feeds then their status must be reported in writing to the client. 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+ Feed Safety Assurance 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 holders, irrespective of whether they participate or not in chain quality programmes, should always fall under the GMP+-certificate

- 7 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*). A participant who is involved in these forms of transport should have the transport take place in accordance with the requirements of the GMP+ standards mentioned.
 - 8 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 trading 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 a GMP+ standard, then each of them must hold a certificate for these activities. See GMP+ A1 *General Regulations*.

4.2 Documentation

4.2.1 General

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

The applicant must have a documentation system for the description of the critical points in the trading 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 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 trading processes;
- e. records required by this GMP+ standard (see section 4.2.4);
- g. all relevant required permits, records and certificates under the 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. 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 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 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 it is retained for whatever reason.

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

4.2.4 Control of 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 under 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 trading 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

- a. 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
- b. 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

- a. The input to the management review must include information on;
- b. results of the monitoring plan (section 7.8.1), the internal audits (section 8.2) and the verification (section 8.3);
- c. the assessment and evaluation of the suppliers (sections 7.11.1 and 8.3);
- d. results of external audits;
- e. feedback from customers;
- f. the extent to which the processes and the feed comply with the requirements;
- g. status of preventive and corrective measures;
- h. follow-up measures from previous management reviews;
- i. changes which may influence the feed safety system; and
- j. recommendation 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.

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 trading of safe feed.

An organisational 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 tasked with auditing.

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.

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 (see section 5.4.2)
- 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 feed 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).

6.4 Work environment

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

6.5 Identification and traceability

Products (as defined in GMP+ A2 *Definitions and Abbreviations*) must be traceable in all stages of trading 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 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.

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.

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 retained¹. 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.

¹ This is a legal requirement from the Feed Hygiene Regulation (Reg. (EC) no. 1831/2003 for the establishment of requirements for feed hygiene. GMP is in agreement with this.

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.

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+ Feed Safety Assurance 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 the GMP+ International. 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 two years after this. The experience gained during this recall simulation should be recorded.

6.7 Trading in and delivery of services

6.7.1 Control of trading and the delivery of services

The applicant must plan trading in feed 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 trading activities by the applicant are carried out in accordance with written instructions and procedures in order to control the critical points in the trading 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.

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 7.5);
- 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 7.6);
- 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 7.7);
- d. to establish and implement effective monitoring procedures at critical control points (see section 7.8);
- e. to establish corrective action when monitoring indicates that a critical control point is not under control (see section 7.9);
- 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 7.10 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 of 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 the various appendices), 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.

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 feed requirements are changed, the applicant must 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 to be traded 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 products used during production 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 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 (section 7.3.3.);

- 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 trading process for each feed or feed group in the form of flow diagrams which enables the organisation to identify and assess hazards.

The flow diagrams must be verified by the HACCP team.

If there is any change to a feed or a step in the process then the applicant must review the procedures and modify them if 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

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

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7.4 Hazards 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 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 Information 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 Safety Database (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.

7.4.2 Risk estimation

The HACCP team carries out a risk estimation 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 risk estimation determines which possible hazards are actually risks and where control by way of control measures is therefore necessary

The carrying out of the risk estimation 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. The assessment is also based on practical experience, experimental data, literature, etc. The applicant must document the data used and the conclusions.

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 estimation 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 the 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.

An 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.

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 trading process.

The plan includes all planned measurements, analyses and observations of features which indicate that the critical control points (section 7.7) are controlled.

The monitoring plan must at least be in accordance with the inspections established in this GMP+ FSA scheme. 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: An 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 by GMP+ International. See GMP+ BA10 *Minimum Requirements for Purchase*.

7.8 Corrective actions

The applicant must ensure that non-conformities (in the feed) to the requirements in this standard are recorded and controlled in order to prevent unintentional use or delivery of the feed. The control and associated responsibilities and competences for dealing with non-conformities must be recorded 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 in-company 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 workers who were not directly involved in the setting up of the HACCP plan. If a participant is unable to do this then he may deviate from this as long as reasons are given. 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 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.

- d. Prior to the purchase of other products (other than feed) or services² (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 Feed Safety Database.

If it is a feed material for which there is no risk assessment in the 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).

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

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 the applicant must state the proposed certification requirements and the method of product release in the purchasing information.

On reception of the products the applicant must carry out an entry inspection. He must verify that the products received comply with the requirements (specifications) and that the transport requirements.

He should also check that the transport complies with the stated requirements (minimum check on the GMP+ certification of the carrier, compliance with the

² Which may (can) not be covered under a GMP+ standard because, for example, no GMP+ standard has been established.

requirements with respect to loading sequence, previous loads and implementation of the necessary cleaning regimes).

7.11 Trading in and delivery for services

7.11.1 Customer property

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7.11.2 Maintenance of the product

The applicant must ensure that the feed continues to comply with the requirements set. This maintenance must include identification, handling, packaging, storage and protection.

7.11.3 Loading and delivery

When the customer is the principle 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.

8 Management, 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 Preventive 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.