



## **GMP<sup>+</sup> Certification Scheme Animal Feed Sector 2006**

### **Animal Feed Road Transport**

#### **GMP<sup>+</sup> Standard B4.1**

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# 1 SUBJECT MATTER AND AREA OF APPLICABILITY

## 1.1 *General*

This standard specifies requirements for a management system for feed safety (referred to hereafter as feed safety system) by way of which an organisation guarantees that feed are transported safely. The aim of this system is to carry out transport in such a way that there is compliance with:

- requirements which arise from the feed legislation which is related to the safety of humans, animals and the environment (see section 2).
- the additional requirements which have been agreed with the stakeholders 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 transport will have no influence on the feed.

### A number of terms

By 'feed' is understood: all substances and products including feed 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, feed additives, semi-produced products, compound feeds or products which may be designated as such following a processing operation.

By 'road transport' is understood: the carrying of feed by road for one's own company or for third parties. In addition to physical transport this includes all the activities required to make the transportation possible including planning, purchasing, cleaning and documentation. This is referred to hereafter as 'transport'.

### Relationship to the other GMP<sup>+</sup> standards

This standard is part of the GMP<sup>+</sup> certification scheme. An organisation may participate in this certification scheme. Refer to the A documents of the GMP<sup>+</sup> certification scheme feed sector 2006.

The layout of this standard is (almost) the same as other GMP<sup>+</sup> standards so that organisations which, in addition to transport also produce, process or trade animal feeds, can apply the transport standard fairly easily. The sections which are designated with a <sup>\*</sup> have been completed by an applicant in another GMP<sup>+</sup> standard through that certification and these sections no longer have to be completed for participation in this standard.

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

### Other basic principles

The applicant always remains responsible for the management of his feed safety system and to check himself on compliance with the requirements.

By complying with the requirements set in this standard for the transport 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 or feed.

## **1.2 Applicability**

The requirements of this standard apply to organisations which transport (products for) feed by road. It does not matter whether the product is the property of the applicant or of a third party. The responsibility of the applicant undertaking the transport is limited within this standard solely to the transport of feed materials. Other GMP<sup>+</sup> standards apply for other forms of transport and physical handling of feed.

### Exclusion from requirements

A requirement may relate to an activity which lies outside the field of activity of an applicant. The applicant may then exclude this requirement but retain the right to certification.

A requirement may well have the status 'not applicable' for an applicant. Or, in other words: an applicant may exclude requirements. He must, of course, provide reasons for the exclusion. The exclusions may in any event not lead to the applicant supplying feed which do not comply with feed safety as defined in the GMP<sup>+</sup> 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.

If an applicant makes use of an external carrier for the transport by road of packaged products then this external carrier does not have to be GMP<sup>+</sup>-certified for the transport activity. (See 7.11).

N.B. If a applicant carries own the transport of packaged products himself then he must include this own transport within the scope of the feed safety system.

## **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 transport which carried out under his responsibility complies with the community legislation, the associated national legislation and good practices which are applicable.

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

### 3 TERMS AND DEFINITIONS \*

See GMP<sup>+</sup> 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<sup>+</sup> 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 all the transport for which the applicant is responsible:
  1. The applicant is responsible for the transport.
  2. The applicant must specify all the transport of feed.
  3. The applicant must bring all business locations from which transport takes place within 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<sup>+</sup> 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. If the applicant contracts transport out then the applicant must ensure that this transport complies with the requirements of this GMP<sup>+</sup> standard (See 7.11).
- b. establish working methods used to carry out the transport effectively
- c. make available resources and information required for carrying out the transport
- d. monitor and evaluate the working methods
- e. implement actions which are necessary to achieve planned results and continuous improvement of the transport.

These working methods must be controlled by the applicant in accordance with the requirements of this GMP<sup>+</sup> standard.

NOTE:

If at one location several companies carry out activities covered a GMP<sup>+</sup> standard, each of them must hold a certificate for these activities. See A1 Regulation.

