



PROCESS DOCUMENT

FORMULATION PROCESS

VERSION 2
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1. Introduction

The FAMI-QS Process Documents are auditable documents established for each process described in Chapter 2 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.

2. Definitions

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. *(COM(2008)124 final & Regulation 767/2009/EC and adapted)*

Check/control: Monitor and measure processes against policies, objectives and requirements for the product and report results. The state wherein correct procedures are being followed and criteria are being met. *(Codex Alimentarius)*

Contamination: The undesired introduction of impurities/contaminant (chemical or microbiological nature or of foreign matter), into or onto a raw material, intermediate, and products covered by FAMI-QS scope during production, sampling, packaging or repackaging, storage or transport. *(Codex Alimentarius and adapted)*

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

Corrective Action: Any action to be taken when the results of monitoring at the CCP indicate loss of control. *(Codex Alimentarius)*

Critical Control Point (CCP): A step at which control can be applied and that is essential to prevent or eliminate a feed/food safety hazard or reduce it to an acceptable level. *(Codex Alimentarius and adapted)*

Critical Limit: Minimum or maximum value to which a biological, chemical (including radiological) or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of the Feed Safety Hazard. *(FDA)*

Cross-Contamination: Contamination of a material or product with another material or product.

Deviation: Failure to meet a critical limit. *(Codex Alimentarius)*

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)*

Feed: 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 harm 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 (including radiological) or physical agent in feed, with the potential to cause an adverse health effect in animals and/or humans. *(Codex Alimentarius and adapted)*

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

Good Manufacturing Practices (GMP): Processes and actions taken to maintain hygienic conditions throughout the food chain that provide the foundation for the HACCP Programme. Equivalent term: PRP (Pre-requisite Programme) *(ISO 22000:2005)*

HACCP (Hazard Analysis and Critical Control Point) Programme: A system which identifies, evaluates, and controls hazards to feed and food safety. *(Codex Alimentarius and modified)*

Hazard Analysis: The process of collecting and evaluating information on hazards, and conditions leading to their presence, to decide which are significant for feed safety and therefore must be addressed in the HACCP Programme. *(Codex Alimentarius)*

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 CCP 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: Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives. *(ISO 9001:2015)*

Point of Attention (POA): Steps in which the risks can be managed with a strengthening supervision and additional monitoring of management measures. When the implementation of these measures is regularly reviewed and modified, then it is assumed that the risks are adequately managed.

Pre-requisite Programme (PRP): See 'Good Manufacturing Practices (GMP)'

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 9000:2005)*

Procedure: Operations to be performed, precautions to be taken and measures to be applied directly or indirectly related to the manufacturing of a material or products covered by FAMI-QS scope. *(Modified from ICH Q7A)*. A specified way to carry out an activity or a process. *(ISO 9000:2005)*

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: Written documents containing actual data. Document stating results achieved or providing evidence of activities performed. *(ISO 9000:2005)*

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 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. Document stating requirement. (*ISO 9000:2005*)

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: Obtaining evidence that the control measures will be effective. (*ISO 22000:2005*)

Verification: The application of methods, procedures, tests and other evaluations to confirm – through the provision of objective evidence – that specified requirements have been fulfilled. (*Codex Alimentarius and adapted*)

Where appropriate: See “*Adequate*”.

3. HACCP Programme

HACCP Programme is a system that helps an operator identify feed safety hazards and evaluate the feed safety hazards associated with their product(s) and processes with the view of controlling their occurrence. The system enables the operator to document, control and verify the effectiveness of these control measures.

3.1. General requirements

The HACCP Programme is a required system to identify, evaluate, and control hazards to feed safety. It ensures the Operator has effective Good Manufacturing Practices (GMPs) or PRPs in place to manage the daily tasks of good hygienic practice. The Good Manufacturing Practices (GMPs) or PRPs are the backbone of any quality or safety system and without it no management program is likely to be successful.

Documents should specify how Good Manufacturing Practices (GMPs) are managed. Documented information about verifications and modifications of the Good Manufacturing Practices (GMPs) must be maintained.

