



THE QUALITY AND SAFETY SYSTEM
FOR SPECIALTY FEED INGREDIENTS

PROCESS
DOCUMENT
PD-02
CHEMICAL

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1. Introduction

The FAMI-QS Process Documents are auditable documents established for each process described in Chapter 2 – Scope - of the FAMI-QS Code of Practice. Such documents include the requirements for the evaluation of the feed safety hazards associated with the Operator's processes with the view of controlling their occurrence.

The Process Documents are required to be used by Operators and Certification Bodies to assure that they operate their programs in a consistent and equivalent manner. Therefore, they have a dual approach: to support the companies under certification to deploy their HACCP system and to support auditors in the assessments of the companies.

2. Definitions

Acceptable level: A level of hazard in a feed at or below which the feed is considered to be safe according to its intended use. (Codex Alimentarius and adapted)

Adequate: The terminologies “adequate”, “where appropriate”, “where necessary”, or “sufficient” mean that it is up to the Operator in first instance to decide whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives stated in this document. In determining whether a requirement is adequate, appropriate, necessary, or sufficient, account should be taken to the nature of the feed and of its intended use. (adopted from EC Guidance Document 2005 on Regulation 852/2004/EC and modified)

Batch: Unit of production from a single site using uniform production parameters or a number of such units, when produced in continuous order and stored together. It consists of an identifiable quantity of feed which is determined to have common characteristics, such as origin, variety, type of packing, packer, consignor or labelling. (COM(2008)124 final and Regulation 767/2009/EC)

Calibration: The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.

Carrier: Substance used to dissolve, dilute, disperse or otherwise physically modify a specialty feed ingredient in order to facilitate its handling, application or use without altering its technological function and without exerting any technological effect itself.

Cleaning: The removal of soil, feed residues, dirt, grease or other objectionable matter. (Codex Alimentarius and adapted)

Check/control:

- when used as a noun: The state wherein correct procedures are being followed and any established criteria are being met.
- when used as a verb: To take all necessary actions to ensure and maintain compliance with established criteria and procedures. (Codex Alimentarius)

Contaminant: Any biological, chemical or physical agent, foreign matter or other substances not intentionally added into or onto a raw material, intermediate, and products covered by FAMI-QS scope during production, sampling, packaging or repackaging, storage or transport, that may compromise feed safety or suitability. (Codex Alimentarius and adapted)

Contamination: The introduction or occurrence of a contaminant in the feed or feed environment. (Codex Alimentarius and adapted)

Control Measure: Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level. (Codex Alimentarius and adapted)

Corrective Action: Any action taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product if any and prevent or minimize reoccurrence of the deviation. (Codex Alimentarius)

Critical Control Point (CCP): A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system. (Codex Alimentarius and adapted)

Critical Limit: A criterion, observable or measurable, relating to a control measure at a CCP which separates acceptability from unacceptability of the feed. (Codex Alimentarius and adapted)

Cross-contamination: Contamination of a material or product with another material or product, including contamination originating from the previous use of equipment. (CAC/GL 81-2013 - Guidance for Governments on Prioritizing Hazards in Feed)

Deviation: Failure to meet a critical limit or to follow a GMP procedure. (Codex Alimentarius and adapted)

Documented Information: Information required to be controlled and maintained by an Operator and the medium on which it is contained. (ISO 9001:2015 and adapted)

Feed¹: Any substance or product, including specialty feed ingredients, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals. (Regulation 178/2002/EC and adapted)

Feed Hygiene: The measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a specialty feed ingredient(s) covered by FAMI-QS scope, taking into account its intended use. (Regulation 183/2005/EC)

Feed Safety: High level of assurance that the feed (feedingstuff, feed material or products covered by FAMI-QS scope) will neither cause adverse health effects to the farm animals when prepared or consumed according to the intended use, nor to the final consumer. Throughout the document, the word 'Safety' is taken to have the same meaning as 'Feed Safety'.

Feed Safety Hazard: Biological, chemical or physical agent in feed, with the potential to cause an adverse health effect in animals and/or humans. (Codex Alimentarius and adapted)

¹ In some jurisdictions the term animal food is also used. In the present document the term feed also refers to animal food and the same definition will apply.

Flow Diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of feed. (Codex Alimentarius and adapted)

Good Manufacturing Practices (GMP): Fundamental measures and conditions applied at any step within the feed chain to provide safe and suitable feed. (Codex Alimentarius and adapted) - Equivalent term: PRP (Pre-requisite Programme) See FAMI-QS Code § 7. Good Manufacturing Practices.

Hazard Analysis and Critical Control Points (HACCP) Plan: Documentation or set of documents, prepared in accordance with the principles of HACCP to ensure control of significant hazards in the feed business. (Codex Alimentarius and adapted)

Hazard Analysis and Critical Control Points (HACCP) System: The development of a HACCP plan and the implementation of the procedures in accordance with that plan.

Hazard Analysis: The process of collecting and evaluating information on hazards identified in raw materials and other ingredients, the environment, in the process or in the feed, and conditions leading to their presence to decide whether or not these are significant hazards. (Codex Alimentarius and adapted)

Labelling: Means the attribution of any words, particulars, trademarks, brand name, pictorial matter or symbol to a feed by placing this information on any medium referring to or accompanying such feed, such as packaging, container, notice, label, document, ring, collar or the Internet, including for advertising purposes. (Regulation 767/2009/EC)

Management System: Set of interrelated or interacting elements of an organisation to establish policies and objectives and processes to achieve those objectives. (ISO 9001:2015)

Manufacture/production: All operations encompassing receipt of materials, processing, packaging, repackaging, labelling, relabelling, quality control, release, storage, and distribution of products covered by FAMI-QS scope and related controls.

