PRODUCTSCHAP DIERVOEDER

GMP+ Certification Scheme for the Animal Feed Sector 2006

Production of Feed Ingredients

GMP+ Standard B2

(Version 2009)

Adopted by the Central College of Experts for the Animal Feed Sector	
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Content

1. INTRODUCTION

1.1 General

A number of product safety assurance schemes have been introduced in the (international) feed sector since the 1990s. These were, on the one hand, initiated by certain countries as a result of demands from stakeholders in the food chain (dairy and meat sectors). On the other hand, because the feed sector is strongly internationally oriented, a number of European branch organisations have also decided to introduce such systems. These systems are characterised by voluntary participation, are aimed at the whole chain and include certification.
The systems are all based on accepted principles for quality assurance (ISO 9001, HACCP, GMP). Participation is not limited to companies which are established in a particular country. Mutual cooperation and harmonisation at system level is seen more and more often and a number of agreements related to mutual recognition have already been agreed. Developments in these areas are continuing.

The feed sector introduced the GMP$^+$ certification scheme for the animal feed sector in 1992 and has continued to develop it. This scheme applies to all links in the feed chain and is intended to ensure that the feed chain provides safe feed. Each link, from production of the feed to delivery to the farm, must provide a system for the assurance of feed safety as a result of GMP$^+$.

The GMP$^+$ scheme contains requirements and conditions for the assurance of the safety of each link in addition to (product) standards for feeds. The method of quality assurance is virtually identical for all the links in the chain and is based on the application of HACCP principles. General GMP$^+$ requirements have also been formulated for the realisation of the desired basic hygiene level in companies so that HACCP principles can be applied successfully. The HACCP and GMP$^+$ requirements are supplemented with ISO requirements in order to establish an effective and robust management system for feed safety.

Since the end of 1999, for the producers of feed ingredients a specific standard was published within the framework of the GMP$^+$-scheme. During the years this standard was named in different ways (QS-standard, and recently GMP$^+$ B2-standard) and the scope was extended to trade and storage, but always the requirements for controlling the feed safety remains more or less the same: a basic level.
In 2008 it was decided to update the GMP$^+$ B2-standard once more, in order to comply with current feed legislation and also to comply with other GMP$^+$-standards and with other feed safety schemes. And last but not least, updating was also necessary because companies, who apply this standard, have reached a certain, higher level of feed assurance.

The GMP$^+$ B2-standard in question is the result of extensive consultations with interested parties and also complies with the relevant EC feed hygiene regulations. Companies which comply with this standard can guarantee the safety of their activities and feed ingredients.

1.2 Structure of the GMP$^+$-scheme

The primary documents in the GMP$^+$ Certification Scheme for the Animal Feed Sector 2006 have been categorized into a number of series. Below you will find a schematic overview:

A General (framework) documents	These documents contain the requirements for participation in the certification scheme for companies and certification bodies (regulation, use of the logos, etc. This series also contains the general list of definitions and abbreviations.
B Normative documents	This series contains the standards for use by the companies for the various feed products and the various stages of production (including agricultural and industrial production, treatment and processing, collection, trade, various types of transport, storage and transhipment).
C Rules of Certification	These documents contain requirements and conditions for the certification bodies (including approval of certification bodies and auditors, audit frequency, minimum audit time, assessment criteria, checklists, etc). Also is laid down how supervision of the certification bodies is carried out
D Interpretations and guidances	Next to these scheme documents, some documents like FAQ-lists, Guidances etc., are categorized as D-documents.

All documents are to be found on the PDV-website

This standard is part of the B-documents. The next table gives a *general overview* of the scope of different B-standards

Activity	Product	B1	B2	B3 (2007)	B4	B5
Production	Compound feed	X				
	Premixtures	X				
	Feed materials	X	X			
	Feed additives	X	X			
Collection	Feed materials	X		X		
Trade	All products	X		X		
Storage and transhipment	All products	X		X		X
Transport (own)	All products		X	X	X	
Transport (for third parties)	All products				X	

1.3 Scope and application of this standard

This standard contains the requirements for a feed safety system for the assurance of industrial production of feed ingredients. This may include the transport of the own-produced feed ingredients.

Guidance
Feed Ingredients: A component part or constituent of any mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, animal or aquatic origin, or other organic or inorganic substances (derived from Codex).

This does include feed materials and feed additives, but also semi manufactured products, which are intended to use in compound feed or premixtures. This does not include
- o *compound feed, to be fed to animals.*
- o *premixtures, to be mixed into compound feed*

The requirements of this standard apply to organisations, irrespective of their type or size, which carry out activities which fall within the scope of this standard. It is not important whether a company carries out these activities on its own account or for a third party.

Each applicant must establish, analyse and control his own hazards through the application of the HACCP principles. This standard describes as accurately as possible for activities or feed ingredients which fall within the scope of this standard what the various risks and the associated control measures are. An applicant may include these control measures in pre-requisite programmes or carry them out as a specific measure to control a particular critical point. This standard also requires inspections and checks.

If a participant carries out other activities with feed ingredients or feeds (such as trade, the production of compound feeds or transport for third parties), then it may be necessary to apply another GMP$^+$ standard instead of, or in addition to, this standard. Refer also to section 1.4

The applicant remains responsible at all times for the safety of the feed ingredients and activities and for the checks on compliance with the requirements which he carries out himself. Compliance with the requirements of this standard and by being certified accordingly the applicant can demonstrate the safety and quality of his services or feed ingredients to third parties

Irrespective of the obligations arising from this standard, the applicant must only market feed ingredients which are sound, genuine and of merchantable trading quality[1].

The applicant must not place any feed ingredients on the market which represent a danger to the health of humans or animals or for the environment. The applicant must also avoid placing feed on the market in a way which could be in any way misleading.

1.4 The structure of this standard

A number of system requirements for feed safety are included in Chapter 4. Chapter 5 contains requirements for a number of prerequisite programmes. These programmes are essential for establishing a basic level of hygiene. Chapter 6 gives the minimum requirements for HACCP.
Additional requirements for the control of some operational activities can be found in Chapter 7. Requirements for verification and improvement are in Chapter 8.

The chapter layout of this standard is almost identical to that of the GMP$^+$ B3 standard (version 2007). The requirements in a number of chapters are also identical. If a (potential) participant comes to the conclusion (see also 4.3) that he also carries out activities for which the requirements in the GMP$^+$ B3 standard are applicable, then he should also comply with these requirements. He can then skip the identical chapters.

[1] *Merchantable quality is legally defined. See Dir. 1996/25/EG, Dir. 2002/32/EG or Dir.. 1979/373/EG.*

Guidance
The identical chapters are in particular chapters 4, 5, 6 and 8

GMP± Appendices, which are also referred to, are separate GMP+ documents which are not attached to this standard. They can be found on the PDV website www.pdv.nl. See also Chapter 2.

Guidance
Guidance has been included for some of the requirements in this standard. This is shown in a separate box. The guidance does not contain mandatory requirements but information which can be used to ensure that a particular requirement is met and which also contains information which is useful for auditors. To distinguish the requirements in the formulation of the guidance, use is often made of the term 'should' instead of 'must'.

1.5 Exclusion from requirements

It may be possible that certain requirements are not applicable to an applicant. An applicant may exclude these requirements. There must of course be reasons for the exclusions. The exclusions may in any event not lead to the applicant supplying feed ingredients which do not comply with feed safety as defined in the GMP+ certification scheme

No GMP+ 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

2.1 GMP+ Appendices

The following normative documents contain requirements which, if applicable, must also be complied with within the framework of references in this standard:

- GMP+ Appendix 01 Product Standards
- GMP+ Appendix 03 Minimum Requirements Negative List
- GMP+ Appendix 04 Minimum Requirements for Inspections and Verification
- GMP+ Appendix 05 Minimum Requirements EWS
- GMP+ Appendix 10 Minimum Requirements for Purchasing.
- GMP+ Appendix 13 Minimum Requirements for Taking Samples
- GMP+ Appendix 14 Minimum Requirements for Road Transport

You will find these documents on the Product Board Animal Feed website (www.pdv.nl).

