



GMP+ Feed Safety Assurance scheme

Storage & Transhipment

GMP+ B5

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<p>This standard has been withdrawn on 31-12-2009. From 01-01-2010 onwards new certification and recertification is no longer possible. Existing certification contracts can continue until their end. See for more info the newsletter dated 19-11-2009.</p>			

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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.

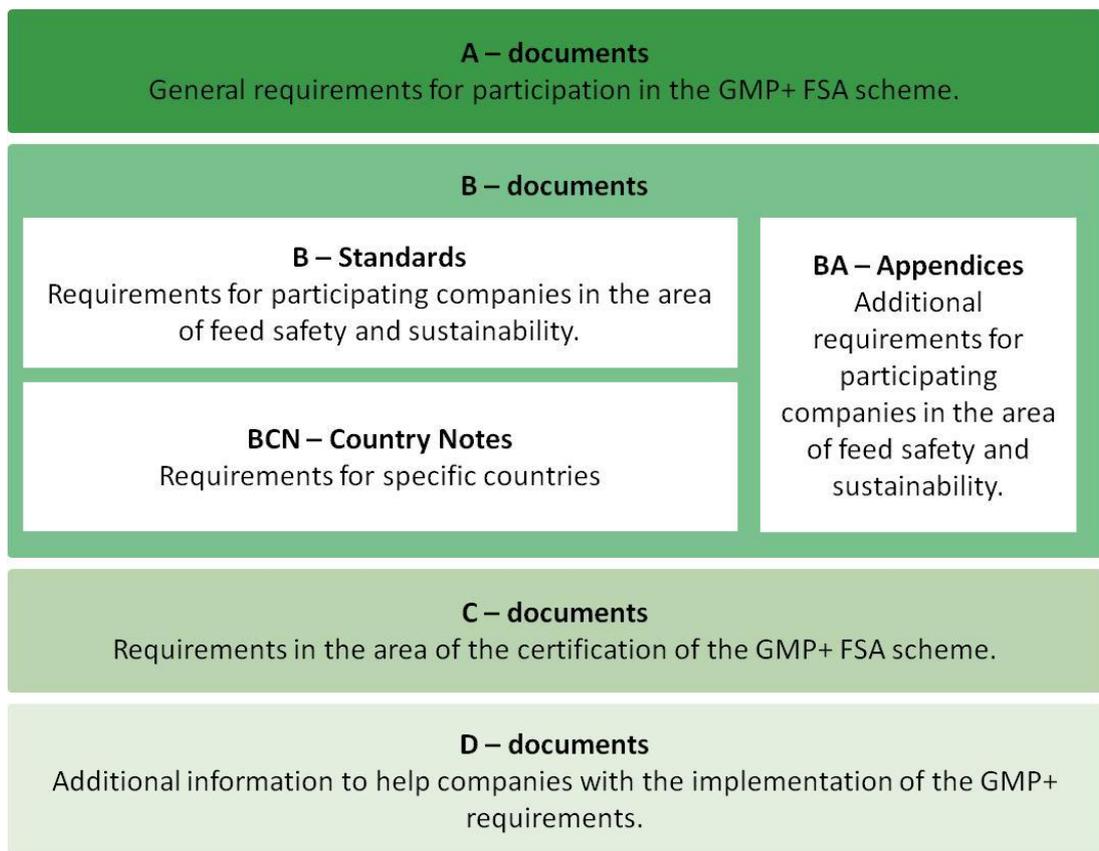
Based on needs in practice, multiple components have been integrated into the GMP+ FSA scheme, such as requirements for the quality management system (ISO 9001), HACCP, product standards, traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

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) . This document is referred to as *GMP+ Storage & Transhipment* 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 storage and/or transhipment of feed.

By ‘storage and transhipment’ is understood: The transferring or storage for a period of time of products. In addition to the actual storage and transhipment, this includes all activities which are required to make the storage and transhipment possible such as planning, purchasing, cleaning, documentation, resources and personnel. This is referred to hereafter as ‘storage and transhipment’.

