Support

S9.4 - Applying HACCP assessment

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GMP+ International

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Index

1. Introduction

1.1. Structure HACCP Guideline

The HACCP guideline is intended to support GMP+ FSA certified companies (or companies who which to) 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 in-sights (as ISO22000), some changes and additions were included in the HACCP requirements.

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

Since the year 2000, the feed sector has taken the initiative of including the HACCP system in the GMP+ Feed Safety Assurance module.

The scope of this guideline is to support in feed and food safety assurance. This guide-line is intended specifically for the management and employees of companies within the feed sector developing a company specific HACCP system. The manner in which HACCP is described in current 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.

For definitions and terminology please check F 0.2 *Definition list*.

Chapter 24 contains a further explanation of the requirements within the management's scope of responsibility. Chapter 3 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 module have been included as much as possible.

Every step of the HACCP process starts with an overview of which paragraphs in the normative documents are applicable. Within the document the wording 'must' is used, this refers to the HACCP principles that must be followed as described in the normative document.

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

2. HACCP system requirements

In order to successful implement a HACCP system, a fundament must be created to fully support the involved employees. This support falls under the responsibility of top management. This includes defining quality policy, defining the scope of the HACCP system, determining tasks, responsibilities and authority, making resources available and management assessment.

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 feed safety. The management is responsible for defining the quality policy by means of practicable objectives and communicating these to the employees.

The scope and extent of the HACCP system should be indicated. Scope relates to the activities that the company is responsible or accountable for. This can or will be broader than the scope of the GMP+ certificate because also non-feed related activities, processes, products or services, can have a negative impact on the feed safety and should be managed by the HACCP system (R1.0 & 4.3).

Management should review requests of the Feed Safety Team(s) relating to resources and facilities required for the creation, implementation and maintenance of the HACCP system and make these resources available. 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.

When the entire HACCP system has been developed and implemented, the management must ensure that the HACCP system is updated and revised if necessary.

For more information on top management responsibilities can be found in the document R 1.0 Feed Safety Management Systems Requirements.

2.1. Management responsibilities

Relating to feed safety, a number of requirements fall directly within the scope of management responsibility.

2.1.1. 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.

R 1.0 *Feed Safety Management Systems Requirements*

2.1.2. Defining the scope of the HACCP system

R 1.0 *Feed Safety Management Systems Requirements*
§ 5.2. Feed safety policy

2.1.3. 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.

R 1.0 *Feed Safety Management Systems Requirements*
§ 5.3.1 Top management's Responsibilities and Authorities
§ 5.3.2 Responsibilities of the Feed Safety Team Leader
§ 5.3.3 Responsibilities of the Validation Team
§ 5.3.4 Responsibilities of all persons involved

2.1.4. Making resources available

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.

R 1.0 *Feed Safety Management Systems Requirements*
§ 7.1. Resources

2.1.5. Management assessment of the HACCP system

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.

R 1.0 *Feed Safety Management Systems Requirements*

3. HACCP Based 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 based plan		
Phase 1		Forming multi-disciplinary Feed Safety Team(s) and Validation Team(s)
Phase 2		Description of feed
Phase 3		Determining the intended use of feed
Phase 4		Determine process information
Phase 5		Testing process information
Phase 6		Define prerequisite programme
Phase 7	Principle 1	Hazard analysis
Phase 8	Principle 2	Determining critical control points (CCP's)
Phase 9	Principle 3	Determining feed safety limits for CCP's
Phase 10	Principle 4	Monitoring CCP's
Phase 11	Principle 5	Determining corrections and corrective actions
Phase 12	Principle 6	Validation and verification
Phase 13	Principle 7	Documentation and registration

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

3.1. Phase 1: Forming multi-disciplinary Feed Safety Team(s) and Validation Team(s)

R 1.0 *Feed Safety Management Systems Requirements*
§ 5.3.1 Top management's Responsibilities and Authorities
§ 5.3.2. Responsibilities of the Feed Safety Team leader
§ 5.3.3 Responsibilities of the Validation Team

As described in the standards, the management of the company is ultimately responsible for the Feed Safety Management System of the company. Management must appoint Feed Safety Team(s) and Validation Team(s). The management shall ensure that members of both the Feed Safety and validation Teams will have adequate time and (if necessary) resources available for setting up and implementing, respectively validating, the Feed safety Management System including the HACCP system.