2.2 Legal compliance

Special attention was paid when drawing up this standard to the inclusion of the relevant requirements in the feed legislation of the European Union. Compliance with this standard does not however guarantee that there is compliance with all the legal requirements or that feed legislation can then be ignored.

In addition to the requirements of this standard the applicant must also verify and ensure that his activities and all the feed ingredients that he supplies are in accordance with the applicable legal requirements both in the country where these are produced or processed and, if applicable, the countries in which they are placed on the market.

3. TERMS AND DEFINITIONS

For definitions and abbreviations see GMP+ document A2 (www.pdv.nl).

4. REQUIREMENTS FOR THE FEED SAFETY SYSTEM

4.1 Management: responsibility and involvement

Management must be aware of its responsibility for the safety of the feed. Feed is part of the food production chain.

Management must:

a. Make the organisation aware of the importance of feed safety and of compliance with both the requirements of the customer and the obligations of the feed legislation.
b. Demonstrate its responsibility and involvement in the development and introduction of the feed safety system to achieve safe feed.
c. Establish a HACCP Team.
d. Ensure that resources are available. The applicant himself must determine what resources are to realise safe feed and ensure that these resources are also available.
e. Assess at least once per 12 months whether the feed safety system is still suitable and effective. See for details about such a management review section 8.4

Guidance
Feed safety is mostly laid down in norms for undesirable substances. Refer to the applicable legislation and to GMP+ Appendix 1.

By resources is meant, among other things, the infrastructure (buildings, work areas and facilities), personnel and other means which are required for a suitable feed safety system. See for this Chapter 5

4.2 HACCP Team

In order to establish a risk assessment system, the applicant must appoint an HACCP Team to produce an effective HACCP Plan.

The HACCP Team must include personnel from all of the relevant operations and functions within the company and at least one member with demonstrably HACCP-knowledge and/or HACCP-experience.

The HACCP Team must carry out a hazard analysis with the object of identifying and controlling risks which could have a negative effect on feed safety. See for this Chapter 6.

The HACCP Team must have sufficient expertise in various disciplines or must be able to make use of expertise for the carrying out of the hazards analysis and the drawing up and maintenance of the required feed safety system.

The members of the HACCP Team must be recorded within the HACCP Plan.

It is acceptable for individual personnel to fulfil multiple roles in the HACCP Team or for the applicant to utilise resources from outside of the company, provided that the role of the team remains effective.

Guidance
To assist a company in identifying, evaluating and controlling hazards that are significant for food / feed safety, a so-called HACCP-Guideline was made. This guideline can be found on de PDV-website.

A HACCP Plan is a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food / feed safety in the sector of the feed chain.

4.3 The feed safety system

The applicant must establish, document, implement and maintain a feed safety system (FSS) in accordance with the requirements of this standard. The FSS must be adapted to regulatory and other safety related developments, as they occur.
The FSS must ensure that all those activities that could impact on the safety of the feed ingredients produced / processed are consistently defined, implemented and maintained in the organisation.

The applicant must determine and record the scope of the feed safety system by identifying the products / product categories and production sites which are covered by the system and ensuring that the feed safety objectives are established. The scope must in any event include all feed ingredients and all activities related to the feed ingredients for which the applicant is responsible.

The applicant shall determine the following:

- The part of the chain for which the applicant is responsible. This begins where the responsibility for the previous link (the supplier) ends and ends where the responsibility for the following link in the feed chain begins.
- All feed ingredients (in specifications) which are produced.
- All activities related to the production of the feed ingredients, including activities which are outsourced
- All relevant locations whether these are the property of the company or not, including locations where administrative activities are carried out.

If an applicant decides to outsource an activity which may have an influence on feed safety then the applicant must ensure that this activity is also carried out in accordance with the requirements of this GMP$^+$ standard and is also certified as such. See GMP$^+$ Appendix 10.

The applicant must also describe all other activities and/or products which are not feed related. The applicant must ensure that these activities do not have a negative influence on the safety of the feed ingredients.

Guidance
The scope of the system should include at least:
- *The original selection and sourcing of raw materials by participants*
- *All transport contracted or controlled by the participant*
- *The process by which feed ingredients are produced*
- *All storage and handling contracted or controlled by the participant*

See also section 6.2.

With respect to transport the applicant must at least include in the description the number and type of transport means, the types of loads which are transported and the cleaning method used. See also the sections containing transport requirements.

The structure of the FSS may be specific to the organisation of the applicant and include policies, requirements and documented procedures that maintain feed ingredient safety.

The description of all activities may result in the participant having to apply a second or perhaps a third standard in addition to this standard. If in doubt, consult your certification body or the PDV- website for more information.

4.4 Documentation and registration

4.4.1 Quality documentation and -manual

Applicants must produce and implement their own set of operating procedures that incorporate the requirements of this standard.

The FSS documentation must include:

- The documented Quality Policy, including feed safety objectives.
- The Quality Manual, covering or referring to:
  a. Description of the scope of the feed safety system as required in section 4.3
  b. All relevant records or approvals in accordance with national and international legislation
  c. The HACCP documentation
  d. All procedures, instructions, registration forms, etc. required by this standard, and/or necessary for the operating of the FSS.
  e. All records of treatment, audits and inspections and all other records which are required under this standard. This register must be set up and maintained as evidence of compliance with the requirements and of the effective operation of the feed safety system.

There must be a clear, unambiguous structure applied to these documents, instructions, forms, etc.

Guidance:

- *It should be clear from the objectives that Management is aware that they also make products which will be designated as 'feed'*
- *Re. b) This may also include legal permits to produce or to export*
- *Documented procedures may form part of a structured and certified feed safety and/or quality management system, or be part of a national, industry or company scheme that delivers equivalent controls. Independently certified HACCP or quality systems are not a pre-requisite for certification against this standard.*

4.4.2 Control of documentation and data

The documents and (registration) data must be controlled. They must be kept and maintained in the correct fashion.

This means that the documentation must:

- Be up-to date
- Be reviewed at least annually, approved, dated, and signed by an authorised person.
- Be readily available and understood by those required to operate to the requirements of the procedure.
- Be revised to reflect any significant changes that have an effect on the operations of the applicant and ensure the content of procedures remain current and accurate.

Applicants must ensure that:
- All records required by this standard are kept for a minimum of three years, unless longer periods are required by legislation.
- Storage facilities for records prevent any deterioration or damage to records under normal storage conditions.
- Records are sorted and filed in such a way that information is complete and easily retrievable.
- Records are legible.

Guidance:
Applicants should demonstrate that they have systems and procedures in place that ensure they remain up-to-date with regulatory requirements and any food / feed safety issues relevant to the feed ingredients they supply.

Information relating to safety issues that may affect the operation of the organisation should be reliably and effectively transmitted to those personnel with responsibility for the areas involved. Any changes in practices or procedures necessitated by new information should be implemented effectively.

4.5 Identification and traceability / sampling

4.5.1 Identification and traceability

Feed ingredients and all other substances which are intended to be processed in a feed or for which it may be expected that they will be processed in a feed, must be traceable in every stage of production, processing and distribution so that, in applicable cases, they can immediately be withdrawn from the market in a specific and precise way and/or the users of these products can be properly informed.

The participant will take suitable measures to ensure that the specified products can be traced effectively during each of the stages referred to above for which the participant is responsible. He will maintain a register with the relevant details with respect to the purchase, production and sale which can be used to trace the specified products from reception to delivery.
The participant must have the necessary information available within 4 hours unless the local authorities have established a shorter time.

The participant must record at least the following details of all products and services:
- Name and address details of suppliers and customers
- Date of delivery
- Type of product or service
- Product quantity
- Batch number, where appropriate

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

Guidance
Products: all substances intended for use as, or processed in, feed for animals. Within the GMP+ certification scheme, the scope of this definition includes all types of feeds (compound feeds, premixtures, feed materials and feed additives) and also, for example, veterinary drugs and processing aids (GMP+ A2 'Definitions and Abbreviations').

The batch number can also be designated as a manufacturer's batch number, a reference number, a batch number or a lot number.

4.5.2 Sampling

In addition, within the framework of traceability sufficient samples must be taken from incoming raw materials and/or outgoing feed ingredients. To do this a previously-determined procedure must be followed by the applicant.

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

See for this GMP+ Appendix 13.

