GMP+ International

GMP+ Guidance

A guide to enable feed producing companies to develop a Feed Safety System

GMP+ D 1.2

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GMP+ Feed Certification scheme

Feed Safety Worldwide

Index

1. Introduction

1.1. Aim of this guidance document

GMP+ certified feed producing companies are often encouraging their suppliers of feed ingredients and services to become GMP+ certified too. The motivation is to realize a closed chain of custody for the control of feed safety risks.
In countries and subsectors with limited experience in the development and maintenance of a feed safety system (FSS), it is not always easy to translate the contents of the applicable standard(s) and related appendices into an operational system. On request of several feed producing companies operating on an international level, GMP+ International wants to support the above-mentioned suppliers by means of a practical guidance / handbook which helps in the development of a FSS. An important condition is to provide the companies with guidance on the implementation, to allow them to learn by doing.

1.2. Scope

This handbook provides guidance for the implementation of the GMP+ B2 (2010) *Production of Feed Ingredients*. This guidance must enable companies who produce feed ingredients to develop and implement a feed safety system in accordance with the GMP+ Feed Certification scheme in a relatively easy way.
The guidance focuses on production of feed ingredients. However, companies that would like to get certified against another GMP+ FSA standard, such as GMP+ B1, can also make use of this guidance. The guidance can also be helpful for transporting and trading companies in the feed chain (GMP+ B3 (2007) or GMP+ B4). In that case, some chapters containing production and storage related issues (chapters 5 and 7) might not be applicable. In annex 1 steps of the GMP+ Guidance refer to paragraph numbers of GMP+ B-documents (B2 (2010), B1, B3 (2007), B4, B4.3 and other GMP+ documents.

1.3. Introduction of this guidance

Each chapter consists of the following subjects:

- Aim: summary of actions to be taken;
- Interpretation: explanation/practical advice on how these actions could be implemented. Also Checklist B2 (2010) under C documents of the GMP+ Feed Certification scheme: GMP+ FSA module on the GMP+ website can be consulted for interpretation of the requirements;
- Input/reference: reference documents GMP+ FSA or other information sources. Paragraph number in GMP+ B2 (2010) or other GMP+ FSA documents (see Annex 1 for other GMP+ B-documents);
- Output: type of document or record you have to generate to meet GMP+ requirements:
    - a document that is part of the quality system manual that you must create. The manual consists mainly of procedures, instructions and forms, but also contains the HACCP analysis and feed safety policy and empty schedules, diagrams or lists that you have to fill in, for it to become a record (see 2);
    - a record you have to create, either in an empty form from the feed safety manual, in minutes or in digital form. Examples include: cleaning records, traceability records, minutes of meetings with HACCP team;

Frequency: how often certain activities have to be performed, or documents have to be adjusted (where relevant).

1.4. Guidance principles

This guidance is aimed at the management and people responsible for feed safety within feed producing companies. Make sure to define who within your company is to work with this guidance. For the purpose of establishing a feed safety system, appoint someone in your company who will be responsible as a feed safety coordinator. This person should implement the system.
The steps to be taken to reach GMP+ B2 (2010) certification are listed below and will be explained to more detail in the various chapters of this handbook. In figure 1 the steps and sub steps are outlined.

1. Read this guidance;
2. Follow the steps and sub steps in chronological order;
3. Draw up quality manual documents and records that are the output of each step, and in doing so, form your feed safety system documentation;
4. Implement the feed safety system;
5. Check and verify the feed safety system;
6. Prepare for certification.

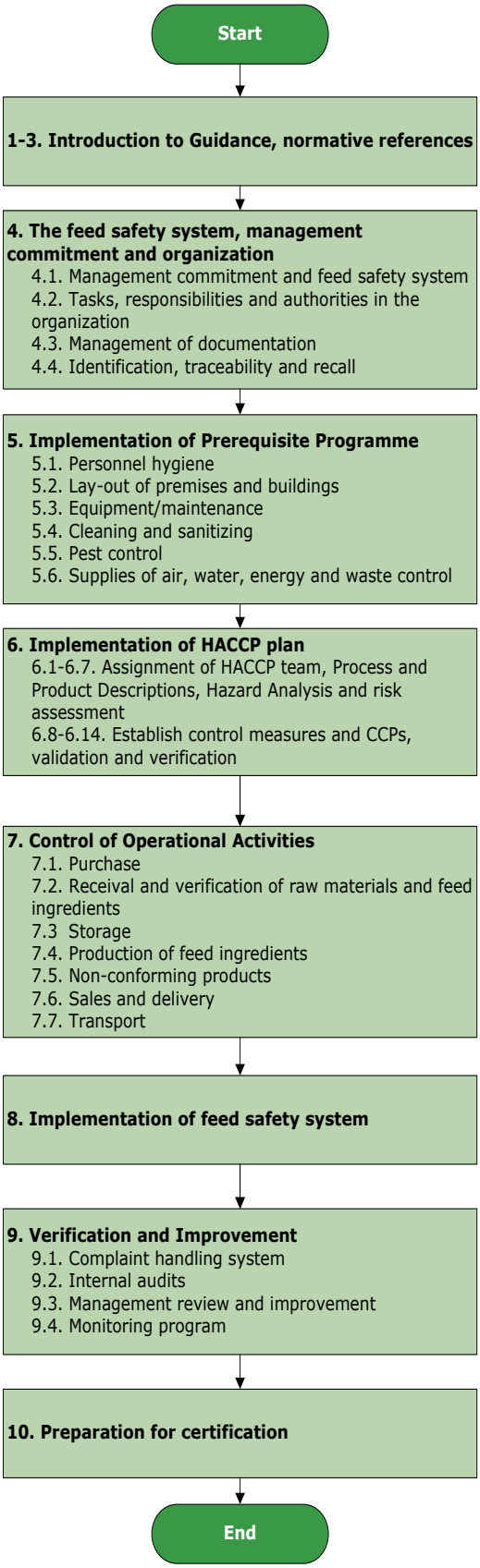
2. Normative references

GMP+ B2 *Production of feed ingredients* and
Checklist B2 and
other GMP+ B standards.