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

Each participant must establish the company-specific hazards relating to the safety of feeds and analyse and control them by applying HACCP principles. This standard describes as accurately as possible for activities or 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.

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 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 The 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.

GMP+ Appendices (GMP+ B_{Axx}), 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 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 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 storage activities and all the feeds that he stores 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 applicant is responsible for storage and transshipment.
 2. The applicant must specify all storage and transshipment which he carries out.
 3. All business locations and processes / process lines where production, treatment, processing, trade, storage, transshipment, affreightment and transport of feed are carried out, must be brought under the scope of the feed safety system.
 4. 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.
 5. All activities related not 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 are covered under the feed safety system.
 6. If the applicant decides to outsource storage and transshipment then the applicant must ensure that these processes also comply with the requirements of this GMP+ standard. The applicant must at least comply with the requirements in section 7.11.
 7. Separate standards have been established for the transport of feed (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.
- 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 record of the documentation of the storage and transshipment process and the audits.

The applicant must have a documentation system for the description of the critical points in the storage and transshipment process and for the drawing up and implementation of a quality management plan. He must keep the results of the audits. All these documents must be kept to be able to trace the storage and transshipment 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 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 laid down for the feed safety system or a reference to them as required as a minimum under the GMP+ standard(s);
- 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. Control measures are laid down in this as required to:

- a. approve documents for suitability before issue;
- 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. indicate the changes made, the change date and the version date of the documents;
- e. having the current versions available at workplaces where activities are carried out which are important for the implementation of feed safety;
- f. keep documents legible and easily recognisable;
- g. keep documents from an external source recognisable as such and controlling their distribution;
- h. prevent of unintended use of lapsed documents and application of appropriate identification if is the are retained for whatever reason.

Records must be administered 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 storage and transshipment 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 that it can obtain it if this is required for the setting up 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+ certification 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 by which it complies 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

- a. the assessment of opportunities for improvement as well as;
- b. the need for changes in the feed safety system, including feed safety policy and feed safety objectives.

Records of these 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.

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 1.5 Exclusion of Prerequisites also apply.

6.2 Personnel

6.2.1 General

Personnel performing work affecting feed safety must be competent on the basis of appropriate education, training, skills and experience. The applicant must have sufficient personnel with the skills and qualifications which are required for the safe storage and transshipment of feed.

The storage and transshipment 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 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 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 storage and transshipment areas which are aimed at preventing 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

Storage and transshipment 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 are clearly present a danger to feed safety such as contaminated sites, waste sites, etc. If the environment entails risks for feed safety then 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 feed¹.

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.

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

6.3.2.2 Production areas

Areas for the storage and transshipment of feed and also equipment, containers, boxes, vehicles and their immediate vicinities 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. storage and transshipment can take place in a tidy and orderly fashion
- f. the quality and safety of the feed can be guaranteed throughout the whole storage and transshipment process
- g. areas or storage units for products which are not part of feed (section 6.3.2.1c) are clearly recognizable and/or marked. If applicable the areas or storage units must be closable to prevent undesirable contamination of feed
- h. there is a good resistance to / protection against pest and other animals which may contaminate the feed.
Windows and other openings must be proofed against pests. Doors must close-fitting and proofed against pests when closed.
They must be closed as much as possible if the storage and transshipment 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 facilities on the ceiling must where necessary be designed, constructed and finished in such a way that no dirt can accumulate and condensation, undesirable mildew and loose particles are limited 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 storage and transshipment 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. Feed are stored and transported in appropriate containers. They are stored in areas which are design, equipped and maintained with good storage conditions in mind.
- o. Feed can be stored and transported in such a way that they can easily be identified and confusion and cross-contamination are avoided and spoilage is prevented.
A separate section of the storage area is intended for the storage of premixes and additives.
- p. If the applicant stores different products in a storage area then 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 then 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) ².
(If this is not feasible in practice then a company may in certain situations use a lower frequency of silo empty reporting. The reasons for this should be given. The company should realise that any recall will be larger in size because the period of time between two silo empty reports will be longer.