Guidance
GMP+ follows the EU Feed Law on this matter. This means that at least all applicants who actually physically produce should take samples.

4.6 Complaints

Applicants must document their procedure for handling complaints from customers. This procedure must in any event describe the registration of relevant aspects of the complaint and the measures taken.

A procedure for recording and handling complaints must at least consist of:

a. The registration of complaints
b. The examination of the sources of complaints
c. Registration of the measures which were taken as a result of the complaint
d. Registration of communication with the customer in question.

5 PREREQUISITE PROGRAMMES

The applicant must implement an effective prerequisite program, which is at least in compliance with relevant requirements of this standard

Guidance
In order to be able to guarantee safe feed ingredients, the HACCP system should be founded on a sound basis: the so-called prerequisite programme. These prerequisites and (hygiene) practices are considered to be a pre-condition for the implementation of an effective HACCP Plan. Prerequisite programmes create the environmental and implementation conditions for the provision of safe feed ingredients. See Codex Alimentarius.

This Chapter 5 describes the requirements for certain elements of the prerequisite programmes with respect to personnel, buildings, production areas and equipment and for maintenance and hygiene control.

Prerequisite programmes do not have to be limited to these elements; other aspects may also be considered to be prerequisites.

Where prerequisite methodology is used, the prerequisites identified must be defined as part of the HACCP Plan and included in any auditing schedule established as a result of the HACCP Plan.

5.1 Personnel

5.1.1 General

All personnel must be aware of their responsibility for feed safety.

There must be:
- an organisational chart
- a description of the qualifications (for example diplomas, summary of professional experience) and the responsibilities of (also temporary employed) personnel.
- a qualified person who is responsible for the production.

All personnel must be informed clearly in writing of their duties, responsibilities and powers with regards to the maintenance of safe raw materials and feed ingredients. This information must be updated in the event of any significant changes.

Protective clothing must be worn wherever contamination of feed ingredients by personnel is identified as a risk by the risk assessment study. All clothing and equipment must be maintained in hygienic condition.

Clear policies on smoking and eating / drinking on site must be made known to employees and visitors and must prohibit eating, drinking and smoking in areas where these activities may adversely affect feed ingredients. If necessary, separate facilities must be provided.

The applicant must ensure that engineers and contractors working on site are controlled in such a way that maintenance and building works do not adversely affect either raw material or feed ingredient safety. There must be a procedure in place to ensure that appropriate cleaning and tidying has been completed prior to recommencing activities in that area.

5.1.2 Competency and training

Personnel who carry out work which may influence feed safety must be competent. Their level of competency is based on suitable courses, training, skills and experience. The applicant must have sufficient personnel with the skills and qualifications which are required for the production of safe feed ingredients.

The applicant must:

a. Establish the necessary skills which the personnel must have if they carry out work which influences feed safety. This also applies to the HACCP Team
b. Offer training or take other measures to meet these needs
c. Maintain personnel records of courses, training, skills and experience.

The above also applies to temporary personnel.

5.2 Infrastructure

5.2.1 Environment

The production of feed ingredients 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 ingredients.

If an environment presents a risk to feed safety then the applicant must show by way of a hazard analysis that the risks are sufficiently controlled.

Guidance
Buildings where production takes place or where work is done on feed ingredients should not be at or near to places which present a clear hazard for feed safety. This includes contaminated ground, proximity of rubbish tips and suchlike.

5.2.2 Facilities and equipment

5.2.2.1 General

Facilities and equipment must be designed, constructed, maintained and managed to ensure that the safety of raw materials and feed ingredients is protected at all times. Consideration must be given to preventing both the malicious and accidental contamination of feed products.

They must be designed and constructed such that, where necessary:
- accumulation of dirt is prevented;
- condensation, undesired mould and falling particles are limited
- cleaning, disinfection and maintenance can be carried out properly.
- that birds and other animals have the least possible chance of getting in.

The facilities must be such that:
- the chance of errors is limited as much as possible and contamination, cross-contamination, carry-over and any other negative influence on the safety of feed ingredients is prevented as much as possible
- There can be no confusion among the various feed ingredients, the feed ingredients are properly identified and no incorrect use of the feed ingredients can take place
- That a strict and complete physical and organisational separation is imposed between the feed and products which do not belong in feed.

This separation is intended with respect to feed safety to prevent feed ingredients coming into contact or being mixed with other products.

The facilities must be provided with proper natural and/or artificial lighting to ensure that cleaning, processing and other activities important to raw material and feed ingredient safety can be undertaken effectively.

Ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of moulds and the shedding of particles that may adversely affect the safety of raw materials or feed ingredients.

Sewer, waste, rain and melt water must be discharged in such a way that the equipment and the safety of the feed ingredients in not influenced. Spilled feed and dust must be controlled to prevent pest.

Drainage facilities are suitable for the intended purpose. They must be designed and and constructed in such a way that any risk of contamination of the feed ingredients is prevented.

Guidance
Examples of products which must not be in feed are: fertiliser, fuel, cleaning and disinfectant agents, glass, crop protection agents, waste.

5.2.2.2 Intake and loading facilities

Proper areas must be provided for reception, loading and unloading and the storage of feed ingredients and potentially hazardous products (such as cleaning agents, lubricants, fuels, etc.).

During reception or loading and unloading the applicant must do everything which is reasonably possible to create such conditions that the risk of contamination is avoided and that, for example, bad weather can not have an influence on the feed ingredients to be loaded.

During loading, unloading and storage the penetration of rain water and contaminated water must be prevented.

5.2.2.3 Storage facilities

Adequate facilities for storage of feed ingredients and potentially hazardous products (e.g. cleaning materials, lubricants, fuels, etc) must be provided.

In the case of a storage area care must be taken that mud, snow and other potential contaminants which may be transferred by vehicles are not able to exert any negative influence on the stored feed ingredients.

There must be sufficient hardened ground (for example a concrete floor) at the entrance to the storage area so that water and mud are not able to penetrate the storage area.

5.2.2.4 Equipment

All equipment used for producing feed ingredients must be fit for the purpose for which it is used.

Equipment coming into contact with feed ingredients must be designed and constructed to ensure that, where necessary, it can be adequately cleaned, disinfected and maintained to avoid the contamination of the feed ingredients.

Where mechanical drying is undertaken, procedures must ensure that any adverse effect on the feed ingredients being dried is minimised.

Where drying operations result in combustion gases coming into contact with raw materials or feed ingredients, applicants must be able to demonstrate that drying does not increase the levels of undesirable substances beyond the maximum levels prescribed for feed ingredients in the regulations of the country of production and the countries where the applicant will put feed ingredients onto the market.

Magnets and / or metal detectors must be included in production systems where indicated as necessary by the risk assessment study.

Critical sieves, screens, filters, separators, magnets and metal detectors must be regularly checked to ensure that they are not damaged and that they continue to operate effectively.

All scales and metering devices which are used in the production of feed must be appropriate for the range of weights or volumes to be weighed or dosed, and their accuracy must be checked regularly. The dosage capacity must also be matched to the quantity of product to be disseminated. The following must be clearly stated and recorded with respect to the weighing equipment:

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

Security must be applied such that the applicant is sure that the weighed and/or dosed quantity of component is actually put into the feed (batch) for which it is intended.
If the applicant makes use during production of dosage silos when filling these silos a proper locking system must be used.

Where screenings (materials separated from the primary production stream by sieves, screens, filters, separators, etc) are reclaimed or reprocessed for inclusion in feed ingredients, the risk assessment study must consider the potential hazards resulting from such practices (for example, where undesirable or unwanted materials are removed from a primary product and concentrated into a by-product supplied as a feed ingredient). Any necessary precautions must be implemented.

5.2.3 Access regulation

Access arrangements must be established for the production areas. Anyone who is not an employee may only be given access to the production areas under the supervision of or with the permission of an authorised person.

5.2.4 Other items

5.2.4.1 Cross-contamination

Technical or organisational measures must be taken to prevent or minimise cross-contamination or errors, including contamination by means of carry-over

Equipment and procedures must be designed and operated to ensure that cross-contamination between different types of feed (or other) materials is minimised.

The processed feed ingredients must be kept separate from the untreated feed ingredients to prevent cross-contamination.