3. Terms and definitions

Reference to GMP+ A2 *Definitions and Abbreviations*.

Figure 1: Main steps in developing a feed safety system



4. The feed safety system, management commitment and organization

4.1. Management commitment and feed safety system

Summary:
Management should always be aware of its responsibility with regard to feed safety. Management is responsible and should be aware that all activities (production, storage, transport, delivery) are controlled and carried out as such that any hazards that may affect feed safety are reduced to a minimum. Proof of commitment is provided by means of a written feed safety policy.

Steps:
4.1.1. Management commitment/feed safety policy
4.1.2. Scope of feed safety system
4.1.3. Establish feed safety system

Interpretation:

4.1.1	Management commitment/feed safety policy
Aim	Ensure strong commitment of management on quality and feed/food safety.
Interpretation	• Management should document its commitment to feed safety and create awareness within the organization regarding the importance of feed safety. Commitment can be demonstrated by establishing a written feed safety policy. The feed safety policy should be signed by the upper management. Minimum requirements for the contents of the feed safety policy include: feed safety is a key issue for management, meet requirements of the GMP+ FSA module, meet feed legislation and customer requirements, responsibility in the feed chain, management responsibility for recall situations if feed safety is at stake. Management commitment on feed safety is demonstrated through the organization's awareness of the feed safety policy, which is enhanced through an effective communication system, i.e. visible policy statement displayed in work areas. • Management should assess quality and feed safety objectives, preferably linked to business objectives. Objectives should be measurable. • The success and effectiveness of a feed safety system relies on employees understanding the feed safety programs.
Input/reference	B2 4.1., mission of organization, business objectives
Output	• Feed safety policy • Feed safety objectives
Frequency	Annual review (see 9.3)

4.1.2	Scope of feed safety system
Aim	Establish the scope of the feed safety management system including outsourced activities.
Interpretation	• The scope of a feed safety system is the description of the part of the chain for which the participant is responsible. For an overview of all processes it may help to draw a figure with primary processes and supporting processes. • Primary processes may be: planning, purchasing, (temporary) storage, internal transport, sales and packaging. All outsourced activities must be included. Outsourced activities may be: transport, storage, laboratory, pest control, cleaning, packing, maintenance, calibration of test equipment and training. Don't forget to describe activities that are not feed related and make sure that these activities do not have a negative effect on feed safety.
Input/reference	B2 4.3., BA10 (2), list of outsourced activities
Output	• Description of the scope • Process overview or business flow chart (diagram)
Frequency	Annual review

4.1.3	Establish feed safety system
Aim	Draw up a plan to establish, document, implement and maintain a feed safety system.
Interpretation	• To establish and implement a feed safety system, start by making a plan. This plan has to be presented in a simple and understandable form (like a schedule) with action plans subject to deadlines, resources, assigned responsibilities and budgets for each step. • Resources: Management should assess what resources are needed to produce safe feed and to set up a proper feed safety system, and must also provide these resources. Resources include financial resources, infrastructure (buildings, working environment, facilities), personnel and other means required to achieve safe feed.
Input/reference	B2 4.3.
Output	Plan for establishing a feed safety system with time frame and budgets
Frequency	Annual review of the system

4.2. Tasks, authorities and responsibilities for feed safety in the organization

Summary:
Management should clearly define tasks, authorities and responsibilities for employees that have an impact on feed safety, and these should be communicated. Employees carrying out activities that affect feed safety must be skilled and competent, and should be aware of their responsibility.

Steps:
4.2.1. Tasks, authorities and responsibilities
4.2.2. Feed safety coordinator
4.2.3. Feed safety team
4.2.4. Communication/awareness
4.2.5. Training needs

Interpretation:

4.2.1	Tasks, authorities and responsibilities
Aim	Clearly define tasks, authorities and responsibilities for employees that have an impact on feed safety and feed quality and make an organizational chart.
Interpretation	• All relevant personnel must be clearly informed of their duties and responsibilities regarding the maintenance of safe raw materials and feed ingredients clearly in writing. This information must be updated in the event of any significant changes. You should make an overview of all processes that affect food safety (see process overview), and assess responsibilities and authorities for these activities. • Make an organizational chart.
Input/reference	B2 5.1.1.
Output	• Organizational chart (diagram) • Overview tasks, authorities and responsibilities (diagram)
Frequency	Review the organizational chart and tasks, responsibilities and authorities schedule annually and in case of any important changes in the organization

4.2.2	Feed safety coordinator
Aim	Appoint feed safety coordinator within the organization.
Interpretation	• It requires knowledge, time, and resources to establish a feed safety system and a manual. It is wise to appoint one employee with the required qualifications for these activities. This person must be trained if qualifications are not sufficient. Depending on the size of the company, quality/feed safety tasks can be combined with other activities. • External expertise should be hired for technical purposes if needed, assigned by top management.
Input/reference	B2 4.2. Qualifications of feed safety coordinator
Output	Job description feed safety coordinator with tasks, authorities and responsibilities

4.2.3	Feed safety team
Aim	Appoint a feed safety team (HACCP team).
Interpretation	• In order to establish a risk assessment system, the participant must appoint a feed safety (or HACCP) team to produce an effective HACCP plan (see 6). The team should include personnel from all relevant operations and positions within the company. The HACCP team must have sufficient expertise in various disciplines or must be able to make use of external expertise. • Appoint at least one member with demonstrable HACCP-knowledge and/or HACCP-experience who can serve as the team leader (production manager or feed safety coordinator). • You can make a HACCP team table to specify the expertise and background of each team member, to prove that it is a multi-disciplinary team.
Input/reference	B2 4.2., D2.1 (5)
Output	Composition of feed safety team in a table with names and expertise (diagram)

