



GMP+ Feed Safety Assurance scheme

Guideline HACCP GMP+

GMP+ D2.1

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1 Introduction

1.1 General

The GMP+ Feed Safety Assurance scheme (GMP+ FSA) has been developed since 1992. It was managed from 1992 up until 2009 by the Product Board Animal Feed, The Hague, The Netherlands. Since 2010, this scheme is managed by GMP+ International.

The GMP+ Feed Safety Assurance scheme (GMP+ FSA) is a scheme for assuring feed safety in all the links in the feed chain. It is also an international scheme, applicable worldwide.

The establishment and development of the scheme was primarily the result of demand from the subsequent links in the animal production chain for better control of feed safety. Another contributory factor was the damage caused by more and less serious contamination incidents.

In the initial phase the demand arose for better differentiation in an increasingly saturated European sales market for animal products. Since 1999, feed & food safety has been a top issue internationally both politically and commercially, because of serious incidents in the feed sector. Because of this, demonstrable assurance of feed safety has become a sales prerequisite.

The basic principle of the GMP+ FSA scheme is that the feed chain is part of the food production chain. Proper assurance of feed safety worldwide is a high priority. Companies must live up to their responsibilities and respond properly and convincingly to the needs of food production chain. The GMP+ Feed Safety Assurance scheme is an aid to realise this.

1.2 Structure of the GMP+ Feed Safety Assurance scheme

The documents within the GMP+ FSA scheme are subdivided into a number of series. A description follows of these:

<p>A General (framework) documents</p>	<p>These documents contain the requirements for participation in the certification scheme for companies and certification bodies (framework regulation, the use of logo's, etc.). This series also includes a general list of definitions and abbreviations.</p>
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B
Normative documents.

These documents contain the international standards and additional country notes for use by companies with respect to the various feed products and production phases including cultivation and industrial production, treatment and processing, collection, trade, means of transport, storage and transshipment.

C
Certification requirements

These documents contain the Rules of Certification including those for the approval of certification bodies and auditors, the frequency of audits, minimum audit time, assessment criteria, checklists, etc. There is also an explanation of how the supervision by certification bodies is implemented and of how GMP+ International supervises the certification process.

D
Interpretations and accompanying texts

In addition to the above-mentioned normative documents, there are also supporting documents in the D series including a list of frequently-asked questions, manuals and guidances with additional information.

Document	Code	Name
	GMP+ DX.X	e.g. GMP+ D2.1 <i>Guideline HACCP GMP+</i>

All these documents are available through the website of GMP+ International (www.gmpplus.org).

The document in the present case is referred to as GMP+ D2.1 *Guideline HACCP GMP+* and was previously published as GMP + Appendix 15 'HACCP manual' in the context of the GMP+ Certification Scheme 2006. It is not a normative document, but gives guidance to comply with specific GMP+-requirements. The choice of words and the tone may be compulsory, but the document should be read as a guideline

1.3 Structure HACCP Guideline

The HACCP guideline is intended to support GMP+ Feed Safety Assurance scheme (GMP+ FSA) participants in setting up their in-company HACCP system. The guideline provides an explanation of the HACCP principles in sections.

The HACCP requirements in the GMP+ standard are predominantly based on the HACCP criteria as laid down in the Codex Alimentarius. Meanwhile, based on new


insights (as ISO22000), some changes and additions were included in the HACCP requirements.

The animal feed sector is already used to working with measures to ensure animal feed safety. The animal feed regulations and the GMP+ Feed Safety Assurance scheme (GMP+ FSA) already cover a wide range of quality requirements for animal feed. This concerns sector-wide measures. Company specific situations cannot always be taken into account when preparing these measures.

Since the year 2000, the animal feed sector has taken the initiative of including the HACCP system in the GMP+ FSA scheme. Since the Animal Feed Hygiene Regulation EC 183/2005 as per 1 January 2006, application of HACCP principles has become mandatory in Europe for all animal feed companies, excluding primary agricultural production.

The scope of this guideline is to support in feed and food safety assurance. This guideline is intended specifically for the management and employees of companies within the animal feed sector developing a company specific HACCP system. The manner in which HACCP is described in current animal feed Regulations (in particular the EC Regulations 183/2005, (EC) Nr. 178/2002 and (EC) Nr. 852/2004), the General Food Hygiene Guidelines recommended by Codex (CAP/RCP 1-1969, Rev. 4-2003) and national and international requirements relating to HACCP management systems (HACCP-NL and ISO 22000) served as a guideline in preparing this guideline.

The second chapter of the guideline refers to definitions and terminology. The relationship with legislation and the GMP+ FSA scheme is explained in section 3. Section 4 contains a further explanation of the requirements within the management's scope of responsibility. Chapter 5 is a phased plan for setting up a HACCP system. In preparing this phased plan, the requirements as set out in current legislation or GMP+ FSA scheme have been included as much as possible.

The symbol  is a reference to the paragraph of the relevant standard in the GMP+ Feed safety Assurance scheme (GMP+ FSA scheme), more specifically the standards where companies are subjected to a mandatory individual HACCP analysis.

Note: as versions of standards may differ, in the table below is stated which version of each standard is meant.

Standard	Full name	Version
B1	B1 <i>Production, trade & services</i>	1-1-2010
B2	B2 (2010) <i>Production of Feed Ingredients</i>	1-1-2010
B3	B3 (2007) <i>Trade, collection and storage</i>	publishing scheduled for 2010
B4	B4 <i>Transport</i>	publishing scheduled for 2010



This symbol signifies supplementary and specific attention for the relevant issue.