The applicant must determine based on 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 ingredient to another through carry-over and may lead to an unsafe feed ingredient or to a feed ingredient which does not comply with the residue standards laid down in GMP+ Appendix 1.

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

The measurement frequency of carry-over in production and transport lines depends on the (feed with) feed additives and feed medicines which the applicant processes and whether he processes feed ingredients for which a residue standard has been established. See GMP+ Appendix 1 for this.
The applicant must measure this carry-over by means of a testing procedure established by the Product Board Animal Feed. See GMP+ Appendix 4 for this.

The carry-over must be re-established in the above situations in the event of major changes to the installation.

Guidance
Carry-over = contamination of a material or product with another material or product that originates from previous use of equipment and would alter the quality and safety beyond the established specifications.

5.2.4.2 Dust Control

Applicants must take reasonable precautions to limit the accumulation of dust and other residual materials in areas where raw materials and feed ingredients are either processed or stored.

5.2.4.3 Air Movement

In cases where air is used for conveying or cooling, the applicant must evaluate the risk of this becoming a vehicle for pathogens and take any necessary precautions.

5.2.4.4 Water and steam

The applicant must be sure that the water or the steam which is used during the cleaning or in the production of the feed ingredients is safe for animals. The applicant must ensure that the feed ingredients are not contaminated by the use of water of poor quality.
Special attention must be paid to processing aids.

5.2.4.5 Processing Aids and Technological Additives

Where processing aids are used during production, a risk assessment must show that the unintentional but technological unavoidable presence of residues of the substance or its derivatives in the feed ingredient do not have any adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed.

Applicants must ensure that control systems provide the correct and effective dosing levels for processing aids and technological additives at all times.

Dosing systems for processing aids and technological additives must be calibrated by a competent person and calibration records maintained.

Guidance

Processing Aid: means any substance not consumed as a feeding stuff by itself, intentionally used in the processing of feeding stuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed;. (Regulation (EC) No 1831/2003)

Technological Additives: Any substance added to feed ingredients for a technological purpose, i.e. preservatives, antioxidants, emulsifiers, stabilisers, thickeners, gelling agents, binders, substances for the control of radionuclide contamination, anti-caking agents, acidity regulators, denaturants. (Regulation (EC) No 1831/2003)

5.2.4.6 Packaging

The packaging of the feed ingredients must be suitable for the kind of feed and the chosen method of delivery or transport. The packaging must be designed for the protection of the feed ingredient during normal storage, treatment and delivery conditions.

Reusable packaging should be sufficiently sturdy, easy to clean and, if necessary, should be able to be disinfected. The participant should establish a cleaning regime on the basis of a hazard analysis. If applicable, special attention should be paid to the recovery from livestock farms of pallets and other reusable packaging material.

5.3 Maintenance and hygiene management

5.3.1 Maintenance

A (written) programme of planned maintenance must be drawn up and implemented for all relevant areas and equipment so that safe and hygienic operations are ensured.

Records of the maintenance activities must show that there is compliance with the requirements.

5.3.2 Maintenance of measuring equipment

All inspection, measuring and test equipment used to confirm that feed ingredients meet specified feed safety requirements must be calibrated at intervals not exceeding 12 months.

Records of the results of calibration and verification must be maintained.

Guidance
The applicant should ensure that:
- *Calibration acceptance criteria are defined.*
- *Calibrated equipment is traceable to national standards or when this is not possible that the basis of the calibration is defined.*
- *All relevant equipment is uniquely identified and traceable to calibration records.*
- *The calibration frequency is defined.*

If equipment is found to be performing outside acceptable calibration limits the applicant should investigate the effect this will have on the conformity of any feed ingredients and take appropriate corrective action to recalibrate the equipment. Depending on the severity of the discrepancy and the nature of the test, the applicant should be able to demonstrate that appropriate action has been taken (for example feed ingredient recall).

5.3.3 Cleaning & sanitizing

Applicants must ensure that at all relevant stages of the production, storage or handling of raw materials and feed ingredients sufficient standards of cleanliness are operated such that exposure to pests and pathogens is minimised.

A cleaning programme must be documented and ensure that feed ingredient production, storage and transport facilities are cleaned in a manner that is sufficient to maintain feed ingredient safety at all times.

Cleaning and disinfection programmes must be monitored for their suitability and effectiveness. An authorised person must carry out inspections of cleaning and a record of all inspections must be kept.

Cleaning and disinfection / sanitising chemicals must be stored, where necessary, separately in clearly identified containers to avoid the risk of (malicious or accidental) contamination.

Guidance
Cleaning should remove residues and dirt that may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the business and may include disinfection / sanitising.
Only food-/feed compatible cleaning and disinfectant / sanitising agents may be allowed to come into contact with feed ingredients and should be used in accordance with manufacturers recommendations and safety data sheet requirements. Where cleaning agents and disinfectants / sanitizers come into contact with feed ingredients, the applicant should ensure that control systems provide the correct and effective dilution levels at all times.

The cleaning programme should contain at least the following elements:
- *(production) areas and production halls*
- *equipment and (internal) transport systems*
- *involved personnel*
- *frequency of cleaning*
- *the cleaning agents used should be recorded and should be suitable for purpose. In addition, these activities may not form any risk at all for feed safety remains of cleaning and disinfectant agents should be minimised*

5.3.4 Pest prevention and -control

Everything which is reasonably possible must be done to keep birds, pets and pest away from the production areas and to prevent their presence. The applicant must take measures to counter pest and set up, implement and document a pest control programme.

Appropriately qualified / trained personnel must carry out any control treatment required.

Activities within the framework of pest control must be planned, carried out and recorded. Records of the control activities must show that there is compliance with the requirements.

Guidance

- *Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites.*
- *Doors should be kept closed whenever possible and should be close-fitting and proofed against pests when closed.*
- *Holes, drains and other places where pests are likely to gain access should be kept sealed wherever possible. Where sealing is not possible measures such as wire mesh screens should be in place to reduce the possibility of pest entry.*
- *Animals should, wherever possible, be excluded from the grounds of factories, and the area surrounding stores and production plants. Where the presence of pigeons, sea-gulls and other pests is unavoidable, procedures should be implemented to protect raw materials and feed ingredients from potential contamination.*
- *In cases where shooting is undertaken as part of the pest control programme lead, or other toxic ammunition, should not be used.*
- *All bait containers should be fixed in their intended position unless there is a specific reason why this is not appropriate.*
- *Open bait containers and loose baits should not be positioned in areas where their use may result in a hazard to raw materials or feed ingredients.*

Pest control procedures should be documented and should ensure that no materials designed to kill or deter pests can contaminate raw materials or feed ingredients. Pest control records should include:

- *Details of any poisons used including safety data sheets.*
- *Qualifications of personnel involved in pest control activities.*
- *Map(s) indicating the location of any bait stations and the baits with which they are baited.*
- *Records of any pests found.*
- *Details of corrective actions implemented.*

5.3.5 Waste management

All materials which are considered to be waste must be visually designated as such and protected in such way that the chance of errors or unintended use is eliminated.

The waste must be collected and stored in separate bins or containers. These must be easily identifiable and must be covered in the case of pest or insect waste.

5.3.6 Glass and breakable materials

The applicant must ensure that glass and breakable materials do not form any hazard to the feed ingredients. All reasonable efforts must be made to minimise the risk of glass breakage and to ensure that no contamination of feed ingredients can take place in the event of glass breakage.

6. HACCP

6.1 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:
- Conduct a hazard analysis
- Determine Critical Control Points (CCP's)
- Determine standards for CCP's
- Set up and implement a monitoring plan for CCP's
- Define corrective measures
- Validate and verify the HACCP plan
- Document and register the HACCP plan

To apply these principles successfully, the applicant must first comply with a number of other requirements which are laid in other chapters and sections of this standard:
- Establishing a HACCP-Team (section 4.2);
- Description of product and process, including the intended use (section 6.2)
- Establishing and implementing a prerequisite program (Chapter 5)

Guidance
Refer to the HACCP manual on the PDV website for a description of a step-by-step approach to the application of the HACCP principles

The results of the application of the HACCP-principes can be recorded in a so-called HACCP Plan, being a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food / feed safety in the sector of the feed chain under consideration. (Codex adapted)

6.2 Description of products and process

6.2.1 Feed ingredient specification

The applicant must determine and specify all (safety) requirements with respect to the feed ingredients to be produced, including storage and/or transport. This specification must be kept up-to-date

This means
- legal requirements
- all additional relevant GMP$^+$-requirements
- other special customer requirements. If the customer participates in a certain feed safety programme then the applicant must ensure that he (the applicant) understands and complies with the specific requirements of the programme such as the specific conditions under which the storage or transport must take place.
- intended use

There must be a description for each feed ingredient. The scope of the description of the feed ingredient must stretch from the ingredients used during production (raw materials, processing aids and/or (technological) additives) up to and including distribution.