4.2.4	Communication/awareness
Aim	Create awareness of responsibility for feed safety among personnel.
Interpretation	• Creating awareness among personnel is one of the most important aspects of a feed safety system. All personnel must be aware of their responsibilities regarding and contribution to feed safety. They must understand the feed safety procedures. Ensure that any person who encounters a problem with feed safety has the responsibility to report to identified persons. • Organize regular meetings where feed safety is discussed.
Input/reference	B2 5.1.1.
Output	List of feed safety related meetings (list)

4.2.5	Training needs
Aim	All personnel must have the appropriate skills and competencies. Determine training needs, establish a training procedure, a training plan and record training activities and experience levels.
Interpretation	• You must assess training needs for all personnel including temporary personnel, especially those with jobs directly affecting feed safety. Based on these needs you must make a training plan. Do not forget temporary personnel. • Establish training procedure that describes how training needs are assessed, how training is offered and evaluated. Especially for a quality coordinator, internal auditors and the HACCP team, training is needed on HACCP principles. • Keep personnel records of courses, training, skills and experience.
Input/reference	B2 5.1.2., personnel qualifications
Output	• Training procedure (procedure) • Training plan (diagram) • Training records (records)
Frequency	Review training needs at least annually and when necessary,

4.3. Management of feed safety system documentation

Summary:
You must have a documentation system in place. You must establish a feed safety manual with procedures, instructions and forms. Documents and records have to be managed and controlled.

Steps:
4.3.1. Feed safety manual
4.3.2. Procedure document creation and control
4.3.3. Approval, distribution, archiving and back-up of documents
4.3.4. Review of feed safety manual

Interpretation:

4.3.1	Feed safety manual
Aim	Establish feed safety documentation including a feed safety system manual with (GMP+) required procedures, instructions and registration forms, collect all the required parts of the quality/feed safety manual and structure into a logic sequence/contents.
Interpretation	• Feed safety system documentation: Minimum GMP+ requirements for the feed safety system documentation are: o Description of the scope of the feed safety system (4.1.2); o The documented Feed Safety Policy, including feed safety objectives (4.1.1); o All relevant records or approvals in accordance with national and international legislation; o The HACCP documentation (6); o All procedures, instructions, registration forms, etc. required by the GMP+ standard, and/or necessary for the operation of the feed safety system; (procedures: at least: documentation, internal traceability, legislative requirements, complaints, recall, internal auditing, HACCP, management review, non-conforming products, primary processes, monitoring and sampling); o All records of treatment, audits and inspections and all other records which are required.
Input/reference	B2 4.4.1.
Output	Feed safety manual (description of all procedures used in feed safety management, instructions and forms, HACCP documentation and feed safety policy)
Frequency	Review at least annually and in case of internal changes that may affect the feed safety system

4.3.2	Procedure document creation and control
Aim	Establish the procedure for the creation and control of documents and records; apply these procedures to all internal and external documents, and records.
Interpretation	• The document control procedure must include: creation, approval, control (distribution and issuances), identification (originator, changes/revisions), storage, protection, finding/location, duration of storage/retention and destruction of records, including retrieved and obsolete documents (internal & external) to ensure that only relevant and current versions of documents are in use. Creation of documents for the manual should refer to a standard format for procedures, instructions and forms. • A procedure defines: which process or task, should be performed when and how, by whom and the resources required. • Documents and records must be legible, easily identifiable and easily accessible. Documentation may also be made available in digital form, and may be controlled and stored as such.
Input/reference	B2 4.4.1, B2 4.4.2.
Output	Procedure for the creation and control of documents and records (procedure)

4.3.3	Approval, distribution, archiving and back-up of documents
Aim	Implement an effective system for approval and distribution of documents and establish a system for archiving and backing-up data.
Interpretation	• Approval and distribution: Determine who are responsible for approval of (which type of) documents. Distribution has to be controlled. Decide who should receive documents and define where the master copy (or digital version thereof) is kept. • Archive and back-up: Documents and records should be archived for at least 3 years. Make sure you have a proper back-up system of electronic data. These elements should be described in the documents and records control procedures.
Input/reference	B2 4.4.2.
Output	• Archived documentation • Back-ups of documents and records

4.3.4	Review of feed safety manual
Aim	Implement an effective system for reviewing the quality manual and internal and external documents (due to changes in legislation or GMP+ requirements)
Interpretation	• Regularly review external documents to ensure that you are using the current versions. Use websites for checking the current versions of external documents. • You must demonstrate that you have procedures in place that ensure you remain up-to-date with regulatory requirements and any food / feed safety issues relevant to your feed ingredients.
Input/reference	B2 2.1, B2 2.2, 4.4.2., Changes in legislation and GMP+ requirements (GMP+ BA1)
Output	• Updated feed safety manual, adjusted in case of regulatory requirements and internal changes (organizational, equipment, facilities, processes) that can affect the feed safety system • Procedure for updating external documents (legislative requirements)(procedure)

4.4. Identification, traceability and recall

Summary:
Feed products must be traceable at all stages of production, processing and distribution. An internal traceability procedure and a recall (withdrawal) procedure must be prepared.

Steps:
4.4.1. Identification and internal traceability procedure
4.4.2. Recall procedure and recall test

Interpretation:

4.4.1	Identification and internal traceability
Aim	Draw an internal traceability procedure and record traceability data.
Interpretation	• Traceability: Describe an internal traceability procedure (see D2.4 Guideline for Traceability, Appendix IV). Include the following in the traceability records: name and address details of suppliers and customers, date of delivery, type of product or service, product quantity, batch number, transport/ distribution details (if the participant is responsible for transport).
Input/reference	B2 5.4.1., D2.4 Appendix IV
Output	• Internal traceability procedure (D2.4 Guideline for Traceability (Appendix IV)(procedure) • Traceability records (records)

4.4.2	Recall (withdrawal) procedure and recall test
Aim	Establish a recall procedure and test it.
Interpretation	• Recall/withdrawal: you must define a recall procedure (see GMP+ BA5 (Minimum requirements Early Warning System). You must be compliant with all regulatory requirements for withdrawal. Define the composition of the recall team. The team should be designated, trained and competent, and authorities and responsibilities must be clear to all team members. • Define a list of internal and external contacts including management, quality coordinator, customers, distributors, authorities, GMP+ International, certification body (with contacts and telephone numbers/email). • Carry out a recall test every year and report the test results.
Input/reference	B2 5.5., BA5
Output	• Recall procedure/protocol (procedure) • Composition of recall team (diagram) • List of internal and external contacts (list) • Test recall report (records)
Frequency	Carry out a recall test at least once a year, within 3 months after defining the procedure.