Must: Compliance with a requirement which is mandatory for compliance with this standard (obligation to follow the exact requirement as stated by this document).

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control. (Codex Alimentarius)

Operator: The natural or legal persons responsible for ensuring that the requirements of food/feed law are met within the feed business under their control. (Regulation 178/2002/EC and adapted)

Organisation: Group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives. (ISO 9001:2015)

Pre-requisite Programme (PRP): Programmes including Good Hygiene Practices, Good Agricultural Practices and Good Manufacturing Practices, as well as other practices and procedures such as training and traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of a HACCP system. (Codex Alimentarius)

Preventive Action: Action to eliminate the cause of a potential nonconformity or other undesirable potential situation. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence. (ISO 9000:2015)

Procedure: Specified way to carry out an activity or a process. Procedures can be documented or not. (ISO 9000:2015)

Quality: Degree to which a set of inherent characteristics fulfils requirements. (ISO 9000:2005)

Raw Material: Any material which enters the manufacturing process of the products covered by the FAMI-QS scope.

Record: Document stating results achieved or providing evidence of activities performed. (ISO 9000:2015)

Regulatory Requirement: Obligatory requirement specified by an authority mandated by a legislative body. (ISO 9000:2015)

Requirement: Need or expectation that is stated, generally implied or obligatory. (ISO 9000:2015)

Reworking / rework: Action on a nonconforming product to make it conform to the requirements. (ISO 9000:2005)

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard. (Regulation 178/2002/EC)

Safety: See 'feed safety'.

Shelf Life: A defined time period for which a product fully complies with its specification, if stored appropriately.

Should: Means "must" and the activities, descriptions or specifications accompanied by the word "should" are intended to be mandatory, unless the manufacturer is able to demonstrate that the activity, description or specification is inapplicable or can be replaced by an alternative which must be demonstrated to provide at least an equivalent level of quality and safety assurance. (Operators are obligated to achieve the goal of the Process Document by appropriate means).

Site: Area in which animal feed (See 'feed') is handled, together with any immediate surrounding area. (adapted from PAS 222)

Specialty Feed Ingredients: Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed or animals/animal products and animal performance. (Codex Alimentarius and adapted).

Specification: A list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the test described. It establishes the set of criteria to which a material must conform to be considered acceptable for its intended use. 'Compliance to specification' means that the material, when tested according to the listed analytical procedures, meets the listed acceptance criteria.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption. (Codex Alimentarius)

Sufficient: See "Adequate".

Top management: Person or group of people who directs and controls an organisation at the highest level. (ISO 9001:2015)

Traceability: The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed through all stages of production, processing and distribution. (Regulation 178/2002/EC)

Undesirable substances: Any substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for the animal feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production. (Directive 2002/32/EC)

Validation of control measures: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome. (Codex Alimentarius)

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended. (Codex Alimentarius)

Where appropriate: See "Adequate".

3. HACCP SYSTEM

The HACCP System helps an operator to identify and evaluate the feed safety hazards associated with their raw materials, product(s) and processes with the view of controlling their occurrence. The system enables the operator to implement, document, control and verify the effectiveness of the control of significant hazards in the feed business.

The HACCP System is science based, systematic and should be able to accommodate changes in equipment design, process, procedures and technological developments.

The successful implementation of the HACCP System requires the commitment and involvement of management and personnel with knowledge and training in its application. Ongoing training is necessary for all levels of personnel, including managers, as appropriate to the feed business.

3.1. General requirements

The HACCP System needs to identify, evaluate, and control hazards relating to feed safety. Prior to the application of a HACCP System, prerequisite programmes (PRP) must be in place. They must be well implemented, fully operational and verified, where possible. Monitoring and verification records should be maintained, whenever necessary.

It is required for the Operator to have effective Good Manufacturing Practices (GMPs) or PRP's in place to manage the daily tasks of good hygienic practice(s). The GMPs are the backbone of any quality or safety system and without these no feed safety program is likely to be successful.

Documents should specify how GMPs are managed. Documented information about verifications and modifications of the GMPs must be maintained. There is a dedicated chapter for GMPs in the FAMI-QS Code of Practice (Chapter 7) providing requirements with a goal of maintaining feed safety and quality.

3.2. HACCP System

The HACCP System consists of the following 7 principles:

1. Conduct a hazard analysis and identify control measures;
2. Determine the critical control points (CCPs);
3. Establish validated critical limits;
4. Establish a system to monitor control of CCPs;
5. Establish the corrective actions to be taken when monitoring indicates a deviation from a critical limit at a CCP has occurred;
6. Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended;
7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

The implementation of the HACCP System follows a logical sequence of 12 steps, including the above 7 principles.

3.3. Assemble a HACCP team and identify the scope (Step 1)

The Operator must form a multi-disciplinary team with a leader (HACCP team leader). The team will have responsibility for establishing, developing, implementing, maintaining and reviewing the HACCP System. It is vital that this group has the full support of the top management. The team must include people who are very familiar with the raw materials, products, processes and associated hazards.