## **4.2 Documentation \***

### **4.2.1 General \***

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<sup>+</sup> standard
- d. documents required by the applicant for the achievement of effective planning, implementation and control of the transport
- e. records required by this GMP<sup>+</sup> standard (see 4.2.4)
- f. all relevant legally-required permits, records and certificates under the feed legislation

The applicant must maintain a register of the following documentation

- Documentation relating to the transport and the controls.
- The applicant should have a documentation system for the description of the critical points in the transport process and for the drawing up and implementation of a quality control plan as laid down in section 7.12 and appendix 14.
- The applicant should keep the results of the controls: All these documents must be kept to be able to trace the history of any batch of transported feed and in the event of complaints to be able to determine responsibility (see also 4.2.4).

NOTE:

The structure of the documentation of the feed safety system may differ per organisation as a result of:

- A The size of the organisation and the type of transport
- B The nature and complexity of the transport
- C The expertise of the personnel

### **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 as required as a minimum under the GMP standard(s) which have been laid down for the feed safety system or a reference to them
- c) a description of the transport activities and the relationships between them
- 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 are regulated. Controls are established in this as needed to:

- a. review documents with respect to suitability before they are distributed
- b. assess documents and update them if necessary and to re-approve them; as in the event of changes to the feed legislation and/or the GMP<sup>+</sup> standard
- c. know changes and the current revision status of the documents
- d. have the current versions of the documents available at workplaces where transport activities are carried out
- e. keep documents legible and easily recognisable
- f. keep documents from an external source recognisable as such and controlling their distribution
- g. prevent of unintended use of lapsed documents and application of appropriate identification if it is retained for whatever reason.

Records must comply with the requirements in 4.2.4.

#### 4.2.4 Control of records \*

Records must be established and maintained to provide evidence of compliance with the requirements for the effective operation of the feed safety system so that the feed safety of the products 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 of the importance of compliance with both the requirements of the customers and the feed legislation and regulations
- 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 transport of safe feed
- b. is matched to the requirements of customers
- c. prescribes that the company 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 transport 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 introduced and maintained correctly in order to comply with both the requirements in 4.1 and the feed safety objectives, and
- b. the operation and cohesion of the feed safety system is maintained when changes relating to the feed safety system are planned and implemented

## **5.4 *Responsibility, authority and communication on feed safety* \***

### 5.4.1 Responsibility and authority \*

Top management must ensure that the responsibilities and competences are defined and made known in writing within the organisation. The applicant must record the responsibility structure in an organisational chart.

### 5.4.2 HACCP team \*

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### 5.4.3 Management representative \*

Top management must appoint a management representative who, irrespective of other responsibilities, must have the responsibility and authority:

- a. to establish a feed safety system and to implement it and maintain it in accordance with this standard, and
- b. to report to top management on the performance of the feed safety system and any need for improvement, and
- c. to ensure that the awareness of the requirements of customers is promoted throughout the whole organisation.

NOTE:

In (small) organisations these responsibilities and competences may lie with the same person.

### 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 in order to comply with the GMP<sup>+</sup> standard.

## **5.5 Management review \***

### **5.5.1 General \***

Top management must review the feed safety system at least once per year with regard to effectiveness and whether it is possible to comply with the requirements of this standard. This review must also include the assessment of opportunities for improvement as well as the need for changes in the feed safety system, including feed safety policy and feed safety objectives.

Records of management reviews must be kept (see 4.2.4).

### **5.5.2 Review input \***

The input to the management review must include information on:

- a. results of the internal audits (section 8.2) and the verification (see section 8.3)
- b. the assessment and evaluation of the suppliers (including hired carriers and suppliers of cleaning and disinfection agents) (see section 7.11 and 8.3)
- c. results of external audits
- d. feedback from customers
- e. the extent to which transport complies with the requirements
- e. status of preventive and corrective measures
- f. follow-up measures from previous management reviews
- g. changes which may influence the feed safety system, and
- h. recommendations for improvement.