There is a dedicated chapter for Good Manufacturing Practices (GMPs) or PRPs in the FAMI-QS Code of Practice (Chapter 7) providing requirements with a goal of maintaining feed safety and quality.

3.2. HACCP Programme

HACCP Programme consists of the following 7 principles:

- 1) Conduct a hazard analysis;
- 2) Determine the critical control points (CCPs);
- 3) Establish critical limits;
- 4) Establish a system to monitor the control of each CCP;
- 5) Establish the corrective action to be taken if controls should fail;
- 6) Establish a procedure to verify that all the aspects of the HACCP Programme are working effectively;
- 7) Document all procedures and records to demonstrate the HACCP Programme is working effectively.

Based on 7 principles, the implementation of HACCP Programme is following a logical sequence of 12 steps, including the 7 principles.

3.3. Assemble a HACCP team

The Operator must form a multi-disciplinary team that will have responsibility for establishing, developing, maintaining and reviewing the HACCP Programme. 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 products, processes and associated hazards.

The HACCP team leader must:

- a) Appoint (where possible) and manage a HACCP team and organise its work;
- b) ensure relevant training, and periodic retraining of the HACCP team members;
- c) arrange for periodic, at least yearly, review of the HACCP plan(s);
- d) report to the top management on the effectiveness of the HACCP programme.

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.

3.4. Formulate the finished product description

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

- composition (e.g. raw materials, ingredients, additives etc.);
- physico-chemical characteristics related to feed/food safety;
- processing;
- packaging;
- storage and distribution conditions;
- required shelf life;
- instructions for use;
- any microbiological or chemical criteria applicable.

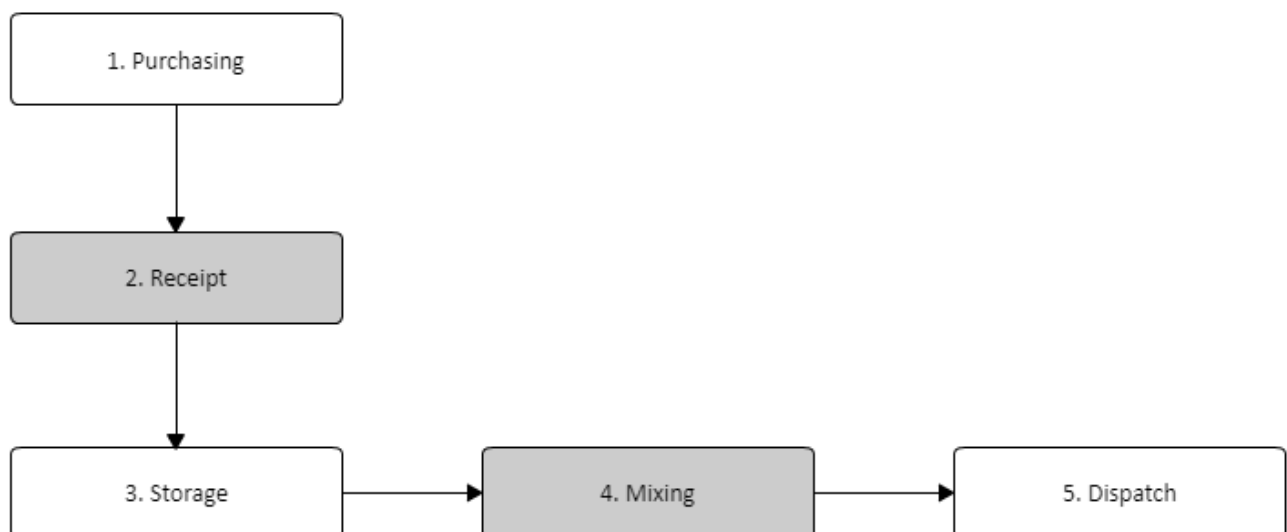
3.5. Identify the intended use of the product

The product specification must detail the target groups for which it is intended. It should also specify the animal species, directions for 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

The Operator must draw up a process flow diagram for each product group. This diagram should indicate the steps taken to produce the product and should include details of by-products, intermediate products, storage, transport *etc.* One block in the process flow should reflect each step in the process.