The HACCP team leader must:

- a) appoint (where possible), manage a HACCP team and organise its work;
- b) ensure relevant training, and periodic retraining of the HACCP team members;
- c) arrange for periodic review of the HACCP plan(s);
- d) report to the top management on the effectiveness of the HACCP programme;
- e) review the corrective actions in case of deviations on the CCP.

Note: The responsibility of the HACCP team leader may include liaison with external parties on matters relating to the Feed Safety and Quality Management system.

The HACCP team must identify the scope of the HACCP System and the associated prerequisite programmes. The scope must describe which products and processes are covered.

3.4. Describe product(s) (Step 2)

Full and detailed information regarding each product is required in order to assess hazards presented by raw materials, ingredients, packaging, process or delivery to the end user. The Operator must consider:

- composition (e.g., raw materials, ingredients, additives, etc.);
- physicochemical characteristics related to feed safety;
- processing;
- packaging;
- storage and/or distribution conditions;

- required shelf life;
- instructions for use;
- any microbiological or chemical criteria applicable;
- regulatory limits already established for hazards.

3.5. Identify the intended use and users of the product (Step 3)

The product description should detail the target groups for which it is intended. It should specify the animal species, the stage in life (if applicable), directions for expected use, storage and shelf life guaranteed and other information required for its use or compliance with relevant requirements.

3.6. Construct a diagram of the process flow (Step 4)

The Operator must draw up a process flow diagram that covers all steps in the production of a specific product. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. This diagram should indicate all steps taken to produce the product and should include details of any applicable rework, by-products, intermediate products, storage, transport etc. One block in the process flow should reflect each step in the process.

The flow diagram should indicate all inputs, including those of ingredients and feed contact materials², water and air, if relevant. Flow diagrams should, as appropriate, include but not be limited to the following:

- the sequence and interaction of the steps in the operation;
- where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;
- any outsourced processes;
- where applicable reworking and recycling take place;
- where end products, intermediate products, waste and by-products are released or removed.

The diagram should, while including the necessary details, be clear with unambiguous terms. For the purpose of this document please refer to §4.2.

3.7. On-site confirmation of the process flow diagram (Step 5)

After the flow chart diagram is drawn up, the Operator must make sure it is accurate by checking it against the actual operating process in its facility. The processing activities must be confirmed against the flow diagram during all stages and hours of the operation and the diagram must be amended where appropriate. The confirmation of the flow diagram must be performed by a person with sufficient knowledge of the processing operation.

² Materials intended to come into contact with feed, or that are already in contact with feed, or can reasonably be expected to come into contact with feed, and that can potentially contaminate feed by transferring substances into it should be considered in the hazard analysis (e.g., toxic paints, hazardous substances that may be present in the composition of the material, etc.)

3.8. Identify, conduct a hazard analysis to identify the significant hazards, analyse the hazards and consider any measures to control identified hazards (Step 6/Principle 1)

The Operator must use the flow diagram to list all potential hazards at each process step (including all inputs – raw materials, vapour, gases, etc – into that step). Hazards must be specific and the reason or source for its presence must be described.

- a) Chemical (including radiological): Pesticides, lubricants, dioxins, heavy metals, cleaning agents, radionuclides, etc.
- b) Biological: Undesirable micro-organisms, parasites etc.
- c) Physical: Foreign bodies such as glass, wood, jewellery, stones, etc.

For example, for Step 1 in the flow diagram of §4.2 of this document, the Operator’s first consideration should always be “How good is the material being supplied to me?”

The Operator must consider the chemical (including radiological), biological and physical hazards associated with each material entering on site. Potential chemical (including radiological), biological and physical hazards must be considered for each step in the process, in each case taking the particular circumstances with regard to the step into account.

The hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which of them are significant.

When conducting a hazard analysis, the following must be considered:

- a) hazards associated with producing or processing the type of feed, including its ingredients and process steps;
- b) the likelihood of occurrence of hazards, taking into consideration prerequisite programs, in the absence of additional control;
- c) the likelihood and severity of adverse health effects associated with the hazards in the feed in the absence of control;
- d) identified acceptable levels of the hazards in the feed e.g., based on regulation, intended use, and scientific information;
- e) the nature of the facility and the equipment used in making the feed product;
- f) survival or multiplication of pathogenic microorganisms;
- g) production or persistence in feed of toxins (e.g., mycotoxins), chemicals (e.g. pesticides) or physical agents (e.g. glass, metal);
- h) the intended use and likelihood of product mishandling by potential consumers that could render the feed unsafe; and,
- i) conditions leading to the above.

Hazards which are such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe feed (because they are reasonably likely to occur in the absence of control and reasonably likely to cause illness or injury if present) should be identified and controlled by measures designed to prevent or eliminate these hazards or reduce them to an acceptable level.

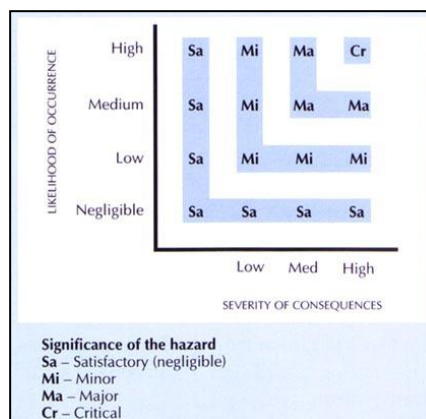
In some cases, this may be achieved with the application of good manufacturing practices. In other instances, control measures will need to be applied within the process, e.g., at critical control points.