2 Definitions and terminology

See GMP+ A2 *Definitions & Abbreviations*

3 Animal feed legislation and GMP+ FSA scheme

Before setting up and developing a HACCP system, a company or organisation should already work in accordance with legislation relating to food and feed safety.

In Europe, as of 1 January 2006, the Animal Feed Hygiene Regulations (Regulation (EC) 1831/2003) has been effective. This Regulation includes requirements relating to hygienic animal feed handling. The Regulation determines that all activities during all stages of animal feed production fall under the scope of the Regulation. The Regulation determines that all animal feed companies shall apply HACCP principles. The HACCP guideline is intended as a tool for preparing and implementing an in-company HACCP system based on these legal HACCP principles.

Within the GMP+ FSA scheme, supplementary stipulations have been included, for example: GMP+ BA1 *Product Standards* and GMP+ BA4 *Minimum requirements for Sampling and Analysis*.

4 HACCP system requirements

4.1 Management responsibilities

Relating to animal feed safety, a number of requirements fall directly within the scope of management responsibility. This includes defining quality policy, defining the scope of the HACCP system, determining tasks, responsibilities and authority, making resources available and management assessment.

4.1.1 Defining quality policy

The quality policy, which forms part of the complete business policy, is the platform for the management to record the organisation's goals in the area of food and feed safety. The management is responsible for defining the quality policy by means of practicable objectives and communicating these to the employees. The quality policy should match customer expectations and it should convey that the organisation is aware it is part of the food and feed chain. The management subsequently ensures that development and implementation of the HACCP system progresses according to plan and is updated and adjusted as and when required.

- ☞ GMP+ B1
§ 5.2 Feed safety policy
- ☞ GMP+ B2, B3 & B4
§ 4.3 The feed safety system

4.1.2 Defining the scope of the HACCP system

The scope and extent of the HACCP system should be indicated. Scope relates to the activities that the company is responsible or accountable for.

- ☞ GMP+ B1
§ 5.2 Feed safety policy
- ☞ GMP+ B2, B3 & B4
§ 4.3 The feed safety system

4.1.3 Tasks, responsibilities and authorisation (TRA)

When setting up a HACCP system, it is important to record the tasks, responsibilities and authorisation of employees relating to food and feed safety.

This pertains to employees involved in the manufacturing process of the animal feed or involved in control and monitoring of feed safety.

- ☞ GMP+ B1
§ 5.4 Responsibility, authority and communication on feed safety
- ☞ GMP+ B2, B3 & B4
§ 4.1 Management; responsibility and involvement

4.1.4 Making resources available

Management should review requests of the HACCP team relating to resources and facilities required for the creation, implementation and maintenance of the HACCP system and make these available in due course.

Where corrective measures, verification procedures or customers indicate that operational improvements are required, the organisation should review and assess these aspects and where necessary make adequate resources available in order to guarantee feed safety.

The employees will be enabled to implement the HACCP system and comply with work agreements by resources and facilities being made available by the management. This may pertain to making control equipment available as well as making personnel and time available in order to allow for inspections to be carried out.

- ☞ GMP+ B1
§ 5.4.4 Provision of resources
- ☞ GMP+ B2, B3 & B4
§ 4.1 Management; responsibility and involvement

4.1.5 Management assessment of the HACCP system

When the entire HACCP system has been developed and implemented, the management must ensure that the HACCP system is maintained and revised if necessary. The quality objectives, where necessary, may be further specified where possible. This will provide a mechanism allowing for assessing the effectiveness of the HACCP system at regular intervals.

- ☞ GMP+ B1
§ 5.5 Management review
- ☞ GMP+ B2, B3 & B4
§ 8.3 Management review and improvement

5 HACCP phased plan

Hazard Analysis & Critical Control Points, HACCP, is a process control system relating to feed and food safety and may be set up and applied in combination with other quality systems. The HACCP plan consists of the following phases:

HACCP phased plan		
Phase 1		Forming HACCP team and validation team
Phase 2		Description of products
Phase 3		Record intended use
Phase 4		Determine process information
Phase 5		Testing process information
Phase 6		Define prerequisite programme
Phase 7	Principle 1	Hazard analysis (based on probability x seriousness)
Phase 8	Principle 2	Determine Critical Control Points (CCP's (based on decision tree)
Phase 9	Principle 3	Determine standards for CCP's
Phase 10	Principle 4	Monitoring CCP's
Phase 11	Principle 5	Define corrective measures
Phase 12	Principle 6	Validation and verification of HACCP plan
Phase 13	Principle 7	Documentation and registration of HACCP plan

These phases will be described in detail in the following paragraphs.

PHASE 1 Forming multi-disciplinary HACCP and validation teams

- ☞ GMP+ B1,
 - § 5.4.1 Responsibility and authority
 - § 5.4.2 HACCP-Team
 - § 6.2 Personnel
 - § 7.9 Validation of the HACCP plan

- ☞ GMP+ B2, B3 & B4
 - § 4.1 Management: responsibility and involvement
 - § 6.2 HACCP team
 - § 5.1 Personnel
 - § 8.3 Management review and improvement

The management of the company is responsible for forming the HACCP and validation teams. The management shall ensure that members of both the HACCP and validation teams will have adequate time and (if necessary) resources available for setting up and implementing, respectively validating, the HACCP system.

The HACCP team is a team within the organisation that supervises setting up and implementation of the HACCP system. In addition to implementation, the HACCP team is designated a role in maintenance and verification of the HACCP system. The HACCP system is specific for each company.