The diagram should be as simple as possible, with clear diagrams and unambiguous terms. A very basic example is given here:



3.7. Confirm the accuracy of the process flow diagram in situ

After the diagram is drawn up, the Operator must make sure it is accurate by checking it against the actual operating process in its facility.

3.8. Identify and analyse the hazards

The Operator must use the diagram to access potential hazards at each process step from the perspective of:

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

For example, for Step 1, 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 subsequent step in the process, in each case taking the particular circumstances with regard to the step into account.

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

- a) the likelihood of hazards occurring;
- b) the severity of their adverse health effects.

3.9. Determine the CCP and control measure(s)

After the hazard identification, it is important to evaluate whether or not a hazard is significant. If a hazard needs a specific control and there is no point further down stream in the process that can reduce or eliminate it, this step is a Critical Control Point (CCP). If the correct application of the Operator's prerequisite programs prevents, eliminates or reduces the hazard to an acceptable level, then the step in question is not a CCP. Useful questions the Operator can ask itself when establishing CCPs are:

- a) *'If I do not control this hazard, is the safety of the end user compromised?'*
- b) *'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?'*

There are two recognised methods to apply when determining CCPs.

One is using a **decision matrix**, that will help the Operator to decide how severe 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 probability that a hazard will occur and the severity if it occurs.

The matrix can be simple or more sophisticated. Three different examples are shown below.

Example a)

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

Significance level 1: no need for measures
 Significance level 2: once-only periodical measures
 Significance level 3: general control measures, control of points of attention
 Significance level 4: specific control measures - control at critical control points (CCPs)

Four significance levels can be determined with the evaluation model.

In the event of significance level 1, no measures are necessary.

In case of significance level 2, periodic measures – often activities to be performed just once – have to be carried out.

Significance level 3 requires general control measures or PRPs, such as hygiene programs, maintenance and calibration, purchasing procedures, etc.

In the event of risk level 4, specific control measures are necessary for that particular situation.

Example b)

Significance		Severity/Potential impact				
		Insignificant	Minor	Moderate	Major	Fundamental
Likelihood	Almost certain					
	Likely					
	Moderate					
	Unlikely					
	Rare					

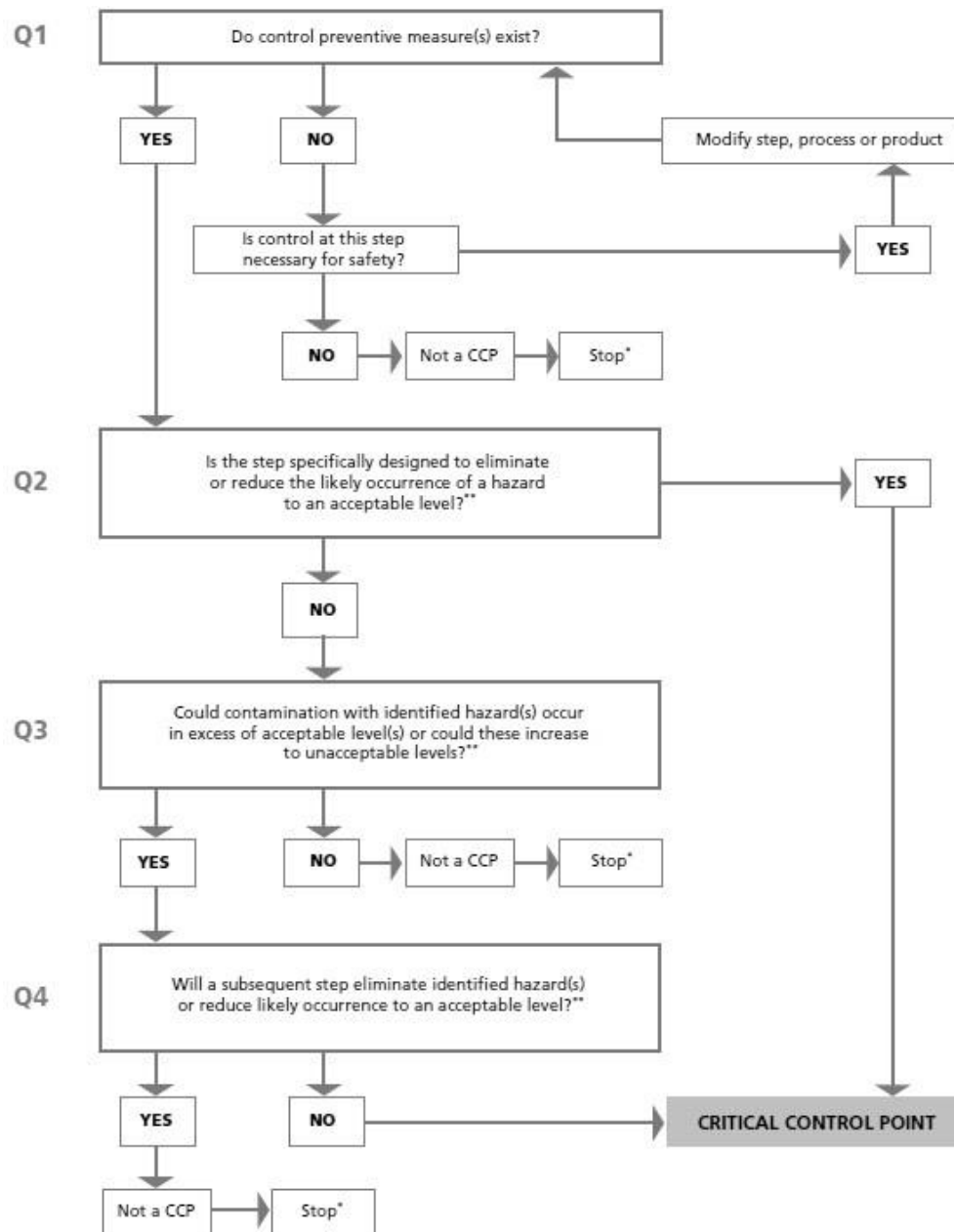
	High significance	CCP
	Significant	POA
	Moderate significance	POA
	Low significance	PRP