5. Implementation of Prerequisite Programmes (PRP)

Summary:
Prerequisite programmes are the basic conditions and activities that are necessary to hygienic conditions for the safe production of feed. If PRPs are properly implemented, maintained and verified, risks for feed safety are reduced. PRPs should be developed and implemented prior to starting HACCP plan development. The PRP should be approved by the feed safety team.
In GMP+ B2 (2010) detailed requirements are listed, these can be added by customer requirements, regulatory requirements and codes of practices. The PRP should consider the following:

Steps:

5.1. Personnel hygiene
5.2. Lay-out of premises and buildings
5.3. Equipment/maintenance
5.4. Cleaning and sanitizing
5.5. Pest control
5.6. Supplies of air, water, energy and waste control

Interpretation:

5.1.	Personnel hygiene
Aim	Establish hygiene policy and access control, and communicate these to all personnel and subcontractors.
Interpretation	• Hygiene policy/regulations for personnel and subcontractors: All employees must sign the policy. • Install hygiene facilities and implement access control (with signs) for visitors.
Input/reference	B2 5.1., list of subcontractors
Output	• Signed hygiene policy (instruction agreed by employees and subcontractors) • Access regulation (instruction)

5.2.	Lay-out of premises and buildings
Aim	Lay-out and maintenance of company premises must be as such that risks of contamination of feed stuff is minimized.
Interpretation	• Evaluate risks to the environment and facilities and minimize risks of carry-over by taking adequate control measures. • Facilities and buildings must be designed and constructed as such that accumulation of dirt is prevented, cleaning, disinfection and maintenance can be carried out properly. Separate materials with possible adverse effect on feed safety.
Input/reference	B2 5.2.
Output	• HACCP risk assessment on environment/company premises (see 6)(HACCP document) • Facility site map (diagram)

5.3.	Equipment/maintenance
Aim	Prevent contamination of feed products due to maintenance, lack of maintenance or not well calibrated equipment. Develop, implement and maintain a maintenance program.
Interpretation	• Establish a procedure on how to deal with maintenance of equipment, including a maintenance program (both corrective and preventive), how to start up production after maintenance and calibration of measurement and testing equipment. • Record maintenance and calibration of equipment.
Input/reference	B2 5.3.1., B2 5.3.2.
Output	• Maintenance and calibration procedure (procedure) • Maintenance program/schedule (diagram) • Maintenance records (records) • Calibration records (records)
Frequency	Review maintenance program at least annually. Calibrate inspection, measuring and test equipment at least annually.

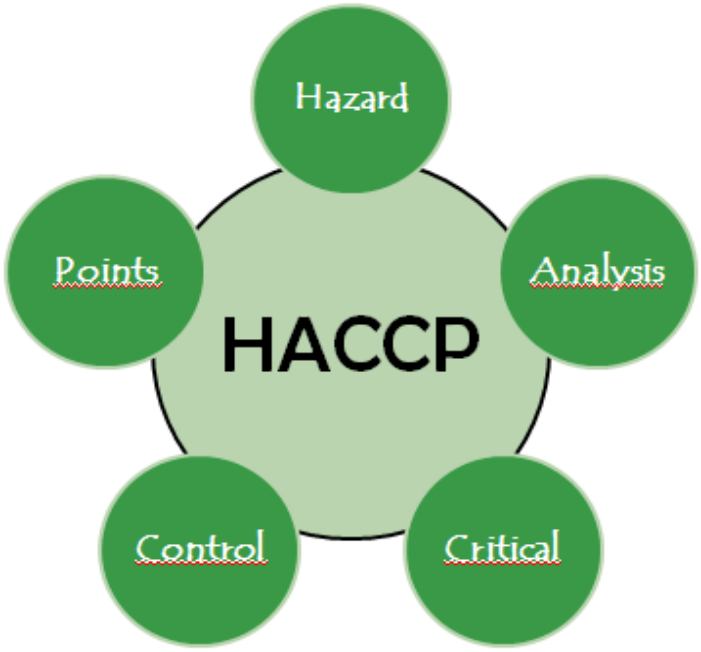
5.4.	Cleaning and sanitizing
Aim	Prevent contamination of feed products due to cleaning/sanitizing or lack of cleaning (dust, pests). lack of maintenance or non-calibrated equipment. Establish, implement and maintain a cleaning procedure and program.
Interpretation	• Establish a cleaning/sanitizing procedure including cleaning and disinfection activities, monitoring of hygiene and prevention of contamination by cleaning (agents). Plan cleaning activities in a documented program. Record cleaning activities. • Monitor the effectiveness of cleaning and sanitation and keep records.
Input/reference	B2 5.3.3.
Output	• Cleaning procedure (procedure) • Cleaning program (diagram) • Cleaning records (records) • Hygiene inspection results (records)

5.5.	Pest control
Aim	Prevent pest (including insects, birds) and increments from contaminating feed products. Draw up a pest control program, implement and maintain.
Interpretation	• Establish a pest control procedure including prevention, control and training of the pest control officer. Implement adequate prevention of pests including mice, rats, birds and insects. • Implement pest control and record inspections and the use of control agents. An external pest control officer is preferred. If an in-house employee carries out pest control, he must be externally trained and competent (through a certificate). Only use registered pest control agents.
Input/reference	B2 5.3.4., Requirements for pest controller
Output	• Pest control procedure (procedure) • Pest control program (diagram) • Pest control records (records)