Where feed ingredient 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.

If the applicant produces a *feed material*
- for which there is not a generic risk assessment listed in the Feed Materials Risk Assessment Database of the Product Board Animal Feed, or
- using a method of production which does not correspond to a generic risk assessment which has already been listed in the Feed Materials Risk Assessment Database of the Product Board Animal Feed

the applicant must ensure that a risk assessment is listed in the database in question. The above does not apply to feed materials which are only processed in feeds for domestic animals.

Guidance
The GMP+-scheme is focussed on assuring the safety of feed. A specification should at least contain information about safety aspects. Finished product specifications provide an initial indication of possible hazards. In addition to the ingredients used (raw materials, additives, processing aids), other features must be mentioned that may influence food and feed safety. This may relate to chemical, physical and microbiological features (in the sense of polluting or undesirable substances) or the required conditions for production, storage and transport.

The conditions and standards as included in the various appendices to the GMP standard must be taken into account and included in the specification if necessary:
- *GMP+ Appendix 1 (with product standards)*
- *GMP+ Appendix 3 (with a negative list of feed ingredients)*
- *GMP+ Appendix 4 (with minimum requirements for inspection and verification)*
- *GMP+ Appendix 10 (with purchasing requirements)*

See the PDV website for the procedure how to send in a risk assessment for publication in the Feed Materials Risk Assessment Database.
*A generic risk assessment of a **feed additive** does not have to be listed in the Feed Materials Risk Assessment Database.*

6.2.2 Raw material specification

Based on the safety specification of the feed ingredient (= finished product), also the raw materials and other products used during production, must be specified. When preparing these specifications the participant must
- take into account the requirements and standards as included in the various appendices to this GMP+ standard,
- specify also information of the production or process from which the raw material is derived.
- information from a risk assessment for each raw material, identifying potential hazards and the means by which these hazards are controlled by the supplier, the applicant or both parties.

Where risk assessments identify the need for specific controls or limits to ensure the appropriate management of potential hazards, these must be included in the specifications agreed with suppliers of the affected raw materials.

Guidance:
This also counts for services

6.2.3 Process description

The HACCP Team must draw up a description of the production process for each feed ingredient in the form of flow diagrams and a layout which enables the organisation to identify and assess hazards.
The flow diagrams and the layout must be verified by the HACCP Team, and must be kept up-to-date.

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

a. representation of all the individual steps in the process order (from purchasing through to delivery), including any work outsourced as well as the description of all products used and also any by-products, customer returns and waste which may be produced during the process.
b. clear, accurate and sufficient detail in order
   - to establish possible hazards
   - to distinguish control measures used

The whole infrastructure of the establishment must be shown in a diagram of the organisation, such as

a. the production units, storage areas and personnel facilities
b. the routing of products
c. the areas/rooms where cross-contamination or incidental contacts are possible between raw materials and auxiliary substances, lubricants and cooling agents, semi-produced and other feed (end products), packaging, pallets, etc.

Guidance
See the HACCP manual on the PDV website for an overview of the useful symbols with which a process can be described schematically

6.3 Hazard analysis

6.3.1 Hazard identification

The HACCP Team must identify and record systematically all potential hazards which may have a negative effect on feed safety.

The hazard identification is based on:
- raw materials and auxiliary substances
- the specification of the animal feed
- the business layout and resources used
- the process diagram drawn up
- the lay-out drawn up
- experience, expertise, research and other sources of information (internal/external)
- the generic risk assessment from the Database of Risk Assessments for Feed Materials (DRV) (if applicable)

For each hazard the HACCP Team also records an acceptable level of presence in the animal feed whereby there is at least compliance with the statutory norms and those laid down in the GMP+ certification scheme.

6.3.2 Risk Assessment

The HACCP Team carries out a risk assessment for each identified hazard. This is also done systematically, and with the purpose 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.

6.4 Establishing control measures and critical control points (CCP's)

6.4.1 Establishing control measures

The HACCP Team must establish, record and implement the measures to control any risk for which it has been established based on the hazards analysis 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.

6.4.2 Establishing critical control points (CCP's)

The HACCP Team must then determine whether this control measure is the last measure in the process for controlling the risk. If this is the case then there is a critical control point (CCP). The reasons for why there is a critical control point (CCP) must be recorded.

6.5 Establishing critical limits

In order to establish whether a specific control measure is effective, the HACCP Team must establish for each Critical Control Point (CCP)

a. which parameters must be measured, analysed or observed, and
b. which product standards (action and rejection limits) apply for these parameters.

The derivation of the product standards must also be established.

In establishing the product standards (action and rejection limits) there must be compliance with the relevant feed legislation and the product standards established under this GMP$^+$ certification scheme. These product standards must be considered to be (contractual) obligations. A appropriate method of working has therefore been established and maintained with respect to the management and application of the relevant product standards.

Guidance

In establishing the critical limits or product standards the applicant should make use of what has been determined in 6.2.

In addition to compliance with the adopted product standards (GMP$^+$ Appendix 1) the applicant should comply with the residue levels of feed additives and feed medicines. GMP$^+$ Appendix 1 contains the maximum residue standards for (critical) feed additives and feed medicines. These product standards apply to compound feed, semi-finished products, feed materials and premixtures.
To control the residue standards the applicant should, among other things, measure the carry-over for the installations and based on the results obtained from this establish the production order. See for this 5.2.3

6.6 Monitoring

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

The plan includes all planned measurements, analyses and observations of features which indicate that the critical control points are controlled and applies to processed materials up to and including the produced feed (end products).

The monitoring plan must at least be in accordance with the inspections established in this GMP+ 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:
- the procedures for and the frequency of the sampling
- the (analysis) methods and equipment to be used These methods must demonstrate the capacity of the processes to achieve planned results.
- the frequencies of the analyses, checks and inspections
- the compliance with the specifications – and the use in the event of non-compliance with the specifications
- all planned inspections and checks and analyses
- the instructions for the carrying out of inspections and checks
- the personnel responsible for the carrying out of the monitoring
- the personnel responsible for the assessment of the monitoring results
- the personnel responsible for releasing the feed.

Guidance
The applicant should –as the occasion arises- check that the established residue standards for feed additives and feed medicines are not exceeded. This should be done at least after the measurement of the carry-over and the setting up of the production order in accordance with 7.12.1 and – if there is reason to do so - at other moments.

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 Animal 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 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 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.

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. See GMP+ Appendix 10.

6.7 Corrective actions

The applicant must ensure that non-conformities (in the feed ingredient or the process) to the requirements in this standard are recorded and controlled in order to prevent unintentional use or delivery of the product. The controls and associated responsibilities and competences for dealing with non-conformities must be defined in a documented procedure.

The applicant must deal with non-conforming feed in one or more of the following manners:

a. by taking measures to remove the observed non-conformities
b. by permitting use, release or acceptance with the approval of a competent authority
c. by taking measures to exclude the originally-intended use or application If products are no longer appropriate for feed they must be transported to a destination that is in accordance with the provisions in the applicable feed legislation.

Records of the nature of non-conformities and any measures taken later, including approvals obtained, must be maintained (see section 4.4).
If a non-conformity is corrected it must be verified again to show that it complies with the requirements.

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

6.8 Validation

An independent validation of the HACCP plan must be carried out. Management must establish a validation team in order to avoid undue influence. The members of the HACCP team can be members of the validation team but the validation team must have independent members. If this is not possible for the participant then he may deviate from this as long as his reasons are given.

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

Guidance
The purpose of validation is to establish independently that the hazards which were originally established by the HACCP team are complete and correct and that they will be effectively controlled using the HACCP-plan.