6.3.2.3 Systems

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

All installations which are used in the storage and transshipment of feed must appropriate for the weights or volumes to be determined and their accuracy must be checked regularly. The dosage capacity must also be matched to the quantity of product to be disseminated.

The following must be clearly stated and recorded with respect to the weighing 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 there is certainty that the applicant is sure that the whole weighed and/or dosed quantity of component is actually put into the feed for which it is intended.

If the applicant makes use during storage and transshipment of dosage silos then when filling these silos a proper locking system must be used.

Control of monitoring and measurement equipment installation

The applicant must determine before implementation of the monitoring plan which monitoring and measurement installations is required to demonstrate the feed

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

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 installations 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+ certification scheme.

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

6.4 Work environment

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

6.4.1 Maintenance

Production areas and equipment which is intended for use in storage and transshipment must be checked properly and regularly in accordance with procedures recorded in writing.

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 the feed material. 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.

Machines which come into contact with dry feed must be dried after wet cleaning or must be dry before 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 storage and transshipment that no pest is 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) that it is clear to everyone 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.

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 storage and transshipment 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 applicant must take appropriate measures to ensure that the feed produced can be traced effectively. 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 applicant must take appropriate measures to ensure that the feed stored and transhipped 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 storage and transshipment which can be used to trace the products effectively 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.

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+ certification scheme, the usual trading quality 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+ certification scheme.

then the participant will undertake the following actions:

- a. immediately inform the customer, and
- b. immediately block the animal feed by order of the customer.

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 Product Board Animal Feed. This should be done in accordance with GMP+ BA5 *Minimum Requirements EWS*.

6.7 Storage and transhipment

6.7.1 Control of storage and transhipment

The applicant must plan storage and transhipment and implement it under controlled circumstances.

There must be supervision of the presence of feeds, 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 shall, where applicable, consist of:

- a. the availability of information describing the characteristics of the storage and transhipment (see section 7.3.3);
- b. ensure that storage and transhipment 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);
- d. the use of appropriate equipment (see section 5.4.4);
- e. sufficient appropriate resources must be available to carry out the measurements, inspections and checks during the storage and transhipment (see section 6.3.2.3);
- f. the implementation of monitoring and measurement (see section 7.8), and
- g. the implementation of activities in the area of release, delivery and after-sales.

6.7.1.1 *Carry-over*

The applicant must determine on the basis of 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 product standards.

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 sections 7.10 and 8.3);
- h. 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 storage and transhipment

7.2.1 Establishment of storage and transhipment requirements

The applicant must determine the requirements with respect to storage and transhipment. These are at least:

- a. the relevant requirements set in the GMP+ FSA scheme including the requirements for delivery and after-care and special customer requirements The applicant must receive a specification of the feed that he is able to make a good risk analysis;
- b. requirements not established in consultation with the parties in the chain but which are necessary for the correct carrying out of the storage and transhipment;
- c. feed legislation requirements related to storage and transhipment, and
- d. any additional requirements determined by the applicant and which relate to safe storage and transhipment.

7.2.2 Review of the storage and transshipment requirements

The applicant must review the storage and transshipment requirements. This review must be carried out before the applicant accepts a commission for storage and transshipment of feed and must ensure that:

- a. the storage and transshipment 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 shall be maintained (see section 4.2.4).

Where storage and transshipment requirements are changed, the applicant 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 storage and transshipment on the basis of requirements

The applicant shall describe the storage and transshipment conditions based on the requirements which have been established to the degree necessary for proper identification and risk assessment.

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 storage and transshipment (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 storage and transshipment process in the form of process diagrams and a map which enables the organisation to identify and assess hazards.

The process diagrams and the layout must be verified by the HACCP team.

If there is any change to the storage and transshipment process then the applicant must review the procedures and modify them if necessary. The steps in sections 7.4 to 7.7 must then be gone through. The verification must be established in a plan.