The Feed Safety Team is a team within the organisation that supervises setting up and implementation of the HACCP system. In addition to implementation, the Feed Safety Team is designated a role in updating 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 Feed Safety 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 Feed Safety 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 feed and food chemistry, toxicology, 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.

Helpful tip :
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 Feed Safety and/or Vali-dation 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 end-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 Feed Safety 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 Feed Safety Team in order to prevent influence: Select employees not directly involved in preparing the HACCP plan.

Helpful tip :
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 Feed Safe-ty Team must attend HACCP training or the team members must have attained a simi-lar level based on experience.

According to the standard, the company must record the members of both the Feed Safety 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.

3.2. Phase 2: Description of feed

3.2.1. Phase 2.1: Description of the end-product in characteristics of end-products

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.5.1.2 Characteristics of end-products

TS 1.2 Purchase
TS 1.3 Product list
TS 1.4 Forbidden Products and Fuels
TS 1.5 Specific feed safety limits

Information regarding end-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 end products (the feed) may entail to humans or animals. The HACP Feed Safety Team shall chart this information based on characteristics of end-products of

Characteristics of end-products provide an initial indication of possible hazards. In addition to the ingredients used (raw materials, additives) and nutritional values of the end 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 feed safety limits from TS 1.5 must be taken into account and included in the specification. The characteristics of the end-products must be considered by the Feed Safety Team when setting up and implementing the company-specific HACCP system.

In principle, each end-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.

Characteristics of end-products can be prepared based on a so-called three- category system.

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

3.2.2. Phase 2.2: Description of ingredients and processing aids

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.5.1.1 Characteristics of ingredients

TS 1.2 Purchase
TS 1.3 Product list
TS 1.4 Forbidden Products and Fuels
TS 1.5 Specific feed safety limits

The requirements that apply to the end-product (for example feed safety limits of contaminants) are partially determined by the ingredients and processing aids used. This includes feed materials, premixes, additives and processing aids. Inspection of ingredients and processing aids based on specifications is necessary.

The information relating to the ingredients and processing aids, 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).

3.3. Phase 3: Determining the intended use of feed

R 1.0 *Feed Safety Management Systems Requirements*
§ 7.4.2 External communication
§ 7.4.3 Internal Communication
§ 8.5.1.3 Intended use

TS 1.8 Labelling

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 characteristics of the end-product serve to record the target species of the feed. Not all feed 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 characteristics of the end-product 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 Feed Safety Team shall review how the feed is to be stored and used as in-tended without any hazards to animal or public health occurring.

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

3.4. Phase 4: Determine process information

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

3.4.1. Phase 4.1: Preparing flow diagrams

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.5.1.4 Flow diagrams and description of Processes
§ 8.5.1.4.1 Preparing flow diagrams

The Feed Safety Team shall prepare a flow diagram of the production process for each product (or product group). These flow diagrams must indicate the process phases to be followed in order to create a certain end -product. The process diagram should also indicate the ingredients, processing aids and auxiliary substances used and any by-products created by the process.

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

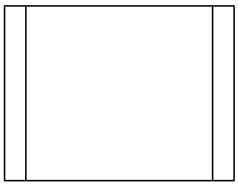
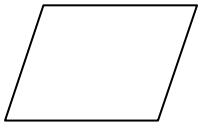
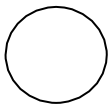
When preparing the flow diagrams, the following are key issues.

a. select a end-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 end-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, processing aids, auxiliary substances, semi-finished products, by-products, end-products, return flows and waste flows

A flow 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.

3.4.1.1. Symbols

Using the following symbols when preparing flow diagrams is recommended.

Symbol	Explanation
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-end product or end 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 risk assessments as part of the Feed Support Products on the website of GMP+ International.

3.4.2. Phase 4.2: Preparing a floor plan

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.5.1.4 Flow diagrams and description of Processes
§ 8.5.1.4.2 Preparing a floor plan

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

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

a. The various company units (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 feed and ingredients through the company, of waste and of personnel in order to make any cross-contamination points visible.

