



GMP⁺ Certification Scheme Feed Sector 2006

Storage and Transhipment of Feed for Productive Livestock

GMP⁺ Standard B5

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1 SUBJECT MATTER AND AREA OF APPLICATION

1.1 General

This standard contains requirements for a management system (referred to hereafter as a feed safety system), whereby an organisation guarantees that feed are safely stored and transhipped. The application of good storage and transhipment practices and the principles of HACCP are part of the feed safety system. The system ensures that there is at least compliance with:

- Requirements which arise from the feed legislation which is related to the safety of humans, animals and the environment (see section 2).
- Additional requirements which have been agreed with the parties in the animal production chain under the quality chain regulations in the cattle, meat, eggs and dairy sector or additional quality regulations.
- The requirement that the storage and transhipment has no influence on the feed.

A number of terms

By 'feed' is understood: all substances and products including additives which are processed, partially processed or unprocessed which are intended for use in the oral feeding of animals (Dir. 178/2002). This includes feed materials, premixes, additives, semi-manufactured products, compound feeds or products which may be designated as such following a processing operation.

'Products' includes, in addition to feed, other substances which may be used in the production of feed (veterinary medical products, processing aids).

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'.

Relationship to the other GMP⁺ standards

This standard is part of the GMP⁺ certification scheme for the feed sector 2006. Also see the A-documents of the GMP⁺ certification scheme.

Separate GMP⁺ standards for the trading in and transport of feed have been adopted, namely B3 (for trading) and B4 (for transport). The layout of these standards corresponds to this standard so that organisations which, in addition to storage and transhipment, also trade or transport feed can easily combine this with the implementation of this standard.

The GMP⁺ standards B3 and B5 are specifically intended for organisations which are only engaged in trade or in storage and transhipment. An organisation which mainly carries out production or processing activities but which also trades in feed or is engaged in the storage & transhipment of feed does not have separately to apply the GMP⁺ standards B3 or B5. The requirements for trading in feed and for storage & transhipment and included in full in the GMP⁺ B1 standard.

For more information refer to the GMP⁺ document "Introduction to the GMP⁺ certification scheme Feed Sector 2006" and section 1 in each GMP⁺ standard.

Other basic principles

The applicant always remains responsible for the management of his feed safety system and for the internal company checks on compliance with the requirements of the GMP⁺ certification scheme. By complying with the requirements set in this standard for the storage and transshipment of feed and the feed safety system, and by having himself certified for this, the applicant can demonstrate to third parties the safety and quality of his services.

1.2 Application

The requirements of this standard are applicable to organisations which are engaged in storage and transshipment of feed irrespective of the type or scope of the organisation. It does not matter whether the product is the property of the applicant or of a third party. The responsibility of the applicant is limited exclusively to the storage and transshipment of the feed. For other forms of physical handling of feed (including transport) other GMP⁺-standards apply.

A applicant must determine the scope of his feed safety system including all activities and products in accordance with section 4.1. The applicant must determine on the basis of this which requirements and conditions in this standard are applicable and whether other GMP⁺ standards are applicable.

Attention: This separate GMP⁺ standard B5 (for storage and transshipment) and also GMP⁺ standard B3 (for trading) are specifically intended for organisations which are only engaged in trading or storage & transshipment. An organisation which mainly carries out production or processing activities but which also trades in feed or is engaged in the storage & transshipment of feed does not have separately to apply the GMP⁺ standards B3 or B5. The requirements for trading in feed and for storage & transshipment are included in full in the GMP⁺ B1 standard.

Exclusion of requirements

A requirement may well have the status 'not applicable' for a applicant and the applicant may exclude this requirement. He must, of course, provide reasons for the exclusion. The exclusion may in any event not lead to the applicant storing or transshipping feed which do not comply with feed safety requirements as defined in the GMP⁺ certification scheme

No requirements may be excluded because the applicant 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.

2 NORMATIVE REFERENCES

There are references in this standard to other documents (for example appendices). These documents belong to this standard and the applicant must comply with the requirements of these documents.

The applicant must also ensure that all storage and transshipment which is carried out under his responsibility complies with the community legislation, the associated national legislation and good storage and transshipment practices which are applicable.

For a summary of the relevant feed legislation within the framework of the GMP⁺ certification scheme feed sector 2006, refer to appendix 12.

3 TERMS AND DEFINITIONS

See GMP⁺ A2 Additional list of definitions

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 or processing, trade, storage or transshipment, affreightment or transport of feed are carried out must be brought by the applicant 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 not to pet foods may be excepted on the condition that they are carried out as such separately and that they do not have an influence on the storage and transshipment of feed which do fall 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 inland waterway affreightment, GMP B4. Inland Waterways Hygiene Code , GMP B4.4 sea transport affreightment and GMP B4.5 rail transport affreightment). A 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 safety of the feed and the storage and transshipment (see 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 measures which are necessary to achieve planned results and continuous improvement of these processes.