It is apparent from the requirements that validation can not be carried out by the HACCP Team itself as independence would not be guaranteed. If a participant has no possibility to establish a separate team then he may deviate from this. The reasoning does have to be provided.
Independent persons are, for example, members of production who were not directly involved in the drawing up of the HACCP Plan.

7. CONTROL OF OPERATIONAL ACTIVITIES

7.1 Purchase

7.1.1 General

The applicant must ensure that the purchasing of raw materials (including processing aids, etc.), services and feed ingredients are in accordance with the GMP$^+$-requirements. The purchase of all raw materials, services and feed ingredients must be clearly recorded.

A documented procedure must be drawn up for the whole purchase process. Specifications must be documented and must be part of the purchase documents and contracts.

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

If the applicant purchases feed ingredients or services, for which there is a GMP$^+$ standard, the applicant must make sure that these feed ingredients or services are:

a. from suppliers who are GMP$^+$- certified at the moment of delivery, or
b. from suppliers which are certified based on a standard approved in the GMP$^+$ certification scheme.
c. Certain feed ingredients and services may also be bought without one of the above certificates (i.e. from a non-certified supplier). Separate requirements have been established for this.

In GMP$^+$ Appendix 10 there are details of the above options.

d. Prior to the purchase of raw materials or other services than storage and transhipment, transport or laboratory, the applicant must carry out its own risk assessment based on HACCP principles. Based on this risk assessment and also the quality assurance, which is applied by the supplier, the applicant must make a selection of suppliers and must adjust his (entry) check accordingly. See section 7.1.3

Each type of *feed material* that is purchased, received or produced must be listed (with a generic risk assessment) in the Database of Feed Materials Risk Assessments (DRV). If the feed material in question is not listed in the Database of Feed Materials Risk Assessments (DRV), the applicant can only purchase, produce or sell it within the framework of GMP$^+$ -certification scheme after this feed material is listed in the database.
For the procedure how to list a feed material in the DRV database, see the PDV website.
The above does not apply to feed materials which are only processed in feed ingredients for domestic animals ('petfood').

Guidance

If the applicant buys products from a certified supplier, he should make sure that the product in question is produced under the scope of the certificate.

In the GMP$^+$-scheme it is possible to be certified for the next services: transport, storage & transhipment and laboratory. If an applicant purchases one of these services, he must make sure these are GMP$^+$-certified, or certified against an other, accepted standard. See GMP$^+$ Appendix 10 for this. When buying other kind of services, like silo cleaning, pest control, maintenance of equipment etc, a certificate is not necessary and 'only' the requirements of subsection a. must be met

Note:

- *For subcontracting storage and transport there are also some special exceptions. See the relevant sections for this.*

If a participant purchases, for whatever reason, feed ingredients for which a GMP+ certificate is required then these may only be sourced from companies currently certified against GMP+ (or another assurance scheme acceptable to GMP+). See for this GMP+ Appendix 10.

For an explanation of the GMP+ purchasing requirements for foodstuffs companies with a waste flow intended for feeds, refer to: Q&A list GMP+ 2006 Production of Feed.
For the requirements for the purchase of feed additives and untreated agricultural products, refer to: GMP+ Appendix 10 and also the Q&A list GMP+ 2006 Production of Feed for further details

It is not obliged that for each type of feed additive that is purchased or received a generic risk assessment must be listed in the Database of Feed Materials Risk Assessments (DRV).
A lot of feed materials are listed in the Database of Feed Materials Risk Assessments (DRV), but not from all feed materials a generic risk assessment is listed, yet.

7.1.2 Selection of suppliers

The applicant must select and assess (potential) suppliers and choose suppliers who are able to provide raw materials (including processing aids), services and/or feed ingredients, which comply with the specified requirements.

The applicant must have procedures for evaluating his suppliers every year. Criteria must be established for selection, assessment, approval and evaluation. The applicant must demonstrate that all suppliers meet the criteria.

Guidance
Please, refer to 'The supplier under the spotlight – a guide for the supplier assessment', Quality series no. 123, December 2007. To be found on the PDV-website.

If the applicant uses feed ingredients, the applicant should only obtain and use feed ingredients from suppliers who comply with the relevant legislation and regulations. In Europe, suppliers should be registered and/or certified in accordance with EC Regulation No. 183/2005.

Most feed ingredients may only be bought from a GMP+-certified (or an equivalent certified) supplier. See 7.1.1. for more details.

7.2 Verification of received products

There must be a procedure for the acceptance of receiving of all products. This procedure must prescribe criteria for the proper acceptance of the products including criteria for the approval of transport.

Each incoming delivery must be verified on the basis of the specifications. During the entry check all incoming feed ingredients must be released before they can be stored and/or further processed.

In the case of doubt the specifications must be verified by way of analysis. The frequency of this may differ for the various parameters. In addition, batches from 'new' suppliers must be checked at a higher intensity. For the requirements with respect to sampling see section 4.5.

The received products must not be accepted if they do not comply with the specifications unless they are treated to ensure that the batch does comply with the safety specifications.

Guidance

Inspections should include, as appropriate, assessment of:
- *Colour*
- *Physical form*
- *Odour*
- *Contamination by insect pests, droppings and other extraneous matter*
- *Mould*
- *Excessive damage*
- *Compliance with specification*

With regard to transport, the applicant should check:
- *that the three previous loads were acceptable as prior loads for the transportation of feed ingredients*
- *that proper cleaning has taken place*
- *that an inspection has been carried out before loading.*

7.3 Storage

7.3.1 General

The applicant must control all storage activities of both raw materials and feed ingredients with his own feed safety system, in accordance with the requirements of this standard. This applies to storage at both own and hired sites, and both packaged and unpackaged feed ingredients or raw materials

Storage can be outsourced to a company which is also GMP$^+$-certified, or which has another, accepted storage certificate within the GMP$^+$-scheme. In some specific situations, storage can also be outsourced to a non-certified company. See GMP$^+$ Appendix 10 for accepted storage certificates and further details.

Guidance

Decay is influenced by the duration, temperature and relative moisture content during storage. In storage conditions which are too damp and/or too hot there is a risk of decay through microbes, fungus and the creation of mycotoxins. The correct conditions should be controlled.

Applicable legal obligations relating to feed: For Europe, for example, there is a duty of registration under Reg. (EC) 183/2005.

Feed ingredients and raw materials must be transported (internally) and stored in such a way they are and remain easily identifiable. This is to avoid confusion, (cross-)contamination and degradation of the quality.

Stock control measures must be documented and adequate to ensure that neither raw materials nor feed ingredients deteriorate prior to use / despatch, or during storage. Wherever practical, raw materials must be used and feed ingredients must be supplied on a first in, first out basis.

The applicant may only use stock protection agents if:
- they are approved by the competent authorities, and

- they are in accordance with the user instructions, and
- they are applied by qualified persons.

The responsible person must document which agent is used, when it is used and for which feed ingredients. It is then important that the prescribed waiting times are taken into consideration.

7.3.2 Identification of Products Not Intended For Feed Use

Any raw materials, intermediate or finished products produced or stored in the same premises by the applicant but not intended for feed use must be clearly segregated from feed ingredients and identified as such during all stages of production, packing, storage, despatch and supply.

7.4 Production

7.4.1 General

All activities must be carried out in conformity with this standard.

Production must be planned, scheduled and controlled by a designated and competent person, to ensure compliance with documented feed ingredient specifications and documented parameters for critical processes.

There must be sufficient suitable checks during the activities. All process controls relevant to the safety of the feed ingredients being produced must be demonstrably effective and managed in accordance with formal HACCP principles.

Procedures must include corrective actions to be taken in the event of critical process parameters being breached.

Where production processes contain an effective 'kill step' that is critical in maintaining the acceptable micro-organism count in feed ingredients, the applicant must ensure that adequate controls are in place to prevent feed ingredients becoming re-contaminated with pathogens at subsequent process stages. The applicant must pay particular attention to areas where condensation may occur or where material is allowed to bypass the kill step and rejoin the finished goods stream.

Where mixing or dispersion forms an essential part of the process, tests must be carried out to establish initial effectiveness of equipment and, on a subsequent frequency determined by risk analysis, to ensure that no loss of efficiency occurs through the effects of wear and tear. Records must be kept of such tests.