3.5. Phase 5: Testing process information

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.5.1.4.3 On-site conformation of Flow diagrams and Floor plan

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After preparing process information (flow diagram and floor plan), these must be tested against practice by the Feed Safety Team.

This 'reality check' entails for the Feed Safety 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 flow 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 flows 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 retested to practice and re-validated (see phase 12). The changes must also be implemented in the flow 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.

3.6. Phase 6: Define prerequisite programme

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.2 Prerequisite programmes (PRPs)

TS 1.1 Prerequisite programme

A minimum level for controlling 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 feed. The prerequisite programme is part of the GMP+ FSA module.

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

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

The GMP+ certified company must check which elements in the prerequisite programme are applicable to the company.

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

3.7. Phase 7: Hazard analysis

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.5.2 Hazard analysis
§ 8.5.2.1 Hazard identification
§ 8.5.2.2 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.

3.7.1. Phase 7.1: Hazard identification

Based on the information collected until this moment (during phases 2 through 6) and the flow 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 Feed Safety 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 deter-mining subsequent control measures simpler (see phase 8).

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

Type of hazard	Description	Examples
Chemical hazards	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. Higher concentrations of desirable substances may also form a hazard, making the product unsafe for consumption.	Undesirable Substances and Products: Residues of pesticides, hormones, antibiotics, heavy metals, environ-mental pollution, mycotoxins, PCB's, dioxins, cleaning agents, lubricants, mineral oils etc. Residues of additives and veterinary medicinal products Processing aids
		Biological degradation products Criteria for fat fraction Minerals and acid residues
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).
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

Helpful tip 1:
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 (end-product and ingredients specifications including intended use and process information, a list of possible hazards must be prepared.

Helpful tip 2:
Generic risk assessments such as those recorded in the Feed Support Products 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 feed sector. These information sources may be consulted on the website of GMP+ International.

Helpful tip 3:
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.

3.7.2. Phase 7.2: Risk assessment

Subsequently, the Feed Safety Team should determine which possible hazards as defined under 7.1 are actually a risk. The term risk is defined by two elements: severity and likely occurence 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 feed (severity and which realistically could be expected to occur (likely occurence).

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	*Serious* diseases, harmful effects and/or wounds, both occurring immediately and long-term effects, possibly with fatal consequences.
Medium	*Substantial* diseases, harmful effects and/or wounds, both occurring immediately and long-term effects.
Low	*Minor* 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.

Helpful tip 1:

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.

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

Likely occurence	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 oocurence results in Risk, which may be classified in four levels:

		Likely occurence 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.

Helpful tip 2:

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 Feed Safety Team made using the hazard analysis table. For an example of such a table, see Appendix 1 of this guideline.

3.8. Phase 8: Determining critical control points (CCP's)

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.5.2.3 Establishing Critical Control Points (CCPs)

3.8.1. Phase 8.1: Determining control measure

After determining the risk category, the Feed Safety 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.