These processes must be controlled 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 the 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 in accordance with Appendix 6, 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 storage and transshipment process
- e. records required by this GMP⁺ standard (see section 4.2.4)
- f. all relevant required permits, records and certificates under the 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 among 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. 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 then to re-approve them; as in the event of changes to the feed legislation and/or the GMP⁺ standard
- c. indicate the changes made, the change date and the version date of the documents
- d. having the current versions available at workplaces where activities are carried out which are important for the implementation of feed safety
- e. keeping documents legible and easily recognisable
- f. keeping documents from an external source recognisable as such and controlling their distribution
- g. prevention of unintended use of lapsed documents and application of appropriate identification if lapsed documents 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 feed legislation
- b. establishing the feed safety policy (see section 5.2)
- c. establishing a management statement (see appendix 6)
- b. establishing feed safety objectives (see section 5.3.1)
- e. carrying out management reviews (see section 5.5)
- f. ensuring the availability of resources.

5.2 Feed safety policy

Top management must ensure that the feed safety policy:

- a. is appropriate for the safe storage and transhipment of feed
- b. is matched to the requirements laid down 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 retained 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 results of the feed safety system and any need for improvement, and
- c. to ensure that the awareness of the requirements of chain parties is promoted throughout the whole organisation.

5.4.4 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 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 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. the results of external audits

- c. the feedback from customers
- e. the extent to which storage and transhipment comply with the requirements
- e. the status of preventive and corrective measures
- g. the measures taken as a result of previous management reviews
- g. any changes which may influence the feed safety system, and
- h. any recommendations for improvement.

5.5.3 Review output

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

- a. the 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. requirements for resources to achieve the proposed improvements.

6 MANAGEMENT OF RESOURCES

6.1 *Provision of resources*

The applicant must establish 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 parties as recorded in the GMP⁺ certification scheme.

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 transhipment 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 storage and transshipment. 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, workspaces 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 transhipment must be carried out in an environment where it is not possible for the presence of potentially hazardous substances to lead to an unacceptable level of those substances in feed.

Production buildings may not stand on or near places which clearly present a danger to feed safety such as contaminated sites, waste sites, etc. If the environment entails risks for feed safety 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 and equipment

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. a strict and complete physical and organisational separation is applied and maintained between on the one hand feed 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 the safety of the feed safety. See section 6.4.4.

6.3.2.2 *Production areas*

Areas for the storage and transhipment of feed and also equipment, containers, boxes, vehicles and their immediate vicinities must be clean.

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

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 transhipment of safe feed
- 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.

6.3.2.3 Systems

The containers and equipment used for transport, storage, internal transport, handling and weighing must be clean.

All equipment which is used in the storage and transhipment 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 equipment:

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

Security must be applied such that 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 transhipment of dosage silos then when filling these silos a proper locking system must be used.

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:

- Spoilage must be prevented as much as possible and kept under control in order to prevent pest invasion.
- 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 are attracted. The purpose of this is to prevent the feed material being contaminated.

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

Post 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 disinfestation 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

The applicant must take appropriate measures to ensure that the feed stored and transhipped can be traced effectively.

The applicant must maintain a register with the relevant details with respect to storage and transhipment which can be used to trace the feed effectively from reception to delivery including export to the final destination.

The applicant then complies with the requirements of appendix 8.

The requirement for traceability is that the applicant controls and records the unique identification of the feed (see section 4.2.4).

7 PROCESS CONTROL

7.1 Prerequisite programme

In order to be able to apply the HACCP principles successfully, the applicant must establish and apply general prerequisite programmes for various parts of the business operation. The basic requirement programmes relate to, among other things:

- a. Personnel: such as the training & education of the personnel (see section 6.2)
- b. Infrastructure: such as the equipping of the buildings and production areas (see section 6.3)
- c. Work environment: such as maintenance, cleaning and pest control (see section 6.4)
- d. Other items: such as identification and traceability and purchasing (see sections 6.5 and 7.11)

The applicant must establish whether the above prerequisite programme provides a satisfactory basis for the successful application of the HACCP principles. If this is not the case then the applicant must work out and implement additional prerequisite.

7.2 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).

7.3 Requirements for storage and transshipment

7.3.1 Establishment of storage and transshipment requirements

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

- a. the relevant requirements set in the GMP⁺ certification 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 transshipment
- c. feed legislation requirements related to storage and transshipment, and
- d. any additional requirements determined by the applicant and which relate to safe storage and transshipment.

7.3.2 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.