A decision matrix that may help the Operator to decide how significant the potential hazard is and how likely it is to occur. It is based on the concept that the significance is the result of the likelihood that a hazard will occur and the severity of the adverse health effect if it occurs.

There are several examples of decision matrices in the literature, and they may be used depending on the experience of the company. There shall be a justification for the matrix used and data/rationale to substantiate the decision.

RISK MATRIX	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare/Remote (1)	1	2	3	4	5

Severity ↓			
Large	3	4	4
Moderate	2	3	4
Small	1	2	3
Likelihood of occurrence →	Small	Moderate	Large



Examples of decision matrixes

3.9. Determine the CCPs (Step 7/Principle 2)

Critical control points are to be determined only for hazards identified as significant based on the result of the hazard analysis.

If a hazard needs a specific control and there is no point further downstream in the process that can reduce it, this

step is a Critical Control Point (CCP). If the correct application of the Operator's prerequisite programs or if a subsequent step eliminates, prevents or reduces the hazard to an acceptable level, then the step in question is not a CCP. Useful questions the Operator can ask themselves when establishing CCPs are:

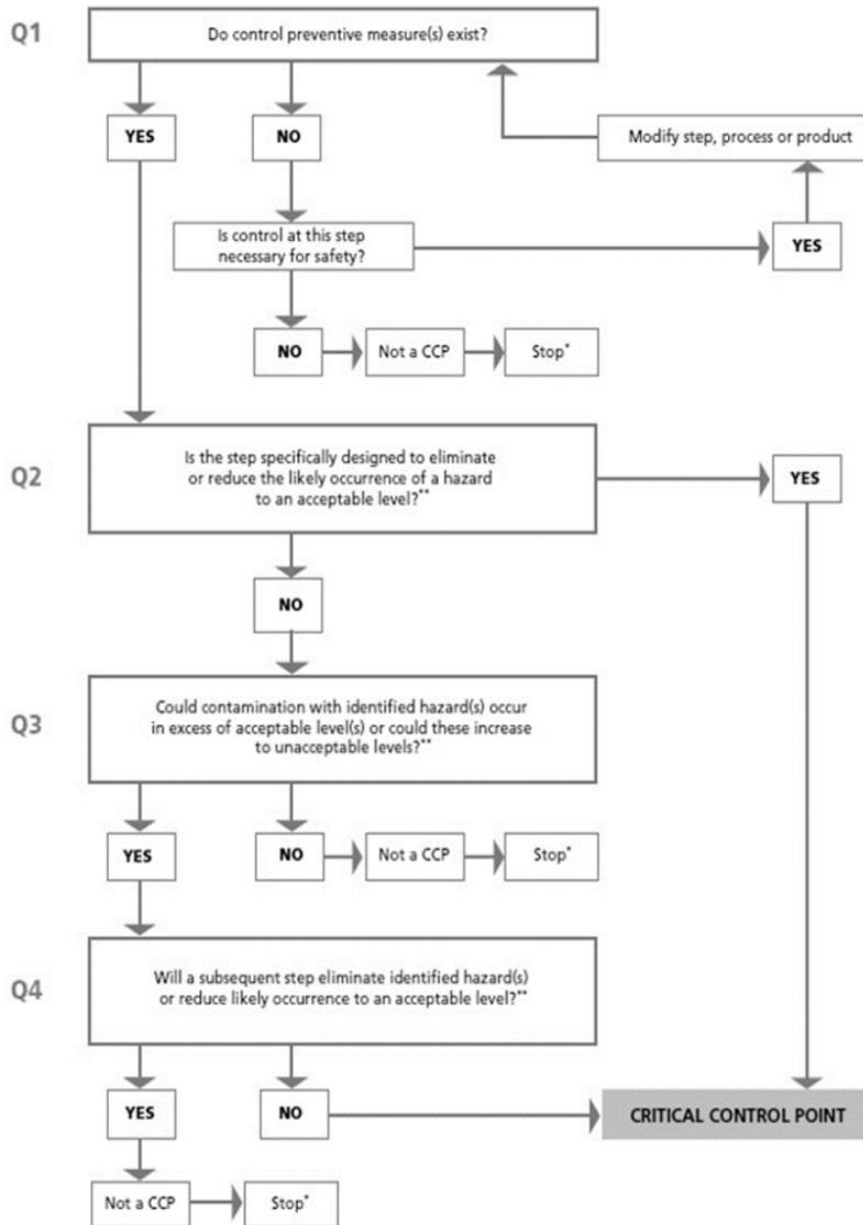
- 'If I do not control this hazard, is the safety of the end user compromised?'
- 'If I do not apply controls to this hazard at this step, are there other controls further on in the process that will ensure animal or consumer safety?'