In situations where breakdown or other unforeseen circumstances result in the production of feed ingredients that do not meet the specification, the resulting products must be treated in accordance with Non-Conforming Product procedures.

7.4.2 Non Conforming Products

Applicants must establish a documented procedure for dealing with raw materials and feed ingredients that do not comply with specifications.

This procedure must include:
- Identification of batches / lots affected.
- Documentation for managing and recording non-conforming products.
- Evaluation of the cause of the non-conformance.
- Segregation of batches / lots affected.
- Communication with relevant parties.
- Preventive or corrective action to avoid repetition of the non-conformance.

Responsibility for review and disposal of non-conforming products must be defined. All incidences of non-conforming raw materials or feed ingredients must be recorded and decisions regarding actions to be taken must only be made by authorised personnel.

Non-conforming feed ingredients must be dealt with in one of the following ways:
- Sent to waste
- Reworked
- Accepted by concession (if agreed in writing by the client)
- Downgraded (if meeting the specification of another feed ingredient)

Requirements for reprocessing non-conforming feed ingredients must be documented and any affected feed ingredients must be re-evaluated on completion to ensure that the batch / lot concerned subsequently meets specified requirements.

The approval and use of reworks (e.g. from quality rejects, customer returns or spillage) must be considered within the HACCP Plan. Those that are not approved must become waste and be disposed of accordingly.

Feed ingredients that do not fully meet a customer specification must only be supplied if the customer is notified of the problem in writing and confirms in writing that he is prepared to accept them.

7.5 Sale & contracts

Feed ingredient specifications must be agreed between the applicant and the purchaser and confirmed in the contract.

Applicants must ensure that all feed ingredients supplied meet the agreed specifications. In all cases, the feed ingredients provided must be demonstrably equivalent to those contracted for supply.

The sale of feed ingredients must be clearly recorded.

Feed ingredients must be sold in accordance with specifications and defined contractual terms that are made available to any potential purchaser. Terms may be in accordance with a recognised industry contract or be included in a contract developed by the applicant or the purchaser of the feed ingredients.

All contracts must clearly state the following with regard to any feed ingredients supplied:
- Feed ingredient name.
- Feed ingredient specification.
- Quantity.
- Collection / delivery period.

All contract terms must be precise and unambiguous.

Applicants must be able to demonstrate appropriate methods for confirming and recording the type, quantity and specification of orders received.

Guidance
Feed ingredients specification: see paragraph 6.2.

7.6 Labelling and delivery requirements

On delivery the batch must be accompanied by the legally-required product information. The documentation with respect to delivery must be clear.

The applicant must provide his customer with the necessary information with respect to the feed ingredients supplied so that his customer (the next link in the chain) can carry out his own proper hazard analysis.

The applicant must ensure that the feed ingredients which are supplied by him comply with the applicable requirements for both the country in which it was produced or treated and, if applicable, the country in which it is placed on the market.

Where feed ingredients are supplied with a certificate of conformity or a certificate of analysis, the applicant must ensure that appropriate documented records are available to support the validity and accuracy of these certificates.
The applicant must inform the purchaser of any specific transport, storage or usage requirements / conditions necessary to maintain the feed ingredients' characteristics.

To avoid any opportunity for confusion with regard to the assurance status of products, all feed ingredients certified against GMP$^+$ must be clearly identified. In order to prevent confusion about the status of the feed ingredient, the status ('GMP$^+$-certified' or 'non-GMP$^+$-certified') must be specified in the sales contract or otherwise recorded in writing by delivery at the latest.

7.7 Transport

7.7.1 General

Transport may not lead to undesired contamination of the feed. To control the risks of contamination of feed ingredients during transport the applicant must at least apply the relevant requirements and prescribed working methods from GMP$^+$ Appendix 14.

All means of transport (whether by ship, barge, road vehicle, rail, container or other transport system) whether owned or contracted by applicants to carry either raw materials or feed ingredients, whether in bulk or packed, must be appropriate and adequately controlled with specific regard to hygiene and potential contamination. Cargoes being carried concurrently with raw materials and feed ingredients must not adversely affect the safety of the raw materials and feed ingredients.

Where transport is used to carry raw materials and feed ingredients, the individual load compartments used must be recorded. For road / rail vehicles this may be the trailer / car number or, where load compartments are split into sections, the individual section must be recorded. For water transport, where load compartments are split into holds, the individual hold numbers must be recorded.

In the case of transporting raw materials or feed ingredients in sealed containers or packaging, risk assessments must consider any potential hazards and ensure that controls effectively preclude any serious risk of contamination.

When the applicant is responsible for arranging transport of feed ingredients to purchasers operating under a certified assurance programme, he must ensure that the specific transport requirements of that programme are met.

When the applicant is not responsible for the transport and is instructed by a buyer to load a batch in a means of transport which does not comply with the requirements then the applicant must consult with the buyer for further instructions before loading. The results of this consultation must be demonstrable. See also 7.7.4

Guidance
For transport of feed ingredients in general it applies that before loading, load compartments should be empty, clean, dry and free from any remnants and odours of previous cargoes, in order to prevent load contamination. This includes:

- *Free of possible "agribulk-unfriendly elements", such as residues of preceding cargo and/or cleansing activities.*
- *Free of vermin, in the broadest sense of the word (insects and vermin, dead or alive).*

In order to comply with this, it may be necessary to clean the load compartment (before loading of the feed ingredients). If cleaning is necessary, this should be done in a way that is adequate in relation to the nature of the previous cargoes. See for this Appendix 14 After this cleansing, the load compartment should be inspected for cleanness.

Furthermore, the load compartment should be adequately shielded to protect the transported cargo against influence from other transported goods and be provided with resources to cover the cargo during transport.

7.7.2 Road transport with own means of transport

7.7.2.1 General

The road transport of feed ingredients must comply with the relevant GMP+ requirements from this standard and GMP+ Appendix 14 and be certified as such. The following options are possible for road transport of own feed ingredients.

Transport of own feed ingredients	**Certification in accordance with**
By own means of transport	GMP+ B4.1 or GMP+ B2 (= this standard), see section 7.7.2
By external carrier (applicant is responsible)	GMP+ B4.1 GMP+ B2 (= this standard), see section 7.7.3
By external carrier (applicant is not responsible)	see section 7.7.4

Guidance
The above means that under this standard only the transport of own products can be assured and certified. If the participant also carries out road transport for third parties, then he is considered to be, in addition to a producer, a service-providing carrier and must meet the requirements in the GMP+ standard B4.1 and be certified as such.

If the transport of own products is carried out under the responsibility of the participant then various options have been established to guarantee this (7.7.2 and 7.7.3).
If the participant is not responsible for the transport then a limited number of requirements are still set (7.7.4).

7.7.2.2 Loading

Before loading feed ingredients a visual inspection must be carried out to determine whether the loading compartment is clean and, if necessary, dry. In addition, the outside of the vehicle, including the chassis, must be free of all visible remains of the previous load.

The driver must visually check the loading category of the feed during loading (see GMP+ Appendix 14). The results of this check must be recorded.

7.7.2.3 Transport

Feed ingredients may (in combined transports) not become mixed together.

The applicant must ensure that the loading compartments are covered during transport. Penetration of rainwater, contamination by the excrement of birds or other forms of contamination of the loading compartment must be prevented even if the loading compartment is empty. If the covering of loading compartments is not possible then the loading compartment must be wiped dry, if necessary after hosing clean, before another load is loaded. Tarpaulins to be used for covering loading compartments are to be clean before bulk loading and in the case of loading dry feed ingredients they are also to be dry.

7.7.2.4 Unloading

After unloading the applicant must visually check the loading compartment for remains of the load. If applicable the applicant must remove the load remains as much as possible.

7.7.2.5 Cleaning

Cleaning and/or disinfection must take place before loading feed ingredients. The applicant must apply the relevant requirements and the working method as prescribed in GMP+ Appendix 14.
After each cleaning, at least a visual inspection must be carried out.

Each cleaning programme drawn up for a certain loading compartment must be checked for effectiveness (validated). The applicant must draw up a control programme which includes the minimum frequency for carrying out these checks. Then this cleaning programme can be used as the official cleaning method for each similarly constructed transport space.