5.6.	Supplies of air, water, energy and waste control
Aim	Identify waste and minimize the risk of unintended use as feed ingredient. Identify production processes which use air, water and energy to avoid contamination or mixing with feed materials being processed.
Interpretation	• Establish a procedure for separating and identifying waste and record waste disposal. Minimize the risk of unintended use/delivery as feed ingredient. Retain waste disposal records. • Control and monitor supply of air, water and energy and make sure that these do not negatively influence feed safety.
Input/reference	B2 5.3.3., B2 5.3.5.
Output	• Waste handling procedure (procedure) • Procedure for water, air and energy supply (procedure) • Waste removal and disposal records (records)

6. HACCP system (HACCP team, Hazard Analysis and Risk Assessment)

Summary: You must introduce, implement and maintain a HACCP plan, based on the 7 Codex HACCP principles (see GMP+ D2.1.).



Interpretation:

6.1-6.7	HACCP system part 1: steps 6.1-6.7.
Aim	Establish HACCP team, describe products and processes, perform Hazard Analysis and Risk Assessment.
Interpretation	• You must read GMP+ D2.1, the HACCP manual. • Make a HACCP procedure including all HACCP steps (see Guideline HACCP GMP+ D2.1). • Each feed ingredient must be registered on the GMP+ product list of the Feed Support Products (FSP). You must have HACCP specifications for all feed products. List all raw materials, ingredients and materials in contact with product. List end products and describe product characteristics and expected use. • Establish feed safety/HACCP team (see 4.2.3). • Gather all relevant information for hazard analysis and risk assessment. The HACCP Team carries out a risk assessment for each identified hazard. Complete the Hazard analysis and risk assessment table.
Input/reference	B2 4.2., 6.2., 6.3., D2.1 (Appendix 1), GMP+ generic fact sheets and risk assessments
Output	• HACCP plan and procedure (procedure) • Composition of feed safety (HACCP) team (4.2.3)(diagram) • HACCP product specifications including critical limits (HACCP document) • Process flow charts (diagram) • Hazard analysis and risk assessment table with hazards and risks (GMP+ D2.1. Appendix 1)(records)
Frequency	Review HACCP/hazard analysis at least annually or as necessary

6.8-6.14	HACCP system part 2: steps 6.8-6.14.
Aim	Establish control measures and CCPs, monitoring, validation and verification
Interpretation	• You should read GMP+ D2.1, the HACCP manual. • The HACCP team must establish, record and implement the measures to control high feed safety risks. • Monitoring: see 9.4. • Validation: to assess whether the hazards which established by the HACCP team are complete and correct and are effectively controlled using the HACCP-plan. • Verification: the use of additional information to check whether the system is still effective, performed by the feed safety-HACCP team.
Input/reference	B2 4.2., B2 6.4.-6.8., D2.1 (Appendix 1 and 2)
Output	• CCP table (GMP+ D2.1. Appendix 1)(records) • HACCP verification minutes (records) • Validation report (records)
Frequency	HACCP Verification at least annually. Validation if changes occur with impact on feed safety.

7. Control of Operational activities/primary processes

Summary:
Evaluate risks and control activities in primary processes to prevent contamination of feed ingredients.

Steps:

7.1. Purchase/ingredient-supplier management
7.2. Receipt and verification of raw materials and packaged feed ingredients
7.3. Storage of raw materials and end products
7.4. Production of feed ingredients
7.5. Non-conforming products
7.6. Sales, labeling and delivery
7.7. Transport

Interpretation:

7.1.	Purchase/ingredient-supplier management
Aim	Establish a procedure for purchasing related to ingredient-supplier management, define raw material specifications, perform ingredient-supplier assessment and monitor supplier performance.
Interpretation	• Establish a procedure for purchasing ingredients and services including selection and assessing supplier performance. Keep purchase records. Define raw material specifications. Make a list of ingredient-supplier combinations. • Assess which raw materials/ingredients/services must be GMP+ certified by checking GMP+ BA10. Make a list of approved ingredient-supplier combinations. Assess criteria for supplier performance e.g. quality, delivery time, GMP+. Check supplier performance based on these criteria every year and report the results in a schedule.
Input/reference	B2 7.1., D2.5., BA10 (2)
Output	• Raw material specifications (GMP+D2.5 Appendix 1) • List of approved ingredient-supplier assessment (list) • Supplier performance report (Guide to supplier assessment D2.5)(records)
Frequency	Ingredient-supplier assessment at least annually

7.2.	Receipt and verification of raw materials and packaged feed ingredients
Aim	Establish a procedure for verification of incoming raw feed materials, inspect incoming raw feed materials and packaged ingredients on inspection criteria as follows: customer requirements, process/equipment and other internal requirements, including transport documents.
Interpretation	• Draw a procedure for verification of incoming raw feed materials and packaged ingredients including criteria for acceptance and actions after rejection. Status of out-of-specs materials must be identifiable to preclude accidental use. Include check on obligatory transport documents (proper certification (GMP+ certificate if applicable), oil leakage, previous cargoes, load compartment inspection, proper cleaning. Record inspection results and non-conformities. (also see 7.5). • Establish a sampling procedure including sampling of raw materials and finished products, sealing, identification and storage of samples (see GMP+ BA13).
Input/reference	B2 7.2., B2 5.4.2., BA13, BA10 (3), raw material specifications, inspection criteria.
Output	• Procedure verification of raw materials (procedure) • Records of inspection results/non-conformities on incoming materials (records) • Sampling procedure (procedure)
Frequency	All deliveries of inbound raw feed materials/packaged feed ingredients