### **5.5.3 Review output \***

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

- a. improvement of the effectiveness of the feed safety system
- b. improvement of the transport with respect to the requirements of customers, and
- c. requirement for resources.

## **6 MANAGEMENT OF RESOURCES**

### **6.1 *Provision of resources* \***

The applicant must determine which resources are needed and ensure that these resources are available

- a. to implement and maintain the feed safety system and continually to improve its effectiveness
- b. to improve feed safety through compliance with the requirements of the stakeholders as established in the GMP<sup>+</sup> certification scheme.

## **6.2 Personnel \***

### 6.2.1 General \*

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

An organisation chart must be drawn up. There must also be a description of the qualifications (for example diplomas, professional experience) and the responsibilities of the supervisory personnel which must be made available to the competent authorities who are responsible for inspection.

The personnel involved in transport must be clearly informed in writing of their tasks, responsibilities and authority, especially in the event of changes, to obtain the desired product quality.

Where relevant, a person with relevant qualifications must be designated with quality control.

### 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 the safe transport of feed.
- 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 for the safe transport of feed.

Infrastructure includes, as applicable:

- a. buildings, working areas and associated facilities
- b. means of transport and/or loading compartments
- c. process equipment (both hardware and software)
- d. supporting services (for example communication).

### 6.3.1 Basic requirements \*

The applicant will ensure that the means of transport:

- a. are made of appropriate materials which can be effectively cleaned and maintained to avoid contamination of the feed. This applies in particular to materials and surfaces which come into direct contact with feed.
- 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/practices possible
- e. are free on the outside, including the chassis, from visible particles from prior loads.

### 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 cross-contamination and decay is prevented

Effective programmes must be used for combating harmful organisms.

#### 6.3.2.2. *Production areas*

Areas for the means of transport and loading compartments and their immediate surroundings must be clean.

The lay-out, design, construction and size of the production areas and equipment must be such that:

- a. cleaning and/or decontamination and maintenance can be carried out in a proper fashion.
- b. the areas, including the company site around them, are only accessible for persons who have been given permission to do so by the applicant.

### 6.3.2.3 Loading compartments

The company shall ensure that the loading compartments:

- a. are clean, fully emptied, free of load residues and free of the odour of previous loads
- b. are dry and/or dried in case of dry subsequent loads.
- c. are covered. Penetration of rainwater, contamination by the excrement of birds or other forms of contamination of the loading compartment should 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 cargo is loaded. Sheets to be used for covering loading compartments are to be clean before bulk loading and in the case of loading dry feed they are also to be dry.

## 6.4 Work environment

### 6.4.1 Maintenance

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### 6.4.2 Cleaning

The penetration of harmful organisms into feed must be prevented to counter decay. Where necessary the temperature must be kept as low as possible in order to prevent condensation or decay.

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.

### 6.4.3 Waste control

Waste and material which is created at the applicant that is not appropriate as feed must be identified as such and kept separate. This must be removed properly and may not be used as feed.

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 desinfestation programmes.

The applicant must make clear how the waste and its removal are controlled. The applicant must be able to show that the waste does not and can not get into the the feed chain.

## **6.5 Identification and traceability**

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

The applicant must maintain a register with the relevant details relating to the transport so that transported products can be traced effectively.

The applicant undertaking the transport has a reliable administration in which at least the following will be included:

- a. the quantities and types of product<sup>1</sup> per client (i.e. the customer of the transport)
- b. where applicable, copies of any accompanying documents, guarantees, certificates, etc.;
- c. the loading and unloading addresses
- d. the identification and coding of the bulk load compartments used to achieve the transport sequence of goods transported.

The above data regarding customers and loading and unloading addresses may be documented in coded form, as long as insight can be given into the data pertaining to the codes used, for the external auditors.