7.3.3 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.

7.3.4 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.

7.4 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.

7.4.1 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.
- b. clear, accurate and sufficient detail in order
 - to establish possible hazards
 - to distinguish control measures used

7.4.2 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.

7.5 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 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.

7.5.1 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 (section 7.2.1)
- c. the business layout and resources used
- d. the process diagram drawn up
- e. the lay-out drawn up
- f. experience, expertise, research and other sources of information (internal/external)
- g. the generic risk assessment from the Database of Risk Assessments for Feeds Materials (DRV)

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.

7.5.2 Risk assessment

The HACCP team carries out a risk assessment for each identified hazard. The purpose is to establish whether a hazard is of such a nature that elimination or reduction to an acceptable level is essential for the production of safe feed.

The risk assessment takes place using a decision tree including the risk estimate ('chance x seriousness') from Appendix 15 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.

Risk assessment determines whether this is a critical control point (CCP). This is a point, step or procedure for which it is of vital importance that specific control measures (see section 7.6) are applied to prevent or eliminate the hazard or to reduce them and control them at an acceptable level

The reason for there being a Critical Control Point (CCP) must be recorded.

7.6 *General and specific 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 hazards analysis in section 7.5 that this risk may have a negative effect on feed safety.

Control measures can be classified as specific or general control measures. 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.

Specific control measures

Control measures which are associated with Critical Control Points (CCP) must be designated as specific control measures. Specific control measures are actions or activities which are essential for controlling a significant risk. They are often monitored by physical or chemical parameters such as temperature, time, humidity, pH and sensory parameters such as visual presence and composition.

The applicant must monitor each specific control measure. In addition, the specific control measures must include corrective actions and they must be validated and verified.

General control measures

Control measures which are not associated with Critical Control Points (CCP) must be designated as general control measures.

General control measures are actions or activities which are often part of prerequisite programmes (maintenance, pest control, cleaning, purchasing, training of personnel, etc.). See section 7.1 for this. In general the implementation of these measures gives an acceptable level of control.

General control measures must be validated to demonstrate proper functioning for the individual organisation. After validation, approval by the HACCP team takes place. The effectiveness with which the general control measures control the identified hazards must be verified.

7.7 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.

7.8 Monitoring and measuring

7.8.1 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⁺ certification 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 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⁺ B10 standard by the Product Board Feed See appendix 10.

7.8.2 Management of monitoring and measurement equipment

The applicant must determine before implementation of the monitoring plan which monitoring and measurement equipment is required to demonstrate the safe storage and transshipment 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.

If it is necessary to achieve valid results then the measurement equipment 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 then the basis used for the calibration or verification must be recorded (see 4.2.4) and inspections must be in accordance with standardised checklists.
- b. adjusted or re-adjusted if necessary
- c. identified so that the calibration status can be determined
- d. secured against adjustment which would make the measurement result invalid
- e. protected against damage and deterioration during handling, maintenance and storage.

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

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

7.8.3 Control of monitoring and measurement equipment (supplementary)

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

7.9 Corrective actions

7.9.1 In-company

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 (see Appendix 9 for further guidelines with respect to conditional 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.

7.9.2 Recall

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7.10 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 (HACCP plan).

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

Validation is carried out by demonstrating that:

- a. The list of potential hazards is complete and is based on proper scientific data.
- b. the risk assessment which, with the help of a decision tree including the risk estimate ('chance x seriousness') from Appendix 15 or at least equivalent, is based on practical experience, experimental data, literature, etc.
- c. the general and specific control measures are sufficient to control the hazards.
- d. the characteristics and methods used to monitor the control measures have the capacity to show that the planned results must be achieved.
- e. corrective measures are satisfactory and must prevent unsafe storage and transhipment 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.

7.11 Purchasing

7.11.1 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).

7.11.2 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 transhipment, 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.

7.11.3 Verification of 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.

7.12 *Storage and transhipment*

7.12.1 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)
- c. the use of appropriate equipment (see section 6.1)
- d. sufficient appropriate resources must be available to carry out the measurements, inspections and checks during the storage and transhipment (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.

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.

7.12.2 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).

7.12.3 Maintenance of the product

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7.12.4 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. 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.

8.4.4 Early warning procedure

The applicant has a documented procedure for the (early) signalling and treatment of signals which indicate that the safety of an feed might not match the statutory product standards or the product standards laid down in the GMP⁺ certification scheme and which might lead to damage to subsequent links in the chain. Signals are assessed on this basis and if desired control measures must be taken to prevent or to control the hazard which has been signalled.

If there is a potential hazard which can not be controlled by the applicant in question and which may also cause damage to others then the applicant is obliged to inform the Product Board Feed. This must be done in accordance with Appendix 5.