7.3.	Storage of raw materials and end products
Aim	Control all storage activities in accordance with the requirements of this standard. This applies to storage at both owned and rented sites, and to both packaged and unpackaged feed ingredients and raw materials.
Interpretation	• Establish a storage procedure/instruction for the control and documentation of storage measures including the required cleaning, disinfection and maintenance of storage facilities. Record critical controls for storage like temperature and visual inspections. • To enhance the control measures in product storage, an access policy must also be established. • In case of outsourced storage, agree on requirements (see GMP+BA10) in contract with storage provider.
Input/reference	B2 7.3., BA10 (3)
Output	• Warehousing procedures • Records of control measures (temperature control, stock protection agents, access pass)(records) • Contract with storage provider (if storage is outsourced)

7.4.	Production
Aim	Evaluate feed safety risks during production processes and production environment. Minimize risks by taking adequate measures.
Interpretation	• Establish procedures and instructions for critical production processes and parameter monitoring such as temperature control and mixing, and critical control points. (CCP's). Procedures must include recording of process controls, and corrective actions to be taken in the event of critical process parameters being breached (see also 7.5). • Describe risks in the HACCP analysis with adequate control measures for high risks during production including the risk of carry-over (see GMP+ B2 5.2.4). • Record critical process controls in production (CCP-related).
Input/reference	B2 5.2.4, B2 5.3.6., B2 7.4.1., BA1, BA4, procedure non-conforming products
Output	• Procedures/instructions for critical processes including corrective actions and recording of controls (procedure) • Records of process controls (records) • Risk assessment in HACCP analysis and description of control measures for risks during production including measurement of carry-over, procedure rework (HACCP document) • All non-conforming products especially, feed materials must be properly accounted (see 7.5).

7.5.	Non-conforming products
Aim	Define a procedure for non-conforming products (raw materials and end products) that do not comply with specifications.
Interpretation	Establish a procedure for non-conforming products including identification of batches, evaluation of the cause of the non-conformity, segregation of batches / lots affected, preventive or corrective measures to avoid repetition of the non-conformity and destination of non-conforming products including criteria. Non-conformities must be recorded. Measures to be taken must be approved by authorized positions (whether for disposal, for recycling or downgrade).
Input/reference	B2 7.4.2.
Output	• Procedure non-conforming products (procedure) • Records of non-conformities (records)

7.6.	Sales, labeling and delivery
Aim	Agree with buyer on product specifications in contract and provide delivery information and labels that meet GMP+ and customer requirements.
Aim	Agree with buyer on product specifications in contract and provide delivery information and labels that meet GMP+ and customer requirements.
Interpretation	• Feed ingredient specifications must be agreed with the customer and confirmed in the sales contract. You must record the sale of all feed ingredients to customers. Procedures must be in place to ensure that feed ingredients comply with the applicable requirements in the countries of destination. • On delivery the batch must be accompanied by the legally required product information. See GMP+ BA6 for labeling requirements.
Input/reference	B2 7.5., 7.6., BA6
Output	• Contract with customers referring to specifications (document) • Product information meeting GMP+ and legal requirements (document) • Procedure on checking legal requirements in countries of destination (procedure)

7.7.	Transport
Aim	Transport, whether in bulk or packed, must be appropriate and adequately controlled with specific regard to hygiene and potential contamination.
Interpretation	• General: Inventory all means of transport, including subcontractors. Establish procedures for own transport including requirements that load compartments must be empty, clean, dry and free from any residue and odors of previous loads, in order to prevent load contamination. • Transport by road: record loading compartment inspections, cleaning, previous loads and product categories (see GMP+BA14 and B4.1). Other means of transport (rail, inland waterway): record the LCIs (loading compartment inspections). • In case of outsourced transport, agree on GMP+ requirements in a contract with subcontractors (see GMP+ BA10). • When it is impossible to outsource a GMP+ certified transport in your area, establish your own internal requirements taking into consideration the GMP + requirements.

7.7.	Transport
Input/reference	B2 7.7., BA10 (3), transport database (IDTF)
Output	• Procedure for transport including loading compartment inspections (procedure) • Loading compartment inspection and cleaning records (road transport)(records) • Agreement with carrier (if outsourced) (document) • Correspondence with customer/recording of previous cargoes (if road transport is outsourced)(records) • Loading Compartment Inspection Form (transport by inland waterway)(records) • If non-GMP+ certified transport, inspection procedure of transport facilities (inspection checklist for trucks & container truck)(procedure)

8. Implementation of feed safety system

8	Implementation of feed safety system
Aim	Implement the feed safety system in the organization
Interpretation	Chapters 4 to 7 describe how to set up the feed safety system documentation. An important step is to truly implement the feed safety system in the organization. This must be done by: • Gathering all feed safety system documentation, put it into a logic sequence and create a feed safety manual (also see 4.3.1). • Inform employees about the existence of the feed safety system manual and let them read and agree on relevant parts. • Train people on the importance of feed safety and their responsibility (also see 4.2.5) • Inform people regularly on the outcome of verification activities, like internal audits, monitoring results, management reviews and complaints. • Encourage employees to keep the feed safety system up-to date and pursue continuous improvement. Put feed safety (system) on the agenda of internal meetings.
Input/reference	B2 4.4.1., B2 5.1.2., B2 8.2., B2 8.3
Output	• Implemented feed safety system

9. Verification and improvement

Summary:
When the feed safety system is established it is important to check whether control measures and procedures are actually implemented. This includes the Prerequisite Programme, procedures and instructions. This activity is referred to as verification: to check whether the feed safety system is efficient and effective.