Example c)

Another and simpler matrix is shown below.

Significance		Severity		
		Small	Medium	High
Probability	High	POA	CCP	CCP
	Moderate	Periodic measures	POA	CCP
	Small	No measures	Periodic measures	POA

The other approach to determine CCPs is to use a **decision tree** (see figure below, which indicates, by means of four questions, a logic approach). The figure below is an example of a decision tree; other logical approaches may be used.



*) Proceed to the next identified hazard in the described process

***) Acceptable and unacceptable levels need to be determined within the overall objectives of the HACCP Programme

The number of CCPs will depend on the Operator's system but a well controlled process will have few CCPs. The Operator can monitor a few key CCPs much more effectively than a vast array.

Once a hazard that needs a specific control is identified, the Operator must identify the process step where the control measure should be associated.

Critical limits must:

- a) be established to ensure that the identified acceptable level of the feed safety hazard in the end product is not exceeded;
- b) be measurable (quantitatively and qualitatively) and the rationale for their determination must be supported by scientific or other documented information.

3.10. Determine the target values and critical limits for the CCP

The Operator must establish a target value which it expects as an average and a critical limit that will separate the acceptable from the unacceptable. These limits must comply with all legislative obligations but if there are no legal limits, one's own research (analytical; bibliographic) and experience should be used to strike the right balance between safety and operability.

3.11. Construct monitoring procedures for the CCP

For each CCP, a monitoring system must be established to demonstrate that the critical limits are controlled. The system must include all scheduled measurements or observations relative to the critical limit(s).

The monitoring system must consist of documented information including procedures, instructions and records and should include, but are not 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 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 is used or consumed.

3.12. Determine corrective actions

These are the decisions that must be taken once a critical limit has been breached. For example, a faulty 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 responsibility for this process.

3.13. Verify the system

The system must be verified periodically to ensure it is effective and up to date. This review should cover all aspects of the HACCP Programme including the prerequisites, deviations and customer complaints. All records of this review should be documented and be part of the company's internal audit schedule.