The validation team is also a team within the organisation. The validation team's aim is to determine if the HACCP system as set up by the HACCP team will perform as intended in practice. This is referred to as validation (see phase 12).

Both large and small businesses are required to compose both a HACCP team and a validation team. The size of these teams depends on the organisation's size as well as the expertise of the team members. The implementation of a HACCP system requires technical expertise as well as expertise in animal feed and food chemistry, toxicology, animal feed microbiology and quality management. The more comprehensively these fields of expertise are represented in both teams, the more complete the HACCP system can be expected to become.



If necessary, companies should deploy the services of qualified external experts.

In addition to the various fields of expertise, team members should come from the various hierarchical levels of the company. This should ensure that the HACCP system will be supported throughout the company.

The following fields of expertise may be represented in the HACCP and/or validation team:

- a **Management representative:** Decision-maker
- b **Process expert:** An employee responsible for, or closely involved in, the production process (for example the production manager). This employee should have knowledge of the operating methods on the production floor.

- c **Quality coordinator**, with insight into quality of ingredients and finished product, with knowledge of microbiological, chemical and physical hazards relating to specific products / processes.
- d **Production employee**: an employee (for example production supervisor) with knowledge of the hygienic status of the company, production spaces and installations.
- e **Other**: Depending on the company's activities, i.e. if applicable, the following fields of expertise should also be represented: Expert relating to purchasing, storage, forwarding, sales, nutritional and agricultural issues.

Members of the HACCP team may be a member of the validation team too. However, the validation team must preferably also contain independent members who are not a member of the HACCP team. in order to prevent influence: Select employees not directly involved in preparing the HACCP plan.



Companies with a limited number of employees (or companies without any staff) should hire external support for the implementation and validation of their HACCP system (for examples suitable persons working within the sector or external consultants).

Both the management representative and the quality coordinator within the HACCP team must attend HACCP training or the team members must have attained a similar level based on experience.

The company must record the members of both the HACCP and validation teams as well as the fields of expertise of their team members in a document or add this to existing documentation. The fields of expertise must be verifiable, for instance based on diplomas or demonstrable work experience. If the required expertise is not available within a company, external experts may be involved in the team's activities. External expertise must also be recorded in the documentation.

PHASE 2 Description of animal feedstuffs

Phase 2.1 Description of the finished product in finished product specifications

- ☞ GMP+ B1,
§ 7.2.3 Description of the feed based on requirements (specifications)
- ☞ GMP+ B2, B3 & B4
§ 6.3.2 Specification of feed
- ☞ GMP+ BA1 Product standards
- ☞ GMP+ BA3 Minimum requirements negative list
- ☞ GMP+ BA10 Minimum requirements purchasing

Information regarding finished products is required in order to be able to correctly assess the hazards that may occur during the manufacturing process or the type of hazards that the finished products (the animal feedstuffs) may entail to humans or animals. The HACCP team shall chart this information based on the finished product specifications of animal feedstuffs.

Finished product specifications provide an initial indication of possible hazards. In addition to the ingredients used (raw materials, additives) and nutritional values of the final product, 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 (see box above). The features as included in the specification must be considered by the HACCP team when setting up and implementing the company-specific HACCP system.

In principle, each finished product must be described separately in a specification. For practical reasons, creating product groups is allowed. However, the products must be classified into groups in such a manner that differences in ingredients or processing steps do not lead to additional hazards.

Finished product specifications can be prepared based on a so-called three-category system.

- a Generally applicable requirements and features for animal feed can be recorded once. These features can then apply to all animal feedstuffs manufactured in a company. This applies, for example, to Microbiological requirements, such as 'salmonella not present in 25 grammes'.
- b The same can be done for features similar for a certain animal species (often a product group).
- c Features specific to a product can be recorded at article level.

Phase 2.2 Description of the ingredients and auxiliary substances

- ☞ GMP+ B1,
§ 7.2.3 Description of the feed based on requirements (specifications)
§ 7.10.2 Purchasing data
- ☞ GMP+ B2, B3 & B4
§ 6.3.2 Specification of feed
- ☞ GMP+ B2, B3
§ 7.1.2 Purchasing
- ☞ GMP+ BA1 Product standards
- ☞ GMP+ BA3 Minimum requirements negative list
- ☞ GMP+ BA10 Minimum requirements purchasing

The requirements that apply to the finished product (for example limits of contaminants) are partially determined by the ingredients and auxiliary substances used. This includes feedstuffs, premixes, additives and technological auxiliary substances. Inspection of ingredients and auxiliary substances based on specifications is necessary.

Furthermore, when preparing the specifications, the requirements and standards as included in the various appendices to the GMP+ standard must be taken into account (see box above).

The information relating to the ingredients and auxiliary substances, and their growing/harvesting/mining process is required for the execution of the hazard identification of the company's manufacturing process (see phase 7 of the HACCP analysis).

PHASE 3 Determining the intended use of animal feed

- ☞ GMP+ B1,
 - § 7.2.3 Description of the feed based on requirements
 - § 7.2.4 Communication with the customer
 - § 7.11.3 Loading and delivery

- ☞ GMP+ B2, B3 & B4
 - § 6.3.2 Specification of feed

- ☞ GMP+ B2
 - § 7.5 Sale and contracts
 - § 7.6 Labelling and delivery requirements

- ☞ GMP+ B3
 - § 7.1.6 Sale and contracts
 - § 7.1.7 Labelling and delivery requirements

Considering the target group(s) prevents hazards from being overlooked. This concerns hazards to animals as well as hazards that may be incurred by the human customer of the animal products.