Bulk load compartments must be identified and there must be traceability of the order of consignments using the loading compartments in question, including for instance by means of coding of the compartments and, by means of consignment notes, whether or not in electronic form, which are held on the vehicle.

N.B. Registration requirements are also stated in section 7.12.6.

<sup>1</sup> Incl. At least the loading category coding as specified in appendix 14.

## **7 PROCESS CONTROL**

### **7.1 Basic requirements programme \***

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### **7.2 Planning of the realisation of a safe product \***

The applicant must ensure the introduction, implementation and maintenance of one or more permanent, 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).

The HACCP principles described above have been detailed generically in this standard for the transport of feed and have resulted in the specific control measures with respect to transport sequence and cleaning and disinfection regimes. The applicant implements the HACCP principles by using these control measures as specified in section 7.12 of this standard and the instructions with respect to transport sequence, cleaning and disinfection (appendix 14).

### **7.3 Transport requirements**

#### **7.3.1 Determination of transport requirements**

The applicant must determine the requirements with respect to transport.: These are at least:

- a. the relevant requirements established in the GMP+ certification scheme and the special requirements of customers
- b. requirements not established in consultation with customers but which are necessary for the correct carrying out of the transport
- c. feed legislation requirements related to transport, and
- d. any additional requirements determined by the applicant and which relate to the safe transport of animal feed.

#### **7.3.2 Review of transport requirements**

The applicant must review the transport requirements.

This review must be carried out before the applicant accepts a transport commission and must ensure that:

- a. the transport requirements have been established (see section 7.3.1)
- b. a solution is found for requirements from the contract or from orders which deviate from requirements which were made earlier, and
- c. the applicant has the ability to meet the established requirements.

Records of the results of the review and actions arising from the review must be maintained (see 4.2.4).

Where transport requirements are changed, the applicant must ensure that the relevant documents are amended and that the relevant personnel are made aware of the changed requirements.

#### 7.3.3 Description of the product based on requirements (specifications) \*

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#### 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 transport
- b. enquiries, contracts or order handling including amendments, and
- c. customer feedback

The applicant must have a system in place for the recording and handling of complaints.

### **7.4 *Process information \****

#### 7.4.1 Flow diagrams \*

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#### 7.4.2 Diagram of the organisation \*

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### **7.5 *Hazards analysis \****

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#### 7.5.1 Identification of hazards \*

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7.5.2 Risk assessment \*

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**7.6 General and specific control measures \***

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**7.7 Standards \***

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**7.8 Monitoring and measuring \***

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7.8.1 Monitoring plan \*

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7.8.2 Monitoring plan (supplementary for processing of feed additives / feed medicines) \*

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7.8.3 Management of monitoring and measurement equipment \*

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**7.9 Corrective actions \***

7.9.1 In-company \*

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7.9.2 Recall \*

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**7.10 Validation of the HACCP plan \***

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**7.11 Purchasing**

### 7.11.1 Purchasing process

The applicant must ensure that purchased products and services comply with the requirements of this standard. All external carriers who are used should be GMP<sup>+</sup> -certified. An exception to this are those external carriers who are only used for the transportation of packaged products.

### 7.11.2 Purchasing data

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### 7.11.3 Verification of the purchased product \*

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## **7.12 Transport**

### 7.12.1 Control of the transport

The applicant must draw up a description of the transport activities which he carries out. This description must contain at least the number and type of means of transport, the types of loads which are transported and the method of cleaning used. If there is any change to the transport process then the applicant must review the description and the procedures and modify them if necessary.

The transport of feed should be carried out in such a way that a situation is avoided where previously carried products lead to contamination of subsequent feed transports.

The applicant must ensure this by, after every load, cleaning, inspecting and checking in the correct way and recording everything properly. See appendix 14.

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

Transport of packaged products must take place in a clean and dry loading compartment. The loading compartment should be completely emptied and free of load remains and odour from previous loads.