Steps:

9.1. Complaint handling system
9.2. Internal audits
9.3. Management review and improvement
9.4. Monitoring program

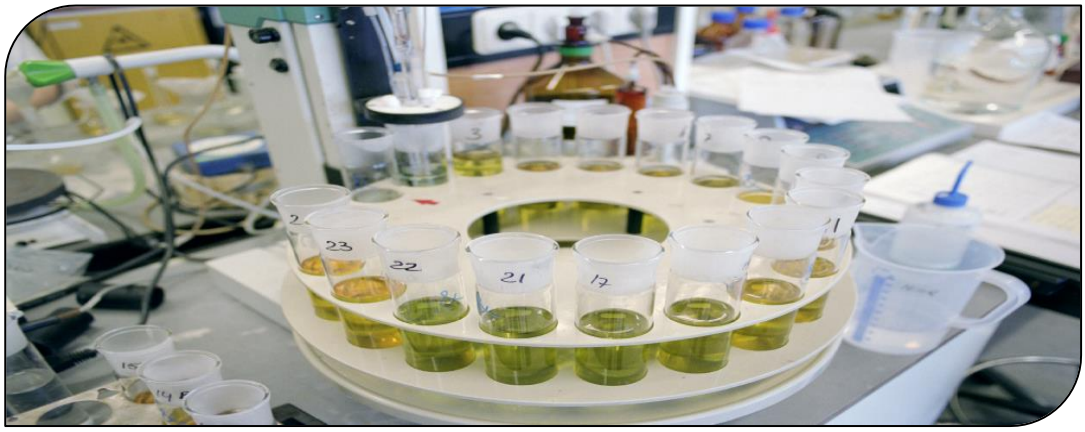
Interpretation:

9.1.	Complaint handling system
Aim	Effectively handle complaints from customers and use corrective and preventive actions to improve the feed safety system.
Interpretation	• Complaints are defined as all remarks from customers relating to feed safety and quality. • A procedure for recording and handling complaints should at least consist of: the recording of complaints, the examination of the sources and causes of complaints, recording of the measures which were taken as a result of the complaint: both corrective and preventive, recording the communication with the customer in question. A link should be made to the recall procedure (5.7). • Customer handling procedure can be linked to procedure for handling non-conforming products. • Complaint analysis is input for management review (9.3).
Input/reference	B2 8.1.
Output	• Procedure complaint handling (procedure) • Complaint records (records)
Frequency	Evaluation of complaints at least annually

9.2.	Internal audits
Aim	Perform internal audits to assess whether the feed safety system is effective, and define corrective and preventive measures to improve the feed safety system.
Interpretation	• An internal audit is an investigation to check that internal systems are operating as intended, are in compliance with requirements, and are effective (feed safety is achieved). During an audit, interviews are taken with the people responsible, and documents are checked. • Establish a procedure for internal audits including the audit plan, the preparation, competencies of auditors, responsibilities in the audit process, reporting and follow-up, e.g. taking corrective measures. • Audit program: The internal audit program must ensure that all relevant activities are audited at least once a year. • Performing internal audits: check compliance with requirements of this GMP+ B2 (2010) standard, with applicable legislation, with your own procedures, customer requirements and requirements in your HACCP plan (PRPs, CCPs). • All personnel carrying out internal audits must be competent for the task by means of training or education (internal or external), or experience. An external audit training is recommended, as well as carrying out audits with an experienced auditor. Auditors must be independent from the activity to be audited. • Audit reports: establish a standard format for audit reports and follow-up actions. • Internal audits analysis is input for management review (9.3).
Input/reference	B2 8.2.
Output	• Procedure internal auditing (procedure) • Audit program (diagram) • Audit non-conformity form to formalize audit findings (records) • Audit reports (records)
Frequency	All feed safety related activities must be audited at least annually or where necessary depending on the results of internal and external audits and other process monitoring activities

9.3.	Management review
Aim	Management should periodically evaluate the feed safety system to identify areas for improvement and create programs and allocate required resources to support its realization.
Interpretation	• Establish a procedure for management review, establish, collect and analyze suitable data at least once per year in order to demonstrate that the feed safety system is suitable and effective, and to assess whether continuous improvement in the effectiveness of the feed safety system is possible. • The input for such a management review should contain information on: o Evaluation of feed safety policy and objectives (4.1.1); o Assessment of the prerequisites programme (PRP); o Assessment of analysis results for products ; o Verification of the hazards analysis; o Assessment of the level of knowledge of the personnel; o The results of the supplier evaluation; o Feedback /complaints from customers; o Evaluation of non-conformities including the effect of preventive and corrective actions; o Assessment of the implementation of legislation and regulations; o The results of internal and external audits; o Changes that affect the feed safety system; o Define the funds (financial, resources, time) needed to execute the proposed improvements. • The management review must result in conclusions stating to what extent the feed safety system should be modified, and the possibilities of improving the feed safety system.
Input/reference	B2 4.1., B2 8.3., complaint analysis, internal audit analysis, monitoring results (analysis of products)
Output	• Management review minutes/report (records) • Improvement projects (records)
Frequency	Management review at least annually

9.4.	Monitoring program
Aim	Establish a monitoring plan for analysis of contaminants with risk for feed safety
Interpretation	• You must draw a procedure monitoring, including selection of parameter/feed product combinations to be monitored, frequencies, selection of laboratories, performing analysis, compliance with specifications and evaluation of analysis results. See GMP BA4. • Establish a monitoring program based on high risk contaminants with parameter-products and frequency.
Input/reference	B2 6.6, BA4, CCPs from HACCP analysis related to contaminants
Output	• Procedure monitoring plan (procedure) • Monitoring plan with parameters and frequency (diagram)
Frequency	Update annually or when necessary especially in case of changes that might affect the feed safety system.



10. Preparation for certification

10	Preparation for certification
Aim	To get certified for GMP+B2 (2010) or other GMP+ standard, through an audit by a GMP+ International accepted Certification Body.
Interpretation	Get prepared for GMP+ certification, contact a certification body (CB), schedule a GMP+ pre-audit, take corrective measures on non-conformities, plan a final GMP+ audit, take corrective measures again, and get certified.
Input/reference	GMP+ C, A1 (3.4), C2 (appendix 2), GMP+ Relation management system (Companies database including CBs)
Output	• Contract with Certification Body (CB)(document) • Audit report (by CB)(records) • Action plan on non-conformities (records) • Final audit report (by CB)(document) • GMP+ certificate (issued by CB)(document)
Frequency	External audit at least annually (see GMP+A1).