The finished product specifications serve to record the target species of the animal feed. Not all animal feedstuffs are (in their normal form) suitable to all animals. For example in the case of raw soy beans. Before being used as an ingredient in piglet feed, these must be toasted in order to remove the harmful trypsin inhibitor. Another example is that high copper levels in sheep feed have a toxic effect, whereas copper must be added to the feed of many other animal species.

The product specification must also record the animal species, the age of the animal and the instructions of use (including storage conditions). This may also be subject to varying requirements.

The HACCP team shall review how the animal feed is to be stored and used as intended without any hazards to animal or public health occurring.

The information on the label must at least comply with the applicable animal feed legislation, but if improper use of animal feed may lead to unsafe animal products, a (supplementary) set of instructions relating to transport, storage, processing and feeding must be supplied with the relevant products.

PHASE 4 Determine process information

The HACCP team shall prepare a comprehensive and up to date description of all business processes in the form of flow diagrams and a floor plan.

Phase 4.1 Preparing process diagrams

☞ GMP+ B1,
§ 7.3.1 Flow diagrams of the process

☞ GMP+ B2, B3 & B4
§ 6.3.3 Process description

The HACCP team shall prepare a process diagram of the production process for each product (or product group). These process diagrams must indicate the process phases to be followed in order to create a certain finished product. The process diagram should also indicate the ingredients and auxiliary substances used and any by-products created by the process.

Each process, production or processing phase must be indicated separately in the process diagrams. Hazards can be identified based on these company specific process diagrams (see phase 7 and further).

When preparing the process diagrams, the following are key issues.

- a select a finished product or product group
- b define the description of the process (start - end)
- c prepare simple, clear diagrams
- d to enhance clarity and overview, restrict the number of symbols
- e use uniform terminology for products and/or processes
- f try to work top down and left to right as much as possible
- g prepare a core process for the finished product or product group
- h divide the core process into sub-processes
- i indicate the links between sub-processes with start and end symbols
- j indicate ingredients, auxiliary substances, semi-finished products, by-products, finished products, return flows and waste flows

A process diagram may be subdivided into a core process and sub-processes. Defining a core process may be useful if the process is complicated and includes many process phases and/or a large number of inbound and outbound flows.

The key process phases of the production process are included in the core process diagram. Each core process phase is specified in a sub-process diagram, where all process steps are indicated separately.

Symbols

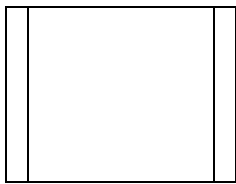
Using the following symbols when preparing process diagrams is recommended.

Opening or closing symbol



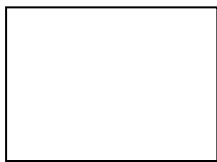
This symbol indicates the beginning and end of the process diagram. If it is used as a start symbol, the name of the relevant sub-process can be entered. If it is used as an end symbol, the name of the next sub-process can be entered. This shows how the various sub-processes are interlinked.

Core process phase



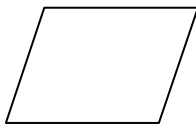
This symbol indicates the main activities or actions within a section of the process in the core (global) process diagram. The core (global) process phases are described in further detail in sub-process diagrams.

Process phase



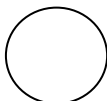
This symbol indicates an activity or action (a process phase). Based on the process phases, the hazards are always identified (see phase 7).

Product



This symbol indicates a tangible product (for example an ingredient, semi-finished product or finished product) or other tangible matter (for example steam or air) that enters or exits the process.

Connection symbol



This symbol indicates that the specific product flow is shown in detail in a different place in the process diagram. It is also possible that the product flow is derived from a different place in the production process.

Indicating a letter or digit in the symbol can help distinguish the connections.

For a detailed example, please refer to the Feed Safety Database Risk Assessments on the website of GMP+ International www.gmpplus.org

Phase 4.2 Preparing a floor plan

☞ GMP+ B1,
§ 7.3.2 Diagram of the organisation

☞ GMP+ B2, B3 & B4
§ 6.3.3 Process description

A floor plan of the company spaces offers support when systematically charting and verifying the production processes.

A floor plan serves to indicate the company's infrastructure. This concerns an overview of:

- a The various company spaces (for example production and storage) and personnel facilities.
- b Machines and equipment present (for example technical drawings of the conveyor installations).
- c The routing of animal feed and ingredients through the company, of waste and of personnel in order to make any cross-contamination points visible.

PHASE 5 Testing process information

☞ GMP+ B1,
§ 7.3 Process information

☞ GMP+ B2, B3 & B4
§ 6.3.3 Process description

After preparing process information (process diagram and floor plan), these must be tested against practice by the HACCP team.

This 'reality check' entails for the HACCP team to walk through the processes during working hours on site (verification of the process diagram). If the same actions are carried out by various persons and/or teams, it is important to test the process diagrams against the working methods of all these persons and/or teams - for example, does the night shift work in exactly the same manner as the day shift? If practice indicates that process phases were overlooked, the process diagrams must be adjusted.

The accuracy of the lay-out of the floor plan must be checked and adjusted where needed.

Furthermore, when a process is updated or changed, the process must be re-tested to practice and re-validated (see phase 12). The changes must also be implemented in the process diagrams.

This test is intended in order to ensure that the further HACCP steps are followed with the correct process information. If the process information and the observations in working practice are matches, the teams may proceed with the next phase.