3.14. Draw up the necessary documentation

The HACCP programme must be maintained as documented information and must include the following:

- a) information for each identified Critical Control Points (CCP);
- b) feed safety hazard(s) to be controlled at the CCP;
- c) control measure(s);
- d) critical limit(s);
- e) monitoring procedure(s);
- f) corrections and corrective action(s) to be taken if critical limits are exceeded;
- g) list of responsibilities, designated responsible personnel, including for certain authorisations;
- h) records of monitoring.

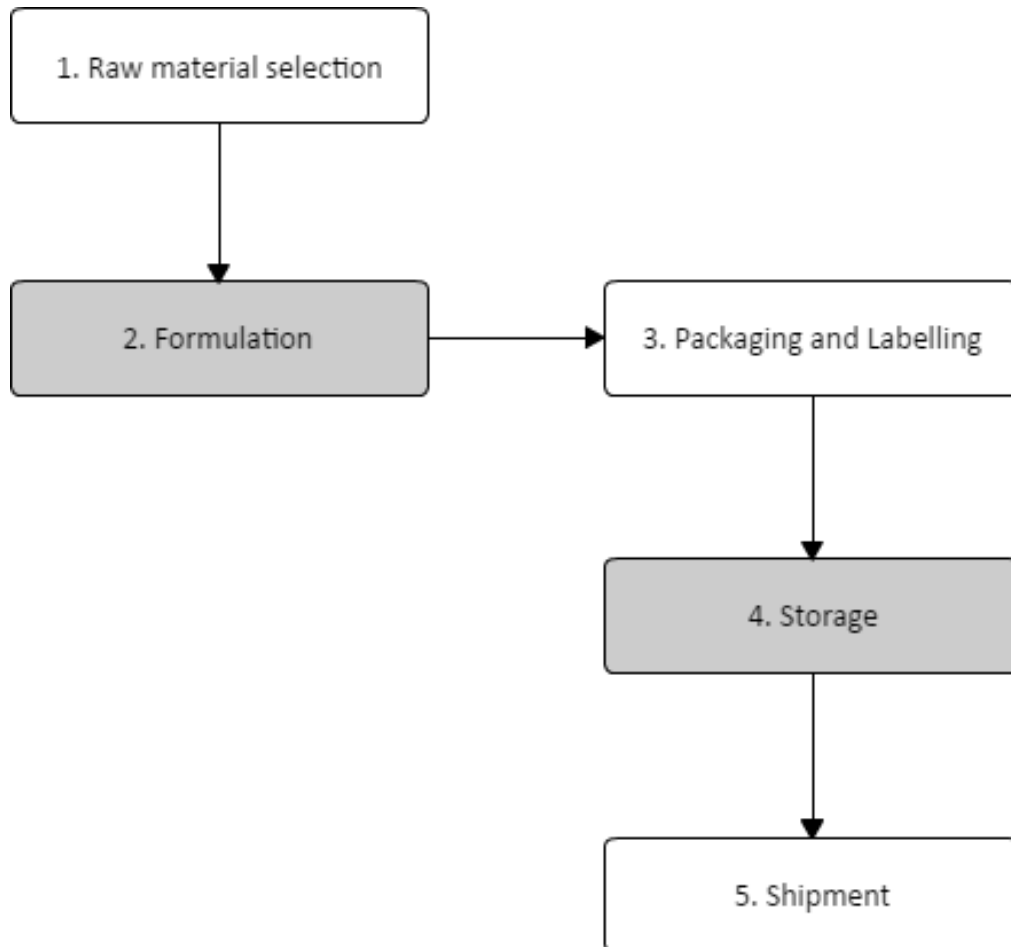
4. Requirements for Formulations

4.1. Description of the process

The typical production process consists of mixing organic and/or inorganic raw materials in a solution until dissolved followed by drying the solution with a carrier before packaging of the final product. Processing aids such as steam, water, air, gas and solvents could be used in the process. Process is carried out under defined conditions.