7.7.2.6 Registration

Unless risk assessment specifically establishes that no potential hazards exist from the carriage of previous loads, records must be available showing the previous three loads carried by bulk transport and any cleaning subsequently undertaken as a consequence.

Guidance
At least the following details should be maintained and available:

- *The loads should be maintained by way of a journey sheet in the case of bulk transport for each loading compartment and the means of transport. The details of the last three loads should be available for checking unless it is specifically determined in the hazard check that the previous loads do not form a potential hazard. This may be the case, for example, if the same type of feed is always carried in the transport means.*
- *The legally-prescribed documentation including the way bill*
- *The cleaning and disinfection measures carried out for each bulk transport compartment.*

- *The results of the cleaning and disinfection measures should be visually checked and recorded on the journey sheet.*

7.7.3 Road transport, carried out by subcontractors

Note: This option is only permitted for transport which takes place entirely outside the Netherlands. For transport from and to companies registered in the Netherlands the requirements apply in section 7.7.2.

Preferable, the road transport is carried out by a GMP+ B4.1-certified transporter, or by a transporter with an equivalent certificate. See for this GMP+ Appendix 10.

For road transport it is also permissible to subcontract a non-certified external carrier. These external carriers must be properly instructed with respect to the relevant transport requirements. These must be checked by the applicant (by way of an internal audit) and inspected. Any terms for hiring bulk transport must clearly specify the controls required and include a similar obligation for any subcontractors used.

The applicant and/or the external carrier who has been subcontracted must provide the following during the transport of feed ingredients:
- A record for each loading compartment with details of the previous loads
- Details for each loading compartment about the cleaning and disinfection procedures which are carried out
- Details of the cleaning inspection prior to the loading for the loading compartment
- Details of the inspections which are carried out per loading compartment.

If the result of the inspection is positive then the loading compartment is approved for the transportation of feed ingredients. This inspection must be carried out by a loading inspector. A 'loading inspector' is a position which is specified in the quality system. This role is fulfilled by an employee who, on the basis of training and experience, has the knowledge and skills required for the inspection of a loading compartment for its suitability for the loading of feed ingredients.

7.7.4 Road transport contracted by third parties (applicant is not responsible for transport)

Where the means of land transport is contracted by a third party, applicants must take reasonable precautions to avoid potential hazards.

Where feed ingredients are to be loaded into transport contracted by the purchaser of the feed ingredients, applicants must ensure that any transport offered is suitable to receive the feed ingredients supplied.

For bulk loads, the three previous loads carried must be recorded and assessed for compatibility by a competent person prior to loading.

Should applicants be instructed by a purchaser to load transport that is considered unsuitable by the applicant, applicants must advise the purchaser of any concerns in writing and obtain written confirmation of such instructions from the purchaser, prior to loading. Copies of associated correspondence must be retained.
Where suppliers of raw materials provide the means of transport, applicants must ensure that such transport complies with the requirements of this standard.

7.7.5 Transport via inland waterway, by sea and by rail

a1) inland waterway transport to GMP± B1-certified companies

If the inland waterways affreightment takes place on the responsibility of the participant then the affreightment must always be GMP+ B4.2-certified.
The carriage (= the actual transportation by inland waterway vessel) should be GMP+ B4.3-certified.

Guidance
'On the responsibility of' means in this case that the participant carries out the affreightment himself or engages a freight broker

a2) sea transport and rail transport to GMP± B1-certified companies

Transport by sea or by rail should comply with the requirements of GMP B4.4 Sea Transport Affreightment and GMP B4.5 Rail Transport Affreightment. The customer for the sea transport or rail transport should be certified as such.

b) inland waterway transport, sea transport and rail transport to other GMP±-certified companies

In the event of transport via inland waterway, sea transport and transport per rail, an inspection should take place to check the cleanliness of the loading compartments (LCI = Loading Compartment Inspection) before loading is started. The loading process should also be controlled to be able to guarantee feed safety.

The inspection and quality assurance may be carried out by:

a. an inspection agency at EN 17020 level which specialises in, and is accredited for, feed / grains or liquid agri-bulk and operates internationally on the basis of a certified quality system such as ISO 9001 or equivalent
b. a loading inspector from a GMP+ B2-certified company which has purchased the transport or, at his request, the loading inspector of the supplier. The position of load inspector is a function specified in the quality system of the company and should be performed by an employee who on the basis of training and experience has the knowledge and skill to assess loading compartments on their suitability for use with feed ingredients.

The participant who himself acts as the affreightment party must have the LCI carried out by an external audit organisation. The freight broker can not undertake an LCI.

In the event of the transport of GMP+-assured feed ingredients and non-GMP+-assured feed ingredients there must be a strict physical separation of these feed ingredients.

8. VERIFICATION AND IMPROVEMENT

8.1 Recall Procedure

Applicants must develop a documented recall procedure that ensures customers can be informed promptly in the event of any irregularity that may adversely affect feed ingredient safety.
The recall procedure must detail responsibilities and include actions to be implemented in the event of a recall.

Products that have been recalled may only be reprocessed or otherwise put back into circulation following formal assessment that it is both legal and safe to do so. Records must be kept of any such assessment.

The recall procedure must be tested at least annually to ensure its effectiveness. Such tests must be documented and evaluated for improvements.

As part of the recall procedure, all relevant contacts must be listed and kept up-to-date. Contacts listed must include the Competent Authorities to be notified in the following circumstances:
- In the event of a serious safety risk.
- When legal limits are exceeded and national legislation requires notification.

Recall procedures must include systems for:
- Identifying the non-conforming feed ingredient batch / lot, including consequences to other feed ingredients, batches / lots or raw materials.
- Ensuring that where recall of a non-feed product is required, recall of feed ingredients is also considered and, if necessary, implemented;
- Identifying the location of affected batches / lots.
- Management of returned feed ingredients, including segregation from other products.
- Recording the destination of any recalled products.

Guidance
On the PDV-website a guidance is published with information about recall and how to implement a procedure for recall

8.2 Early warning procedure

The applicant has a documented procedure for warning at an early stage and for handling these signals which warn that the safety of feed ingredients may not comply with the legal standards or the standards set in the GMP$^+$ certification scheme and may lead to damage in subsequent links in the chain. The signals must be assessed on this basis and if necessary or desirable control measures must be taken to prevent or control the hazard which has been signalled. In relevant cases the competent authority must be informed.

In the case of a potential hazard which can not be controlled by the applicant in question and which can also cause damage to other parties then the applicant must inform the Product Board. This must be done in accordance with GMP Appendix 5.

8.3 Internal audit

Applicants must have a documented procedure for internal auditing.

Internal auditing procedures must require the applicant to carry out a programme of planned audits to check that internal systems are operating as intended and are also effective. Such internal audits must encompass:
- Compliance with the requirements of this standard.
- Compliance with the requirements of the applicant's HACCP Plan.
- Compliance with the applicant's formal procedures.
- Compliance with legislation pertaining to feed ingredient safety and quality.
- Satisfaction of specified customer requirements.

The programme of internal audits must ensure that all relevant activities are audited at least once a year (= every 12 months).

All personnel carrying out internal audits must be trained to carry out such audits and be able to demonstrate their effectiveness in the role.

Internal audits must be formally reported to those with responsibility for the area audited and record any aspects where the operations are not in compliance with operational requirements. Such areas of non-compliance must be corrected and audit report records signed off by an authorised person to indicate that problems have been corrected satisfactorily.

8.4 Management review and improvement

The applicant must establish, collect and analyse suitable data at least once per year
a. in order to show that the feed safety system is suitable and effective, and
b. to assess whether continuous improvement in the effectiveness of the feed safety system is possible

This must be part of the management review (see section 4.1)

A documented procedure must be established up for this.

Guidance
The input for such a review must in any event contain information on:
- the results of the control plan and other verification elements of the HACCP system
- the results of the supplier evaluation
- the results of internal and external audits
- feedback / complaints from customers
- changes to, for example, the feed legislation which may have an influence on the feed safety system.

This review must in any event contain information about:
- the extent to which the feed safety system must or can be modified
- the possibilities and chances of improving the feed safety system