PHASE 6 Define prerequisite programme

- ☞ GMP+ B1,
Chapter 6 Prerequisite programme
- ☞ GMP+ B2, B3 & B4
Chapter 5 Prerequisite programme

A minimum level for controlling food and feed safety must be applicable before implementing HACCP. This basic level must be realised by determining and applying a prerequisite programme. Prerequisite programmes create environmental and operating conditions required for delivery of safe animal feed. The prerequisite programme is part of the GMP+ FSA scheme.

The prerequisite programme consists mainly of general control measures ¹ for controlling general hazards. These include pest control plans, cleaning plans, training plans and buying procedures. These general control measures form a basis for effective application of the hazard analysis for each animal feed company (Principle 1).

The prerequisite programme as included in the GMP+ FSA scheme is based on the HACCP Certification Scheme Foodstuffs, the General Principles of Food Hygiene' of the Codex Alimentarius and the applicable animal feed legislation (Animal Feed Hygiene Regulation 183/2005).

The participant must check which elements in the prerequisite programme are applicable to the company. These are to be defined in further detail within the company in compliance with the minimum requirements as included in the GMP+ standard appendices.

The participant must determine if the prerequisite programme is an adequate basis for successful application of the HACCP principles. If this is not the case, the participant must specify and implement supplementary prerequisites.

¹ These general control measures were called PVA's in the old system.

PHASE 7 Hazard analysis

- ☞ GMP+ B1,
 - § 7.4.1 Identification of hazards
 - § 7.4.2 Risk assessment

- ☞ GMP+ B2, B3 & B4
 - § 6.4.1 Hazard identification
 - § 6.4.2 Risk assessment

The hazard analysis consists of 2 components, the hazard identification (possible hazards) and risk assessment (from possible hazard to realistic risk). Phase 7.1 further specifies hazard identification and phase 7.2 further explains risk assessment.

Phase 7.1 Hazard identification

Based on the information collected until this moment (during phases 2 through 6) and the process diagrams, a list is prepared of the hazards that may realistically be expected in each phase of the process. This activity is referred to as hazard identification and forms part of the hazard analysis.

The HACCP team determines the hazards for each process phase as comprehensively as possible. Where necessary it is recommended to deploy external experts in these brainstorm sessions in order to preclude incompleteness, as external people will notice things overlooked by those working in a company every day.

Identified hazards are to be described. When defining the hazard, a brief description of the cause and/or source/root cause of the hazard can be included. This makes determining subsequent control measures simpler (see phase 8).

A **hazard** can be described as a contamination of animal feed, or a condition leading to contamination of animal feed, with possible negative implications for human or animal health.

Three types of hazard can be discerned:

Type of hazard	Description	Examples
Chemical hazards	<p>Undesirable chemical substances that may render the product unsafe for consumption. These may be present in the ingredients or contaminate the product during production, for example due to carry-over.</p> <p>Higher concentrations of desirable substances may also form a hazard, making the product unsafe for consumption.</p>	<p>Undesirable Substances and Products: Residues of pesticides, hormones, antibiotics, heavy metals, environmental pollution, mycotoxins, PCB's, dioxins, cleaning agents, lubricants, mineral oils etc.</p> <p>Residues of additives and veterinary drugs</p> <p>Auxiliary production substances</p>

Type of hazard	Description	Examples
		Biological degradation products Criteria for fat fraction Minerals and acid residues

Type of hazard	Description	Examples
Microbiological hazards	Pertaining to presence of undesirable micro-organisms. The micro-organisms may cause contamination or growth due to their (natural) presence, making a product unsafe for consumption. Consumption of the product may in such cases cause food infections or food poisoning. We can distinguish vegetative micro-organisms, toxigenous (toxin-forming) micro-organisms and spore-forming micro-organisms.	Veterinary risks (animal diseases) Pathogenous organisms: Salmonella, Enterobacteriaceae and fungi (the latter group as indicator organisms).

Type of hazard	Description	Examples
Physical hazards	Foreign bodies that may be present in ingredients or may enter the product. This makes the product unsafe for the animal.	Glass, plastic, metal parts, stones, bone, pieces of packaging



The hazard should be described in as much detail as possible. In the case of pathogens, the description should indicate if it concerns for example salmonella or listeria. In the case of contamination with foreign particles, the description should indicate if it concerns glass, plastic or metal for example. These details are also required for any chemical contaminants.

This detailed description is desirable because various possibilities for monitoring and control may be required. For example, metal may be separated by means of magnets, but this control measure would be ineffective for glass. This is why general terms such as 'foreign bodies' cannot be used.

As mentioned above, the information resulting from phases 2 through 6 (finished product and ingredients specifications including intended use and process information, a list of possible hazards must be prepared.



Generic risk assessments such as those recorded in the Feed Safety Database Risk Assessments may be used as a source of information. These generic risk assessments describe any generic hazards per process phase. However, each company should review which (additional) hazards would apply to their specific situation.

Other sources of information are the GMP+ International quality series with details on various subjects, including a study into drying processes within the animal feed sector. These information sources may be consulted on the website of GMP+ International, www.gmpplus.org



The hazards as identified must be recorded per process phase, using the hazard analysis table. For an example of such a table, see Appendix 1 of this guideline.

Phase 7.2 Risk assessment

Subsequently, the HACCP team should determine which possible hazards as defined under 7.1 are actually a risk - this is risk assessment. The term risk is defined by two elements: severity and likely occurrence of a potential hazard. The hazard must be of such a nature that eliminating or reducing to an acceptable level is essential for manufacturing safe animal feed (severity and which realistically could be expected to occur (likely occurrence)).