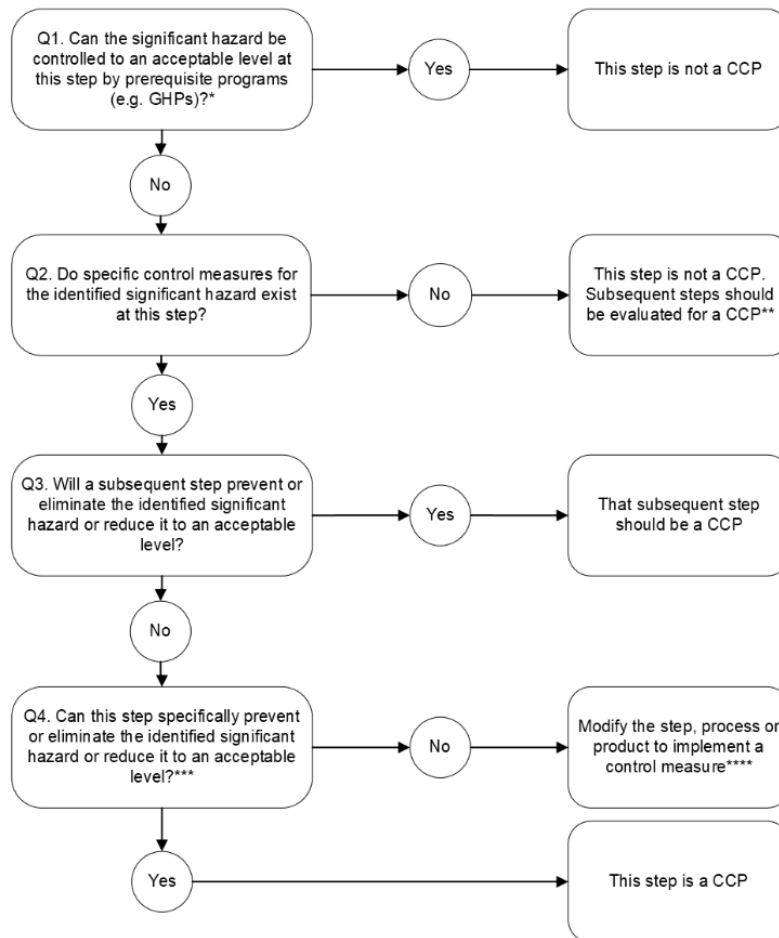
When assessing whether a control measure can be used at the process step being analysed, it is important to consider:

- Whether a control measure at a step is used in combination with a control measure at another step to control the same hazard; if so, both steps must be considered as CCPs.
- If no control measures exist at any step for an identified significant hazard, then the product or process should be modified.

The number of CCPs will depend on the Operator's HACCP plan. Once a hazard that needs a specific control is identified, the Operator must identify the process step where the control measure should be associated. The other approach to determine CCPs is to use a decision tree (see figures below, which indicates, by means of questions, a logic approach). The figures below are examples of decision trees;

other logical approaches may be used. When the matrix to determine significance is used combined with the decision tree, only the significant hazards are taken to the decision tree.





* Consider the significance of the hazard (i.e., the likelihood of occurrence in the absence of control and the severity of impact of the hazard) and whether it could be sufficiently controlled by prerequisite programs such as GHPs. GHPs could be routine GHPs or GHPs that require greater attention to control the hazard (e.g. monitoring and recording).

** If a CCP is not identified at questions 2-4, the process or product should be modified to implement a control measure and a new hazard analysis should be conducted.

***Consider whether the control measure at this step works in combination with a control measure at another step to control the same hazard, in which case both steps should be considered as CCPs.

****Return to the beginning of the decision tree after a new hazard analysis.

3.10. Establish validated critical limits for each CCP (Step 8/ Principle 3)

Critical limits establish whether a CCP is in control, and in doing so, they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable.

Critical limits for control measures at each CCP must be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented. Validation of critical limits may include conducting studies (e.g., microbiological inactivation studies). The Operators may not always need to conduct or commission studies themselves to validate critical limits. Critical limits could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party e.g., studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for a thermal process.

3.11. Construct monitoring system for the CCP (Step 9/Principle 4)

For each CCP, a monitoring system must be established to demonstrate that the critical limits are under control. The system must include all scheduled measurements or observations relative to the critical limit(s). The monitoring procedures must be able to detect a deviation from the critical limit at the CCP.

Where possible, process adjustments must be made when monitoring results indicate a trend towards a deviation from the critical limit at a CCP. The adjustments must be made before a deviation occurs.

Where possible, monitoring of CCPs should be continuous. If monitoring is not continuous, then the frequency of monitoring must be sufficient to ensure, to the extent possible, that the critical limit has been met and limit the amount of product impacted by a deviation.

The monitoring system must consist of documented information including procedures, instructions and records and should include, but not be limited to, the following:

- c) measurements or observations that provide results within an adequate time frame;
- d) monitoring devices used;
- e) applicable calibration methods;
- f) monitoring frequency;
- g) monitoring results;
- h) responsibilities and authorities for monitoring and evaluation of all data.

When monitoring procedures are based on subjective data, e.g., visual inspection of products and/or processes, they must be supported by instructions or specifications. Training must be given to the persons with responsibility for the monitoring activities. The personnel doing monitoring must be instructed on appropriate steps to take when monitoring indicates the need to take action.

The monitoring procedure and frequency of monitoring must be capable of determining when the critical limits have been exceeded in time for the product to be isolated, before it leaves the immediate control of the operator.

Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

3.12. Determine corrective actions (Step 10/Principle 5)

These are the decisions that must be taken once a critical limit has not been met. For example, a contaminated raw material or finished good may be placed on hold, reworked, destroyed, etc. A written procedure must be in place that details how this process should be undertaken and someone must have the responsibility for this process.