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.

### 7.12.2 Acceptance of the order, loading category classification and cleaning regime

The applicant must have at least a documented procedure for the acceptance of an order for the transport of feed.

The applicant must determine the following before accepting the transport order:

- a. what product he is going to transport
- b. in which loading category this product falls. For this the applicant should request information from the client with the transport order about the category in which the product is classified
- c. which cleaning regime applies.

Before loading the loading category of the previous loads and of the new load must be determined, and there must be compliance with appendix 14 in which further requirements for cleaning and disinfection and the loading sequence are set out.

In order to be able to establish this the applicant must be aware of the nature of the product and of the specific product characteristics including its (chemical) composition. If deviations are observed during loading or during transport then the applicant should carry out corrective actions. (See section 8.4.4).

#### 7.12.3 Check during loading

Prior to every feed transport, a visual check must be carried out as to whether the load compartment is clean, which means completely emptied and free of material residue and odour from previous loads, and dry or dried in the case of the next load being dry.

The driver should visually check the loading category of the feed during loading.

#### 7.12.4 Cleaning

After the transport, cleaning and/or disinfection must be carried out in accordance with the cleaning regimes established and prescribed in appendix 14.

The applicant must draw up a cleaning programme for this which demonstrably complies with the legal requirements and the additional requirements for cleaning (and disinfection) of means of transport as laid down in appendix 14 of the GMP<sup>+</sup> certification scheme. This appendix establishes the loading sequences and the cleaning and disinfection regimes.

The cleaning programmes will include as a minimum:

- a. the responsibilities with respect to cleaning
- b. the cleaning methods
- c. the frequency and times of cleaning
- d. the use of the various cleaning and disinfection regimes depending on the previous load
- e. the critical items for attention per type of means of transport where there must be an indication of which parts must be disassembled before the start of cleaning (these are, for example, places which are difficult to clean such as pipes, hoses, hinges, pumps, places which can not be reached, etc.)

- f. cleaning and disinfection agents. These must be appropriate for the purpose for which they are used. They must also not form any risk to the safety of the feed which are being carried in the means of transport. The residues of cleaning and disinfecting agents must be kept as small as possible.

Each cleaning programme drawn up for a certain loading compartment must be checked for effectiveness (validated). Then this cleaning programme can be adopted as the official cleaning method for each similarly constructed loading compartment (see also appendix 14).

After each cleaning, at least a visual inspection must be carried out. The result of this inspection must be registered in the logbook, together with the registration of the transported loads, the applied intervening cleaning regimes with the cleaning and disinfecting agents used.

#### 7.12.5 Monitoring and measuring

##### 7.12.5.1 *Checking the effectiveness of cleaning and disinfection regimes*

The applicant must review the effectiveness of the cleaning and disinfection methods used by way of additional checks. The applicant must draw up a control programme which includes the minimum frequency for carrying out these checks.

##### 7.12.5.2 *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 feed safety of the product. The monitoring and measurement equipment must be registered (see 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 the measurement equipment must:

- be calibrated or verified at specified intervals or prior to use in accordance with measurement standards which are derived from international or national measurement standards; if such standards do not exist the basis used for the calibration or verification must be recorded (see 4.2.4) and inspections will be in accordance with standardised checklists.
- adjusted or re-adjusted if necessary
- identified so that the calibration status can be determined
- secured against adjustment which would make the measurement result invalid
- 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 suitable measures with respect to the equipment and any product which is influenced by it. Records of the results of calibration and verification must be maintained (see section 4.2.4).

If computer software is used in the monitoring and measurement of specified requirements its capacity to comply with the intended application must be confirmed. This must be done before initial use and re-confirmed if necessary.

#### 7.12.6 Registration

Registration will take place of the transports, of the cleaning between consecutive bulk transports and of the inspections.