Severity is the effect on the target animal's health as well as the consequential damage for humans when products of animal origin are consumed. Severity must be based on literature, practical experience and/or experimental data etc., and is classified into three levels:

Severity	Explanation
High	<i>Serious</i> diseases, harmful effects and/or wounds, both occurring immediately and long-term effects, possibly with fatal consequences.
Medium	<i>Substantial</i> diseases, harmful effects and/or wounds, both occurring immediately and long-term effects.
Low	<i>Minor</i> diseases, harmful effects and/or wounds, not or hardly occurring, or only long-term effects after extremely high doses.

Both the severity for the target animal as the severity (consequential damage) for humans must be determined. The highest value is leading.



The Fact Sheets undesirable substances and products may be used as a source of information. These can be consulted on the website of GMP+ International, www.gmpplus.org

Likely occurrence is the chance of a hazard being present in the finished product at the time of consumption by the target animal and/or human. Likely occurrence is based on measurements, observations or expectations of the company specific situation and may be classified in three levels:

Likely occurrence	Explanation
Low	theoretically possible, but hardly occurs in practice
Medium	may occur, it has been known to occur with some frequency
High	occurs frequently

Severity x Likely occurrence results in Risk, which may be classified in four levels:

		Likely occurrence of presence in product		
		Low	Medium	High
Severity of the hazard	High	3	4	4
	Medium	2	3	4
	Low	1	2	3

A company can ensure that likely occurrence of risk is reduced and controlled by taking (control) measures. The next section provides more information about this.

If the risk assessment of the hazard results in 4, it does not involve a critical control point (CCP). This determination will be made during the next phase in HACCP analysis. This serves to determine if a risk actually concerns a CCP. However, the company must realise that action is required for higher risks.



Risk assessment must be recorded for each process phase, including a brief motivation of the elements probability and seriousness. This motivation serves to clarify the choice that the HACCP team made using the hazard analysis table. For an example of such a table, see Appendix 1 of this guideline.

PHASE 8 Determining critical control points (CCP's)

- ☞ GMP+ B1,
§ 7.5 Establishment of Critical Control Points
- ☞ GMP+ B2, B3 & B4
§ 6.5 Establishing control measures and Critical Control Points

Phase 8.1 Determining control measure

After determining the risk category, the HACCP team must determine which measures are required at which part of the manufacturing process in order to control these risks, i.e. prevention or reduction to an acceptable level. These measures are called control measures.

Classification into risk categories determines the control measures to be implemented. The following may be discerned:

Risk category	Control measures
1	No control measures required
2	No control measures required, but conclusion must be re-assessed periodically during the annual verification audit.
3	Control measures required In general, control by means of general control measures from the prerequisite programme will suffice.
4	Specific control measures are required, specifically developed in order to control risk.

Control measures may vary from technical / technological solutions to organisational and/or procedural measures.



Various control measures may be required in order to control a single determined risk. It is also possible for a single control measure to control various risks.

Phase 8.2 Determining critical control points (CCP's)

Subsequently, for each risk and associated control measure, the HACCP team must assess if this control measure is to be the last measure in the process for controlling the risk. If yes, that point in the process is a **critical control point (CCP)**.

The assessment if a control measure relates to a critical control point should take place systematically. One of the instruments to be used is the CCP decision tree. Each phase in the manufacturing process with associated risk and control measure must be run through the CCP decision tree.

CCP decision tree animal feed sector

<p>Question 1 What type of control measure (phase 8.1) is required according to the risk assessment (phase 7.2)? ↓ ↓ ↓ ↓ ↓ ↓</p>	<p>→ 1 → 2 → 3</p>	<p>None None General control measure ↓ Are the relevant general control measures present and have these been implemented? ↓ If required, prepare and include in validation and verification procedures (Phase 12)*</p>
<p>4 specific control measure ↓</p>		
<p>Question 2 Are the relevant specific control measures present and have these been implemented?</p>	<p>→ NO</p>	<p>Stop production and change the process or product and start again with question1.</p>
<p>↓ YES ↓</p>		
<p>Question 3 Is this control measure specifically intended for eliminating this risk or reducing it to an acceptable level during this process phase?</p>	<p>→ YES</p>	<p>→ CCP</p>
<p>↓ NO ↓</p>		
<p>Question 4 Will the risk be eliminated or reduced to an acceptable during one of the subsequent process phases?</p>	<p>→ NO</p>	<p>→ CCP</p>
<p>↓ YES ↓</p>		
<p>No CCP → include in validation and verification procedures (Phase 12)</p>		
<p>* continue with next risk</p>		

Control measures related to critical control points (CCP's) are classed as Specific Control Measures. **Specific control measures** may relate to (process) parameters that can be controlled in such a manner that hazards relating to feed and food safety are prevented, eliminated or reduced to an acceptable, for example time, temperature, humidity and pH.

Specific control measures must be supported by instructions or specifications, training and education. Control measures must be monitored (see phase 10), accompanied by corrective measures (see phase 11) and the control measures must be validated and verified (phase 12). These obligations will be described in detail in the following phases.

Control measures not related to critical control points (CCP's) are classed as General Control Measures. **General control measures** are actions or activities that are often part of the prerequisite programme, such as training of personnel, lay-out and interior of the company premises, pest control and cleaning programmes, purchasing etc. In general, these general control measures ensure an acceptable control level.