Specific written corrective actions must be developed for each CCP in the HACCP system in order to effectively respond to deviations when they occur. When critical limits at CCPs are monitored continuously and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe. When a deviation in meeting a critical limit occurs and monitoring was not continuous, Operators must determine what product may have been impacted by the deviation.

A root cause analysis must be conducted where possible to identify and correct the source of the deviation in order to minimise the potential for the deviation to reoccur. A root cause analysis could

identify a reason for the deviation that limits or expands the amount of product impacted by a deviation.

Details of the corrective actions, including the cause of the deviation and product disposition procedures, must be documented in the HACCP records. Periodic review of corrective actions must be undertaken to identify trends and to ensure corrective actions are effective.

3.13. Validation of the HACCP Plan and verification procedures (Step 11/Principle 6)

3.13.1. Validation of the HACCP Plan

Before the HACCP plan can be implemented, its validation is needed; this consists of making sure that the following elements together are capable of ensuring control of the significant hazards relevant to the feed business: identifying the hazards, critical control points, critical limits, control measures, frequency and type of monitoring of CCPs, corrective actions, frequency and type of verification and the type of information to be recorded.

Validation of control measures and their critical limits is performed during the development of the HACCP plan.

During the initial implementation of the HACCP system and after verification procedures have been established, evidence must be obtained in operation to demonstrate that control can be achieved consistently under production conditions. Any changes having a potential impact on feed/food safety must trigger a review of the HACCP system, and when necessary, a revalidation of the HACCP plan.

3.13.2. Verification procedures

After the HACCP system has been implemented, procedures must be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are effectively controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.

Verification must be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions.

The frequency of verification activities must be sufficient to confirm that the HACCP system is working effectively.

Verification of the implementation of control measures must be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly.

Verification must include a comprehensive review (e.g., reanalysis or an audit) of the HACCP system periodically, as appropriate, when changes occur to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system must confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that monitoring and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. The review must include confirmation that various verification activities have been executed as intended.

3.14. Establish documentation and record keeping (Step 12/Principle 7)

- The HACCP system must be maintained as documented information.
- Examples of documentation include:
 - HACCP team composition;
 - Hazard analysis and the scientific support for the hazards included or excluded from the plan;
 - CCP determination;
 - critical limit determination and the scientific support for the limits set;
 - validation of control measures;
 - modifications made to the HACCP plan.

Examples of records include:

- CCP monitoring activities;
- deviations and associated corrective actions;
- verification procedures performed.