- Loads should be recorded by the driver in the event of bulk transport for each loading compartment in a journey sheet, which may be in electronic form, on the means of transport. The registrations of the three prior loads in the loading compartment (with the carrier's signature and date) should be available for checking. The data in the vehicle journey reports must be transferred to the logbook at the offices of the transport company. See also the registration requirements in 6.5.
- The legally records including the waybill should be available.
- The cleaning and disinfection actions for each bulk load compartment must be noted and initialled in the consignment note by the driver, whether or not in electronic form. The result of the cleaning and disinfection actions must be checked visually and recorded in the consignment note, along with the previous loads and the cleaning and disinfection actions.
- The prescribed inspections and checks and also any other inspections and checks must also be registered.

The carrier must be able to demonstrate that in the past no 'prohibited loads' from loading category LR1 have been transported in a loading compartment (see appendix 14). Following carriage of a prohibited load, no feed may be transported, unless the means of transport and/or loading compartment has been released according to the procedure specified in appendix 14.

#### 7.12.7 Corrective actions

The applicant must ensure that non-conformities 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-conformities in one or more of the following manners:

- a. by taking measures to put an end to the observed non-conformity
- b. by permitting use, release or acceptance with the approval of the client and/or the relevant authority
- c. by taking measures to exclude the originally-intended use or application

If there have been feed and undesirable substances and/or germs in a bulk loading compartment, then this loading compartment must be cleaned such that no contamination of the next load can take place. Records of this must be available.

Records of the nature of non-conformities and any measures taken later, including approvals obtained, must be maintained (see 4.2.4).

If a non-conformity 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 products and for notification to the involved parties, both internal and external.

## **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 transport 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 planned arrangements (see 7.2), to the requirements of this GMP<sup>+</sup> standard and to the requirements of the feed safety system established by the applicant, and
- b. is effectively implemented and maintained.

An annual (which means a minimum audit frequency of 1x per 12 months) audit programme must be planned and implemented in which all parts of the transport process must be addressed. Account must be taken of the results of the previous audits.

The audit criteria, scope, frequency and methods must be established. Selection of the auditors and the conduct of audits must ensure the objectivity and impartiality of the audits. Auditors must not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see section 4.2.4), must be recorded in a documented procedure.

The management responsible for the area being audited must ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities must include the verification of the actions taken. The applicant must also record the verification results.

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

The applicant must determine, collect and analyse appropriate data at least once per year (which means with a minimum frequency of 1x per 12 months) to demonstrate the suitability and effectiveness of the feed safety system and to evaluate whether continuous improvement in the effectiveness of the feed safety system is feasible. This must include monitoring and measurement data from other relevant sources (including internal/external audits, complaints, records, evaluations).

The analysis of the data must provide information with respect to:

- a. compliance with transport requirements (see section 7.3.)
- b. characteristics and trends of the transport including opportunities for preventive measures, and
- c. the suppliers

NOTE: The result of this analysis partly forms the input for the management review (see 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 actions\***

The applicant must take action to eliminate the cause of non-conformities in order to prevent recurrence. Corrective actions must be appropriate to the effects of the non-conformities encountered.

A documented procedure must be established to record requirements for:

- a. reviewing non-conformities (including customer complaints)
- b. determining the causes of these non-conformities
- c. evaluating the need for action to ensure that non-conformities do not recur
- d. determining and implementing action needed
- e. records of the results of action taken (see section 4.2.4), and
- f. reviewing corrective action taken.

#### 8.4.3 Preventative action \*

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

A documented procedure must be established to record requirements for:

- a. determining potential non-conformities and their causes
- b. evaluating the need for action to prevent non-conformities
- d. determining and implementing action needed
- e. records of the results of action taken (see section 4.2.4), and
- f. reviewing preventive action 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 a feed might not match the legal standards or the standards established in the GMP<sup>+</sup> 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 Animal Feed. This must be done in accordance with Appendix 5.