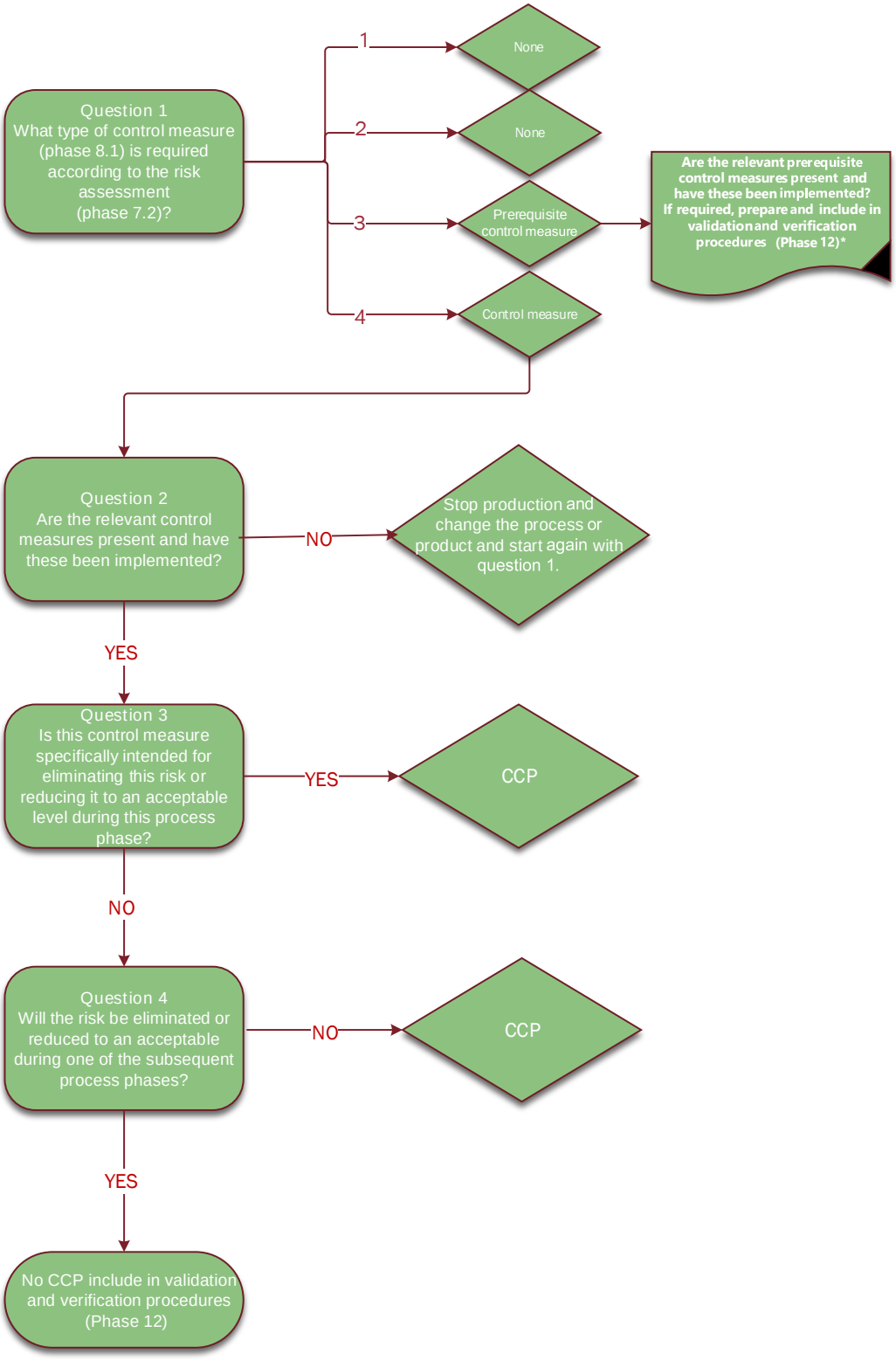
Control measures may vary from technical / technological solutions to organisational and/or procedural measures.

Helpful tip :
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.

3.8.2. Phase 8.2: Establishing critical control points (CCP's)

Subsequently, for each risk and associated control measure, the Feed Safety 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.



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

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 Prerequisite control measures. **Prerequisite 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 and sanitising programmes, purchasing, etc. In general, these prerequisite control measures ensure and acceptable control level.

Prerequisite control measures must be validated in order to demonstrate adequate performance of the prerequisite programme (see step 12.1). The prerequisite control measures are approved after validation by the Feed Safety Team.

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

Helpful tip :
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.

3.9. Phase 9: Determining feed safety limits for CCP's

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.5.3 CCP control
§ 8.5.3.1 Determine feed safety limits for CCPs

TS 1.5 Specific feed safety limits

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 module, 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 feed.

In order to limit the presence of risks as much as possible and prevent rejection of product, an action limit can 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 feed legislation and the GMP+ FSA scheme. In TS 1.5 Specific feed safety limits)-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 feed safety limits relating to the CCP's must be set, supported and recorded based on internal research.

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

3.10. Phase 10: Monitoring CCPs

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.5.3 CCP control
§ 8.5.3.2 Monitoring CCPs

TS 1.2 Purchase
TS 1.6 Sampling
TS 1.7 Monitoring

The 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.

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

3.11. Phase 11: Determining / corrections and corrective actions

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.7 Control of Product and Process nonconformities
§ 8.7.1 Define corrections and Corrective actions
§ 8.7.2 Handling of potentially unsafe products

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

Corrections
Corrections are actions to eliminate a detected nonconformity. A correction may be, for example, reprocessing, further processing and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling).