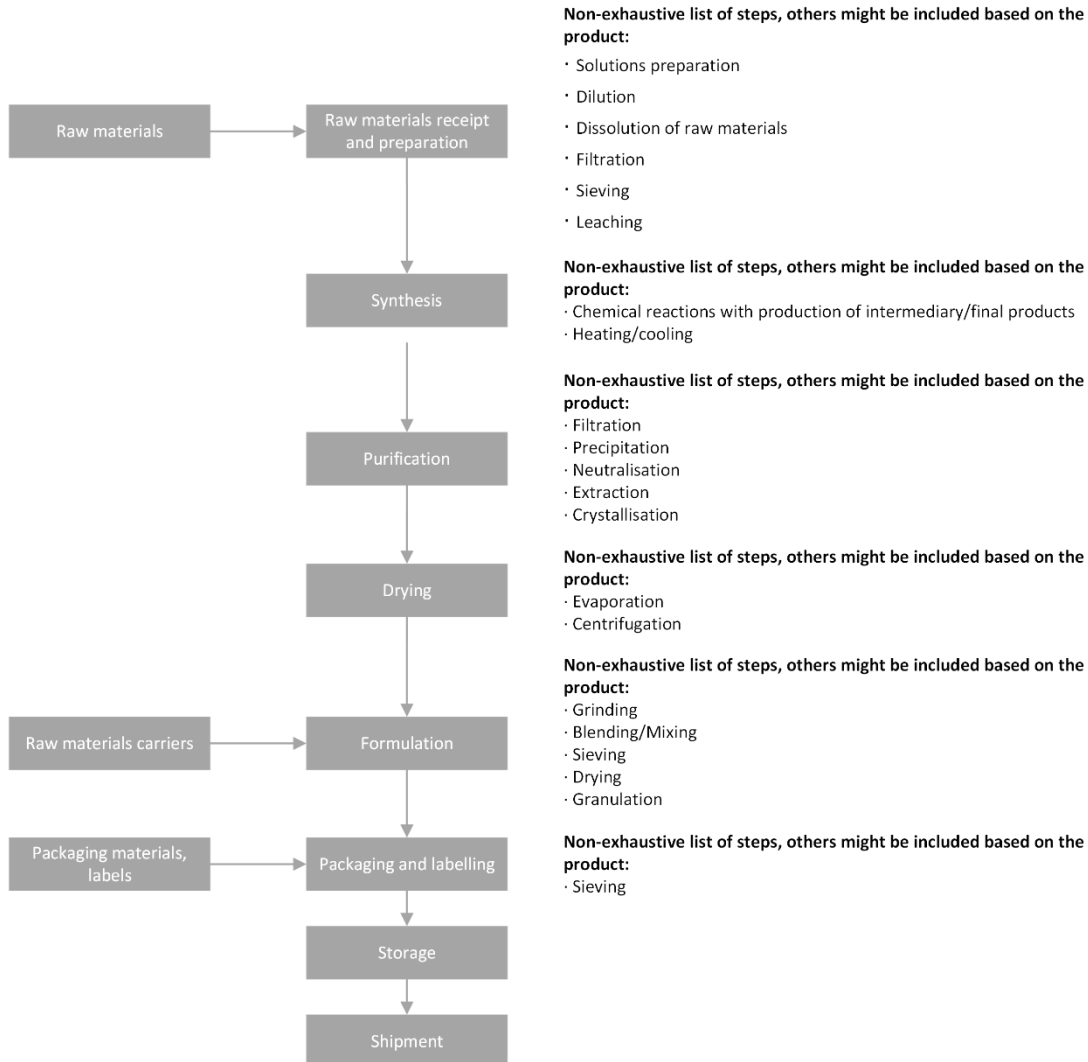
4. Requirements for Chemical Processes

4.1. Description of the process

The typical production process consists of a chemical reaction of organic and/or inorganic raw materials under defined conditions whereby organic and/or inorganic processing aids, steam, water, air and gas could be inserted into the process. After the synthesis, the final product can be purified by e.g. distillation/ crystallization/ filtration and dried.

Different processes may be used to produce chemical products. The flow chart below (4.2) describes a general and typical set of processes which may be involved in the feed production and the subsequent hazard analysis (4.3) is an example on how to analyse the process. Both a flow chart and hazard analysis shall be established for the actual process(es).

4.2. Flow chart of the process: example



4.3. Hazard analysis

PROCESS STEPS	PROCESS DESCRIPTION	HAZARD DESCRIPTION	REASON OR SOURCE OF THE HAZARD	EXAMPLES OF CONTROL MEASURES (CONTROL MEASURES CAN BE SPECIFIC MEASURES AT THE PROCESS STEPS AND ALSO PPR PROGRAMS)
Raw materials receiving and preparation	Preparation of raw materials for processing	Heavy metals, dioxins, pesticides, mycotoxins, radionuclides, etc.	<p>Unwanted chemicals from raw materials due to contamination or wrong grade of raw materials.</p> <p>Radionuclides resulting from accidental contamination, e.g., contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility, from a natural disaster and contamination of natural resources near the facility or as a result of raw materials and other ingredients obtained from a region that has experienced an accidental release of radiation.</p> <p>Lack of control during irradiation process of raw materials, when allowed by country regulation.</p>	<p>Supplier and raw materials assessment combined with receiving inspection, periodic analysis and process controls like sieving and filtration controls (e.g., after a precipitation step).</p> <p>Monitoring of accidental releases of radiological hazards and verification of the possible impact on raw materials during its manufacturing, storage, transport.</p> <p>Irradiation statements documentation from the suppliers.</p>
		Foreign matter in raw materials	Piece of equipment/supplier control measures insufficient.	Supplier and raw materials assessment Sieving, filtration.
		Pathogenic and/or toxin producing organisms	Raw materials contaminated with pathogenic and/or toxin producing organisms.	Supplier and raw materials assessment combined with receiving inspection, periodic analysis and process controls.

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Synthesis (intermediates possible)	Synthesis of the "active molecule" (more than one synthetic reaction is likely to take place)	Unwanted by products	Unwanted by products formed during synthesis.	The downstream process removes the by-products/hazardous solvents/chemical reagents to an acceptable level (neutralization, filtration, centrifugation, etc). Selection of suitable contact materials.
		Residual levels of hazardous solvents and/or chemical reagents	Use of hazardous solvents and/or chemical reagents	
		Heavy metals, plastic monomers	Migration of metals and plastic monomers from contact materials.	
		Parts and pieces	Physical contamination from equipment including contaminants from wear and tear (pieces of glass, metals, etc.)	Preventive maintenance programme, sieves, filtration.
		Physical, chemical, biological, radiological hazards from utilities (water supply, steam, other gases, compressed air, etc.). Physical, chemical, biological hazards from cleaning agents, lubricants.	Failure in the water and air treatment, use of inadequate products for steam production. Use of inadequate cleaning and lubrication products, use of excess of lubricants.	Requirements for utilities (filtering of air, use of oil suitable for feed products etc.), including analyses of water (well or municipal), used for steam. Analyses or verification of reports on water source (well or municipal) on a regular basis. Preventive maintenance programme (e.g., to prevent oil leaks). Cleaning programme.
Purification	Physical separation of a chemical substance of interest from foreign or contaminating substances	Pathogenic microorganisms	Pathogenic and/or toxin producing organisms from environment, personnel and equipment	Cleaning program. Temperature and other controls in the process. Preventive maintenance programme. Procedures for personnel hygiene.
		Physical hazards from equipment, personnel during open handling.	Loose pieces from equipment, utensils and personnel, failure in maintenance.	Preventive maintenance programme. Procedures for personnel hygiene.