General control measures must be validated in order to demonstrate adequate performance of the prerequisite programme (see step 12.1). The general control measures are approved after validation by the HACCP team.

The effectiveness of controlling the identified hazard by means of general control measures must be verified (see phase 12.2) by means of planned regular intervals.



Determining a critical control point (CCP) must be recorded. The hazard analysis table may be used for this purpose. For an example of such a table, see Appendix 1 of this guideline.

PHASE 9 Determining standards for CCP's (action and rejection limits)

- ☞ GMP+ B1,
§ 7.6 Standards
- ☞ GMP+ B2, B3 & B4
§ 6.6 Establishing critical limits
- ☞ GMP+ BA1 *Product standards*

Based on the decision tree, the critical control points (CCP's) within the process have been determined. This concerns the (process) parameters (for example time and temperature) that can be controlled to such an extent that risks are prevented, eliminated or reduced to an acceptable level.

During this phase, the measuring values for these CCP's where safe product can be delivered must be determined. Within the GMP+ FSA scheme, these values are referred to as the rejection limits. A **rejection limit** is a value indicating the line between acceptable and non-acceptable product. If this limit is exceeded, the product is not suitable for use as animal feed.

In order to limit the presence of risks as much as possible and prevent rejection of product, an action limit must also be determined. An **action limit** for the relevant product or process parameter is derived from the rejection limit and must be substantially lower. When this limit is exceeded, the cause must be found and corrective measures must be implemented in order to either resolve or limit the cause.

When determining the action and rejection limits relating to CCP's, it is mandatory to comply with requirements as set out in the relevant animal feed legislation and the GMP+ FSA scheme. In GMP+ BA1 *Product Standards* of the GMP+ FSA scheme, these action and rejection limits are included in an overview.

If action or rejection limits are not set out in legislation or the GMP+ FSA scheme, the standards relating to the CCP's must be set, supported and recorded based on internal research.



See Appendix 2 for an example of a summary overview of a CCP.

PHASE 10 Monitoring CCP's

- ☞ GMP+ B1,
§ 7.7 Monitoring and measuring
- ☞ GMP+ B2, B3 & B4
§ 6.7 Monitoring
- ☞ GMP+ BA4 *Minimum requirements for sampling and analysis*

The animal feed company must prepare and implement a monitoring plan. Monitoring is measuring, analysing and/or observing (visual supervision) of process parameters according to a plan in order to be able to determine if a CCP is controlled.

Monitoring CCP's may relate to continuous, semi-continuous or random sample measuring, depending on the process phase and the nature of the (process) parameter to be measured.

The results of monitoring must be documented.



See Appendix 2 for an example of a summary overview of a CCP.

PHASE 11 Determining / recording corrective measures relating to CCP

☞ GMP+ B1,
§ 7.8 Corrective actions

☞ GMP+ B2, B3 & B4
§ 6.8 Corrective actions

After determining the action and rejection limits and preparing a monitoring programme, the company must determine which corrective actions must be carried out when a rejection limit is exceeded in spite of the measures. The safety of the finished product is then no longer controlled.

In the absence of continuous monitoring, corrective action must relate to the relevant lot from the previous measuring moment.

The GMP+ FSA scheme includes the permissible corrective actions, discerning between corrective actions to be taken internally (within the company in order to prevent delivery of the relevant product) and corrective actions to be taken externally, including product recall.

Such corrective measures must include the following:

- a Designating the person(s) responsible for carrying out the corrective action;
- b A description of the instruments and action in order to adjust/resolve the detected deviation;
- c The actions that must be taken relating to products manufactured during the period where the situation was not controlled;
- d A documented registration of the action taken, such as: Date, time, type of action, person involved and the subsequent inspection.

PHASE 12 Validation and verification of the HACCP system

Before being implemented, the HACCP system must be assessed in order to ensure it can perform as intended. This is referred to as validation. This is phase 12.1. Subsequently, the HACCP system is implemented, whereupon the company must verify if it works as intended within the operational environment. This is phase 12-2.

Phase 12.1 Validation of the HACCP system

☞ GMP+ B1,
§ 7.9 Validation of the HACCP plan

☞ GMP+ B2, B3 & B4
§ 6.9.1 Validation

Before implementing the HACCP system, the company must determine if the HACCP system can perform in the operating environment. The company must determine if the control measures developed, including the cleaning programmes or the metal detectors present will be adequate for controlling hazards. This is referred to as validation.

The following aspects must be assessed:

- a is the list of potential hazards based on sound scientific data and is it complete;
- b were the questions asked in order to test the impact of the risks answered based on sound scientific data and technical knowledge;
- c are the control measures (both general and specific) sufficient to control the hazards;
- d will fluctuations within the features to be controlled (equivalent to process criteria) within the recorded critical limit values have no impact on product safety;
- e are the features and methods used in order to monitor the control measures adequate;
- f are corrective measures adequate and will these prevent an unsafe product from being released and do these demonstrate that the situation may be corrected immediately;

Each time the organisation implements changes that may have a negative impact on feed safety, the assessment must be updated. Examples of changes are:

- a new ingredients or new products, the production conditions (company spaces and buildings and the immediate surroundings of the company, cleaning programmes);
- b storage or transport conditions;
- c changes to the customer's use of the product;
- d all information indicating a new hazard relating to the product.

The validation must be conducted by the validation team. More information is included in phase 1 Forming the HACCP team and validation team.