Corrective actions
Corrective actions: *eliminates the cause of a non conformity and prevents recurrence*. These actions ensures that the cause of the nonconformity is detected and eliminated and can therefor not result again in an exceeded limit. Corrective actions can be, for example, adjustments to equipment, adjusting the production process and/or choosing different suppliers or country of origin of feed ingredients.

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

3.12. Phase 12: Validation and verification

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.

3.12.1. Phase 12.1: Validation of the HACCP system

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.6 Validation & Verification
§ 8.6.1 Validation
§ 8.6.2 Verification

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 units 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 Feed Safety Team and Validation Team.

3.12.2. Phase 12.2: Verification of the HACCP system

R 1.0 *Feed Safety Management Systems Requirements*
§ 8.6 Validation & Verification
§ 8.6.1 Validation
§ 8.6.2 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 in- tended. Verification is conducted by the Feed Safety 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 Feed Safety Team must review if the prerequisite programme as prepared still matches the actual situation.

c. Assessment of product analysis data.
Periodical testing of end -products on microbiological and chemical features is a way to check if the HACCP system still works as intended. The end product specification must be used. If analysis results do not comply with end- product specifications, corrective measures must be taken.

d. Verification of the hazard analysis.
The flow 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 Feed Safety Team shall record how frequent such a revision should be conducted, but must at least be re-
viewed once per year and immediately after new relevant information is avail- able.

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, end- 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 Feed Safety Team must review if all actions are still in accordance with the applicable legislation and regulations relating to food and feed safety. The Feed Safety 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 Feed Safety 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 Feed Safety 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.

3.13. Phase 13: Documentation and registrations

R 1.0 *Feed Safety Management Systems Requirements*
§ 7.5 Documented information

All other sections of the scheme can also indicate the required documented information

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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.

The following documents can be considered as relevant document information related to the HACCP system:

a. Document Feed Safety Team (members and fields of expertise)
b. Motivation of HACCP analyses with support of choices made, for example:
   Minutes of the Feed Safety Team meetings
c. End- product specifications or end-product group specifications;
d. Flow 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 1 Completing the hazard analysis table

When identifying hazards in each process phase and walking through the CCP decision tree, the hazard analysis table can be completed line by line. This also ensures that the HACCP analysis has been demonstrably conducted (with documented evidence).

Please Note: The template below also applies to the company specific HACCP analysis. A different template should be used for completing the hazard analysis in the context of the Risk Assessments as part of the Feed Support Products.

The hazards are identified for each process step in the flow diagram (phase 7) and entered into the hazard analysis table. The columns Nr, Process phase and Description of Hazard are to be completed in the table line by line.			For each hazard, indicate in which of the three categories the hazard is classified (M: Microbiological, C Chemical, P Physical).	A risk assessment is conducted for each hazard. Probability x seriousness and the resultant risk class are entered into the relevant columns.			The (control) measures for risk class 3 or 4 are summarised in this column. This may concern measures that are part of the prerequisite programme or measures included elsewhere in the GMP+ FC Scheme.		Is the determined control measure the last step in the process to control the risk? This assessment must 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. This column must be completed if it concerns a CCP. (The questions below relate to the decision tree)					This column should always contain a summary motivation of the elements Likelyhood x severity. This motivation serves to clarify the choice that the HACCP made. Additionally, this information may be used for subsequent verifications and also by later Feed Safety Team after their composition has changed. This way, the considerations remain accessible and available.
Nr.	Process phase	Description of hazard	Cat.	Likelyhood of occurence	Severity	Risk	Type of measure	Reference	Q1	Q2	Q3	Q4	CCP	Motivation
1	Purchasing		C	1	2	2			2	-	-	-	-	
			M P	2	3	4			4	Y	N	N	CCP 1	

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						

At GMP+ International, we believe everybody, no matter who they are or where they live, should have access to safe food.

GMP+ International
Braillelaan 9
2289 CL Rijswijk
The Netherlands
t. +31 (0)70 – 307 41 20 (Office)
+31 (0)70 – 307 41 44 (Help Desk)
e. info@gmpplus.org