Different processes may be used to formulate products. The flow chart below (4.2) describes a 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	SUGGESTION OF CONTROL AND PREVENTIVE MEASURES
Raw material selection	Selection of raw materials for processing	Selection of incorrect ingredient or incorrect raw material	Clear Labelling/verification of checked ingredients
		Poor performance/ill health due to unsuitable raw materials	Feed formulations produced or checked by qualified nutritionists
		Raw materials contaminated with pesticides, mycotoxins, dioxins or heavy metals	Supplier and raw materials assessment combined with receiving inspection, periodic analysis and process controls like sieving and infection control
		Physical debris in raw materials	
		Raw materials infected with pathogenic and/or toxin producing organisms	
		Radiological hazards 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	Vigilance regarding accidental releases of radiological hazards and their potential to contaminate feed, either directly due to 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
	Irradiation statements documentation from the suppliers, since in some countries irradiation of food stuff is allowed		
Formulation	Formulating of additives with formulation aids, carriers, preservatives etc.	Radiological hazards from use of contaminated water supply	Analyse water source (well or municipal) on a regular basis.
		Contamination from cleaning agents, lubricants, process air, utilities	Requirements to utilities (filtering of air, use of oil suitable for feed products etc.)
			Preventive maintenance program
		Physical contamination from equipment, personnel or pests during open handling	Procedures for process and personal hygiene, pest control, infection checks, maintenance programs
		Infection from pathogenic and/or toxin producing organisms from environment, personnel or pests	
		Presence of residues due to carry-over	Preventive measures to control carry-over
		Incorrect addition of formulating agents leading to reduced product & microbial stability	Adequate dosing system (dosing and weighing tolerance shall be considered) / Stability testing
Non-uniform distribution of ingredients	Regularly test mixer efficiency		
	Formulation homogeneity (e.g. dispersion of micro ingredients) and particle size shall be considered		

PROCESS STEPS	PROCESS DESCRIPTION	HAZARD DESCRIPTION	SUGGESTION OF CONTROL AND PREVENTIVE MEASURES
Packaging and Labelling	Packaging of the products in bags, boxes, drums, etc.	Packaging not suited for feed products	Selection of suitable packaging
		Contamination with foreign material via the packaging process	Packaging via dedicated production lines and packaging machines
			Cleaning and inspection procedures
	Identify the products with the right label identification according to the applicable legislation and to be able to track and trace the products in cases it is necessary	Inaccurate labelling and identification of the product leading to improper usage of the product or unabling to do a complete recall in case of incident	Usage of new and/or clean packaging materials
			Labelling procedures
			Check on batch identification system
Storage	Storage of products	Exposure to rain and/or damp conditions	Labelling-identification, traceability and legislation of destination countries
			Training and education of employees
		Cross contamination with other feed materials	Weatherproof storage facilities
			Effective segregation of different materials particularly when stored on floors
		Contamination with other non-feed materials such as chemicals, fertilizers	Cleanout procedures between different types of products
		Deterioration of the product due to poor stock rotation	Separate storage areas for feed and non-feed materials
		Storage under temperatures that lead to premature product deterioration and/or microbial instability	Proper stock rotation
Temperature control to prevent microbial growth			
Infestation by rodents/ parasites	Warehousing procedures to ensure hygiene and temperature control according to recommended storage conditions		
		Pest Control Programme in place	

PROCESS STEPS	PROCESS DESCRIPTION	HAZARD DESCRIPTION	SUGGESTION OF CONTROL AND PREVENTIVE MEASURES
Shipment of packed goods or in bulk	Shipment of packed goods	Possible contamination with foreign materials, pests or other goods in case the packaging gets damaged	Contractual agreements with transporters to ensure hygiene and temperature control according to recommended transport conditions
			Inspection before loading /dedicated transport
			Use only certified and registered transporters according the requirements
			Notification of any problems during transport
	Bulk shipment	Possible contamination by previous loads	Contractual agreements with transporters to ensure hygiene and temperature control according to recommended transport conditions
			Inspection before loading /dedicated transport
			Info about previous load(s) and request for cleaning certificates
			Use only certified and registered transporters according the requirements

5. References

Formal guidance on the implementation of HACCP principles is available from the Codex Alimentarius (www.codexalimentarius.net).

General principles of Food Hygiene (CAC/RCP 1 – 1969, Rev 4 – 2003. Annex on Hazard Analysis Critical Control Point (HACCP) System and Guidelines for its Application.)

EN ISO 22000:2005 on Food safety management systems - Requirements for any organization in the food chain.