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		Physical, chemical, biological, radiological hazards from utilities (water supply, steam, other gases, compressed air, etc.). Physical, chemical, biological hazards from cleaning agents, lubricants.	Failure in the water and air treatment, use of inadequate products for steam production. Use of inadequate cleaning and lubrication products, use of excess of lubricants.	Requirements for utilities (filtering of air, use of oil suitable for feed products etc.), including analyses of water (well or municipal), used for steam. Analyses or verification of reports on water source (well or municipal) on a regular basis. Preventive maintenance programme (e.g., to prevent oil leaks). Cleaning programme. Use of adequate cleaning agents and food grade lubricants when in contact with product.
		Parts and pieces	Physical contamination from equipment including contaminants from wear and tear (pieces of glass, metals, etc.)	Preventive maintenance programme, sieves, filtration.
Drying	General drying processes	Dioxins, dl-PCBs and furans; NOx and PAHs	Formation of dioxins, dl-PCBs and furans, NOx and PAHs during process	Use of adequate fuels. Inspection of burners. Preventive maintenance programme.
		Harmful substances from drying aids	Use of inadequate drying aids	Use of correct drying aids
Formulation	Formulating of additives with formulation aids, carriers, preservatives etc.	Physical, chemical, biological hazards from cleaning agents, lubricants.	Use of inadequate cleaning and lubrication products, use of excess of lubricants.	Use of adequate cleaning agents and food grade lubricants when in contact with product.
		Physical, chemical, biological, radiological hazards from utilities (water supply, steam, other gases, compressed air, etc.).	Failure in the water and air treatment, use of inadequate products for steam production.	Requirements for utilities (filtering of air, use of oil suitable for feed products etc.), including analyses of water (well or municipal), used for steam. Analyses or verification of reports on water source (well or municipal) on a regular basis. Preventive maintenance programme (e.g., to prevent oil leaks). Cleaning programme.

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		Physical hazards from equipment, personnel during open handling.	Loose pieces from equipment, utensils and personnel, failure in maintenance.	Preventive maintenance programme. Procedures for personal hygiene.
		Pathogenic microorganisms	Pathogenic and/or toxin producing organisms from environment, personnel and equipment.	Cleaning program. Preventive maintenance programme. Procedures for personnel hygiene.
		Carry-over residues	Presence of residues due to carry-over.	Validated cleaning procedure.
		Ingredient/agent above or below the acceptable level	Incorrect addition of formulating agents leading to reduced product & microbial stability. Wrong calculation of the formula that can lead to hazardous product.	Adequate dosing system (dosing and weighing tolerance shall be considered) / stability and additive/mineral concentration testing. Checking of the formula before delivering it to process.
		Ingredient/agent above or below the acceptable level	Non-uniform distribution of ingredients, inadequate mixing time, equipment failure	Regularly test mixer efficiency. Formulation homogeneity (e.g., dispersion of micro ingredients) and particle size shall be considered in the homogeneity testing. Preventive maintenance programme.
Packaging and Labelling	Packaging of the products in bags, boxes, drums, etc.	Microorganisms, chemical substances from packaging	Contaminants from unsuitable packaging (e.g., not suited for feed products).	Selection of suitable packaging/risk assessment of packaging materials. Migration tests of packaging materials.
		Foreign material	Contamination with foreign material during the packaging process.	Packaging via dedicated production lines and packaging machines (sieves, metal detection). Cleaning and inspection procedures. Usage of new and/or clean packaging materials.

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		Chemical hazard	Inaccurate labelling and identification of the product leading to improper usage of the product or inability to do a complete recall in case of incident.	Labelling procedures. Batch identification system check. Labelling identification, label inventory.
Storage	Storage of products	Residues of other feed products	Cross contamination with other feed products.	Effective segregation of different products particularly when stored on floors. Cleanout procedures between different types of products.
		Residues of foreign products	Contamination with other non-feed materials such as chemicals, fertilizers.	Separate storage areas for feed and non-feed materials.
		Degradation substances	Deterioration of the product due to poor stock rotation. Storage under temperatures that lead to premature product deterioration	Proper stock rotation Temperature control to prevent microbial growth. Temperature control to ensure stability during shelf life. Warehousing procedures to ensure hygiene and temperature control according to recommended storage conditions.
		Extraneous matter from pests, microorganisms due to pest entrance in the warehouse	Entrance of pests in the warehouse	Pest control program
		Physical, chemical and biological hazards	Physical, chemical and biological hazards from previous loads, dirty tanks, dirty silos.	Cleaning programme.

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Shipment of packed goods or in bulk	Shipment of packed goods	Foreign materials, pests or residues from other products	Possible contamination with foreign materials, pests or other goods in case the packaging gets damaged.	<p>Contractual agreements with transporters to ensure hygiene and temperature control according to recommended transport conditions.</p> <p>Inspection before loading /dedicated transport.</p> <p>Check of cleaning certificates.</p> <p>Info about previous load(s) and request for cleaning certificates.</p>
	Bulk shipment	Foreign materials, residues from other products	Possible contamination by previous loads	<p>Communication to the transport/ logistic organization of the necessary requirements e.g.: temperature, hygiene.</p> <p>Inspection before loading /dedicated transport.</p> <p>Notification of any problems during transport.</p>

5. References

- General principles of Food Hygiene (CXC/RCP 1 – 1969, Rev 2020. Hazard Analysis Critical Control Point (HACCP) System and Guidelines for its Application): <http://www.fao.org/fao-who-codexalimentarius/>
- EN ISO 22000:2005 on Food safety management systems - Requirements for any organization in the food chain.
- Hazards associated with Animal Feed. Report of the Joint FAO/WHO Expert Meeting FAO headquarters, Rome 12-15 May 2015. Rome, FAO. (also available at <http://www.fao.org/documents/card/en/c/ca6825en/>)
- Hazard Analysis and Risk-Based Preventive Controls for Food for Animals - Guidance for Industry - <https://www.fda.gov/media/110477/download>.