Phase 12.2 Verification of the HACCP system

☞ GMP+ B1,
§ 7.7 Monitoring and measuring
§ 8.2 Internal audit
§ 8.3 Verification of the feed safety system
§ 8.4 Improvement

☞ GMP+ B2, B3 & B4
§ 6.9.2 Verification

After the HACCP system has been set up, verification of (elements of) the system must periodically (at least annually) take place. Verification is the use of additional information in order to test if the system is still effective and used as it was intended. Verification is conducted by the HACCP team and the findings must be recorded in writing.

Verification of (elements of) a HACCP system must consist of:

- a Evaluation of the HACCP system and the recorded registrations.
This includes testing all specific control measures, deviations and corrective measures in order to confirm implementation and effective control of critical control points (CCP's).
Testing all general control measures in order to confirm implementation and demonstrating effective control of related hazards.
- b Assessment of the prerequisite programme.
The HACCP team must review if the prerequisite programme as prepared still matches the actual situation.
- c Assessment of product analysis data.
Periodical testing of finished products on microbiological and chemical features is a way to check if the HACCP system still works as intended. The finished product specification must be used. If analysis results do not comply with finished product specifications, corrective measures must be taken.
- d Verification of the hazard analysis.
The process diagrams, floor plan and hazard analysis specific to the company must be reviewed as often as required. This enables the company to ensure if these still match reality and if any new or additional hazards may occur pertaining to ingredients or the production process. The HACCP team shall record how frequent such a revision should be conducted, but must at least be reviewed once per year and immediately after new relevant information is available.
This revision is relevant when:
 1. a crisis / calamity has occurred or is suspected;
 2. a report is issued by the Early Warning System;
 3. news in the media is released;
 4. hazard analyses are updated at chain level;
 5. other indications arise (own sampling, databases);
 6. changes are made to the production process.

It is possible that hazards remain denied or undetected for years. At the time where a company has gained insight into the potential hazard, it must immediately be included in the company specific HACCP plan. Not only external factors - also results of internal sampling of ingredients, finished products and/or results from databases can provide input to re-assess and, if necessary, revise, the internal hazard analysis.

- e Assessing implementation of legislation and regulations
The HACCP team must review if all actions are still in accordance with the applicable legislation and regulations relating to food and feed safety. The HACCP team must also continuously remain up to date with any changes to legislation and regulations, including: if there are any changes to the legal or GMP+ standards.
More information is included in chapter 3 of this guideline.
- f Assessment of personnel's knowledge level
The HACCP team must assess if the current personnel knowledge level relating to feed and food safety and hygiene still comes up to required standards. If not, training is required.
- g Internal audits
A large number of hazards are controlled by general procedures, regulations and instructions. These procedures and instructions define many elements of the prerequisite programme. An audit also aims to check compliance with procedures and instructions. In particular verification of the prerequisite programme, which covers a large number of general hazards, is vital for the system's performance.
- h Analysis of complaints relating to food and feed safety of products.
Processing complaints within a HACCP system also provides information relating to the HACCP system's effectiveness.

The results of verification must be documented. The HACCP team, which will continue to play a role in maintenance of the system, must assess the verification results and submit its findings to the management. The management shall use their findings in its own management assessment as described in chapter 4.1.5.

PHASE 13 Documentation and registrations

☞ GMP+ B1,
§ 4.2 Documentation

☞ GMP+ B2, B3 & B4
§ 4.4 Documentation and registration

All other sections of the GMP+ FSA scheme also indicate the required documentation.

Documentation plays a vital part in maintaining a process control system based on HACCP principles. Documentation ensures the demonstrable presence of the HACCP system. Documents also provide information to employees regarding the activities to be carried out and agreements made within a company. The required documentation derived from the implementation of HACCP can be included in the quality documentation as required by the GMP+ standard.

Documents that must be present based on HACCP:

- a Document HACCP team (members and fields of expertise)
- b Motivation of HACCP analyses with support of choices made, for example:
Minutes of the HACCP team meetings
- c Finished product specifications or finished product group specifications;
- d Process diagrams and a floor plan
- e Prerequisite programme as applied by the company
- f Hazard analyses (tables)
- g Determination and description of CCP's (in a table or overview and where required supplemented by documentation)
- h Determining action and rejection limits
- i Corrective measures
- j Description of validation and verification of the HACCP system

Registration

After implementation of the HACCP system, data are collected in various places that must be registered. This concerns:

- a Monitoring data of CCP's and general control measures
- b Verification of CCP's
- c Verification of the HACCP system by means of taking samples and sample analysis of products
- d Verification of the hazard analysis
- e Internal audits
- f Complaints analysis

Appendix 2 Summary overview of CCP's and general control measures

As is apparent from phases 9 through 10 of the phase plan, action and rejection limits, monitoring programmes and corrective actions must be prepared for each CCP. In order to enhance clarity, this information can be entered in an overview for each CCP. This table may also contain a reference to the required procedures, instructions and registration forms (documentation).

From the hazard analysis, it has become apparent that many general control measures (which are often part of the prerequisite programme) play an essential role in reducing the hazard. It is recommended to summarise these control measures in a table as well. Where possible, indicate monitoring frequency and corrective actions (this depends on the general control measure and will not be possible in all cases). Also report the required procedures, instructions, registration forms and other documents.

 Reference to the GMP+ Feed Safety Assurance Scheme (process control)

Example of overview

CCP	Description of the control measure	Standards		Monitoring			Corrective actions after deviations		Documentation
		Action limit	Rejection limit	How	Frequency	Responsible	Description of action	Responsible	
CCP 1			P						