7.3.1 Flow diagrams of the process

The process diagrams must comply with at least the following requirements:

- a. representation of all the individual steps in the process order including any work outsourced as well as any by-products, return products and waste which may be created during the process (purchasing to delivery);
- b. clear, accurate and sufficient detail in order to establish possible hazards and 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-manufactured and other feed, 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 prerequisite programmes are part of the hazards analyses.

7.4.1 Identification of dangers

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 feed which is issued by the customer;
- 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.

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 specifications which have been agreed with the customer. See section 7.3.1.

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 risk estimation can also be done using “chance x seriousness” method 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 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 must also be validated and verified to demonstrate their correct functioning.

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.

The applicant must determine the applicable norms (7.3.1). The norms (action and rejection limits) must comply with the relevant animal feed legislation and the norms defined within the framework of this GMP+ certification scheme. These norms must be considered to be (contractual) obligations with respect to the client. A suitable method of working has therefore been established and maintained with respect to the management and application of the relevant norms.

7.7 Monitoring and measuring

7.7.1 Monitoring plan

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

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

The monitoring plan must at least be in accordance with the inspections laid down 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. all planned measurements, inspections and checks and analyses;
- b. the procedures (including instructions) for and the frequency of the measurements, inspections, analyses and checks;
- c. the (analysis) methods and equipment to be used. These methods must demonstrate the capacity of the processes to achieve planned results;
- d. the compliance with the specifications – and the use in the event of non-compliance with the specifications;
- e. the personnel responsible for the carrying out of the measurements, inspections, checks and monitoring;
- f. the personnel responsible for the assessment of the monitoring results;
- g. 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 the Product Board Feed.

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 then 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-certified for this analysis then the applicant must at any rate have this analysis carried out by a laboratory which is GMP+ B10-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+ BA10 *Minimum Requirements for Purchasing* standard by the GMP+ International see GMP+ BA10 *Minimum Requirements for Purchasing*.

7.8 Corrective actions

The applicant must ensure that non-conformities in the storage and transshipment process with respect 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-conformities 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 the client and the 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. There must be consultation with the customer/owner.

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 in the storage and transshipment process is corrected then there must be verification again of whether there is compliance with the requirements.

NOTE: This control shall provide for identification, documentation, evaluation, segregation (when practical), disposal of non-conforming feed and for notification to the involved parties, 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 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 laid down.

Corrective measures are satisfactory and must prevent unsafe storage and transshipment from taking place 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 laid down 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 production or on the feed to be manufactured.

The applicant must assess suppliers and choose those suppliers who are able to deliver a product which complies with the requirements of the applicant. Criteria for selection, assessment and reassessment must be established. Records of the results of the review and any required actions arising from the review shall 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 storage and transshipment, 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.

7.10.3 Verification of the incoming materials

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

He should also check that the transport complies with the stated requirements (minimum 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).

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

7.11 Storage and transhipment

7.11.1 Property of the customer

The applicant must handle the property of the customer with care.

The applicant must establish, verify, protect and secure the property of the customer which is supplied. If any customer property is lost, damaged or is otherwise considered to be inappropriate for use then 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 whole process in the same way as its own products (in accordance with the requirements of this GMP+ standard).

7.11.2 Loading and delivery

When the customer is the client for the transport and the loading compartment is not clean, free from load remains or the odour of previous loads then the applicant must 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 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 storage and transshipment 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.

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 shall be planned and implemented in which all parts of the process must be addressed. Account shall be taken of the results of the previous audits.

The audit criteria, scope, frequency and methods shall be established. Selection of the auditors and the conduct of audits shall ensure the objectivity and impartiality of the audits. Auditors shall 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), shall be recorded in a documented procedure.

The management responsible for the department being audited shall ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities shall 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 shall 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 assess 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 the storage and transshipment requirements (see section 7.3.)
- b. characteristics and trends of the storage and transshipment process 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 shall 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 shall take action to eliminate the cause of non-conformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the non-conformities encountered.

A documented procedure shall 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 these actions taken (see section 4.2.4), and
- f. reviewing corrective actions taken.

8.4.3 Preventative action

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

A documented procedure shall be established to record requirements for:

- a. determining potential future 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 actions taken.