Annex 1 Cross reference table

Step & number GMP+ Guidance	GMP+ B2 (2010) 'Production of feed ingredients'	GMP+ B1 'Production, trade and services'	GMP+ B3 (2007) 'Trade, collection and storage & transhipment'	GMP+ B4 'Transport'	other GMP+ documents with useful information
4.1.1. Management commitment/feed safety policy	4.1	5.1, 5.2, 5.3.1, 5.5.	4.1	4.1	
4.1.2. Scope of feed safety system	4.3	4.1	4.3	4.3	GMP+ BA10 (2)
4.1.3. Establish feed safety system	4.3	4.1, 5.4.4	4.3	4.3	
4.2.1. Tasks, authorities and responsibilities	5.1.1	5.4.1, 6.2.1	5.1.1, 5.1.2	5.1.1, 5.1.2	
4.2.2. Feed safety coordinator	4.2	5.4.3	4.2	4.2	
4.2.3. Feed safety team	4.2	5.4.2	6.2	n.a. (*)	GMP+ D.2.1 (5)
4.2.4. Communication/awareness	5.1.1	5.4.5	5.1.1	5.1.2	
4.2.5. Training needs	5.1.2	6.2.2	5.1.2	5.1.2	
4.3.1. Feed safety manual	4.4.1	4.2.1, 4.2.2	4.4.1	4.4.1	
4.3.2. Procedure document creation and control	4.4.1, 4.4.2	4.2.3, 4.2.4	4.4.2	4.4.2	
4.3.3. Approval, distribution, archiving and back-up of documents	4.4.2	4.2.3, 4.2.4	4.4.2	4.4.2	

Step & number GMP+ Guidance	GMP+ B2 (2010) 'Production of feed ingredients'	GMP+ B1 'Production, trade and services'	GMP+ B3 (2007) 'Trade, collection and storage & transhipment'	GMP+ B4 'Transport'	other GMP+ documents with useful information
4.3.4. Review of feed safety manual	2.1, 2.2, 4.4.2	2.2, 4.2.3, 7.2.2	2.1, 2.2, 4.4.2	2.1, 2.2, 4.4.2	
4.4.1. Identification and internal traceability procedure	5.4.1	6.5	5.4.1	5.4.1	GMP+ D.2.4 appendix IV
4.4.2. Recall procedure and recall test	5.5	6.6	5.5	5.5	GMP+ BA5
5.1. Personnel hygiene	5.1	6.2.1	5.1.1	5.1.1	list of subcontractors
5.2. Lay-out of premises and buildings	5.2	6.3.1, 6.3.2	5.2	5.2	
5.3. Equipment/ maintenance	5.3.1, 5.3.2	6.4.1, 6.3.2.3	5.3.1, 5.3.2	5.3	
5.4. Cleaning and sanitizing	5.3.3	6.4.2	5.3.3	5.2.2, 7.3.2, 7.3.3	
5.5. Pest control	5.3.4	6.4.3	5.3.4	5.3.2	requirements pest controller
5.6. Supplies of air, water, energy and waste control	5.3.3, 5.3.5	6.4.2, 6.4.4	5.3.3, 5.3.5	5.3.3	
6.1-6.7.: HACCP system part 1	4.2, 6.2, 6.3	5.4.2, 7.2, 7.4	6.1-6.4	6 (not all applicable)	GMP+ D.2.1 appendix 1, Feed Support Products
6.8-6.14.: HACCP system part 2	4.2, 6.4-6.8	7.5-7.9	6.5-6.9	6 (not all applicable)	GMP+ D.2.1 appendix 1 &2, Feed Support Products
7.1. Purchase/ingredient-supplier management	7.1	7.10.1, 7.10.2	7.1.2, 7.1.3	7.1	GMP+ D2.5 appendix 1, GMP+ BA10

Step & number GMP+ Guidance	GMP+ B2 (2010) 'Production of feed ingredients'	GMP+ B1 'Production, trade and services'	GMP+ B3 (2007) 'Trade, collection and storage & transhipment'	GMP+ B4 'Transport'	other GMP+ documents with useful information
7.2. Receipt and verification of raw materials and packaged feed ingredients	5.4.2, 7.2	7.10.3	7.1.4	7.1	GMP+ BA10, GMP+ BA13
7.3. Storage of raw materials and end products	7.3	6.3.2.2	7.2	n.a. (*)	GMP+ BA10
7.4. Production of feed (ingredients)	5.2.4, 5.3.6, 7.4.1	6.3.2, 6.7. 7.11	n.a. (*)	n.a. (*)	GMP+ BA1, GMP+ BA4
7.5. Non-conforming products	7.4.2	7.8	7.1.5	n.a. (*)	
7.6. Sales, labeling and delivery	7.5, 7.6	7.11.3	7.1.6, 7.1.7	n.a. (*)	GMP+ BA6
7.7. Transport	7.7	4.1	7.3	7.3 (& whole document)	BA10 (3), Transport database (IDTF)
8. Implementation of feed safety system	4.4.1, 5.1.2, 8.2, 8.3	4.1, 7.1, 8.4	4.4.1, 5.1.2, 5.3.2, 8.2, 8.3	4.3, 8.3	
9.1. Complaint handling system	8.1	7.2.4	8.1	8.1	
9.2. Internal audits	8.2	8.2	8.2	8.2	
9.3. Management review and improvement	4.1, 8.3	5.5, 8.1, 8.3, 8.4	4.1, 8.3	8.3	
9.4. Monitoring program	6.6	7.7	6.7	n.a. (*)	GMP+ BA4, CCPs from HACCP analysis related to contaminants
10. Preparation for certification					GMP+ A1 (3,4), GMP+ C2 (appendix 2)

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