



FAMI-QS CODE OF PRACTICE

**DRAFT VERSION 6
2017-01-31**

TABLE OF CONTENTS

1. Introduction	5
2. Scope	6
2.1. FAMI-QS Scope	6
2.2. Exclusions to the Scope	7
3. Terms and Definitions	8
4. Context of the Operator	13
4.1. Understanding the Operator and its context	13
4.2. Understanding the needs and expectations of interested parties	13
4.3. Feed Safety and Quality Management System and its processes	13
4.4. Feed Safety and Quality Management System Documentation	14
4.5. Determining the scope of the Feed Safety and Quality Management System	15
4.6. Feed Safety and Quality Policy	15
5. Leadership	16
5.1. Leadership commitment and responsibilities	16
6. Planning	17
6.1. Actions to address risks and opportunities	17
6.2. Feed safety and Quality objectives and planning to achieve them	17
6.3. Planning of Changes	17
7. Good Manufacturing Practices	18
7.1. Establishment	18
7.1.1. Local plant environment	18
7.1.2. Layout and workspace	19
7.1.3. Internal structures and fittings	19
7.2. Equipment	19
7.3. Storage	19
7.4. Utilities	20
7.4.1. Water supply	20
7.4.2. Ventilation	20

7.4.3.	Compressed air and other gases.....	20
7.4.4.	Lighting.....	20
7.5.	Waste disposal.....	21
7.5.1.	Waste control.....	21
7.5.2.	Drains and drainage.....	21
7.6.	Equipment suitability.....	21
7.6.1.	Measuring devices (calibration).....	21
7.6.2.	Maintenance.....	22
7.7.	Measures for prevention of cross-contamination.....	22
7.8.	Cleaning and sanitation.....	22
7.8.1.	Cleaning and sanitizing programmes.....	22
7.8.2.	Cleaning agents and tools.....	23
7.9.	Pest control.....	23
7.10.	Personnel hygiene.....	23
7.10.1.	Personal behaviour and cleanliness.....	24
7.10.2.	Clothing and protective equipment.....	24
7.10.3.	Health status.....	24
7.11.	Transport.....	24
7.11.1.	Driver Responsibility.....	24
7.11.2.	Transport of packed goods.....	25
7.11.3.	Transport of bulk products.....	25
7.12.	Feed packaging information and customer communication.....	26
7.13.	Competence and training.....	26
7.14.	Awareness.....	26
7.15.	Communication.....	26
7.16.	Complaint handling system.....	26
7.16.1.	Feed Safety Incident Communication (Crisis Management).....	27
7.16.2.	Recall procedures.....	27
8.	Operation.....	28
8.1.	Operational planning and control.....	28
8.2.	Determination of requirements for products.....	28
8.3.	Design and development of products.....	28
8.3.1.	Design and development planning.....	29
8.3.2.	Design and development Inputs.....	29

8.3.3.	Design and development controls	29
8.3.4.	Design and development outputs.....	29
8.4.	Change control.....	30
8.5.	Control of externally provided products and services.....	30
8.5.1.	Type and extent of control of external provision – Contract Manufacturers.....	30
8.5.2.	Purchased materials.....	31
8.5.3.	Selection and management of suppliers.....	31
8.5.4.	Verification of incoming materials.....	32
8.5.5.	Production of finished goods	32
8.5.6.	HACCP Programme	33
8.6.	Control of Production	34
8.6.1.	Identification and traceability.....	34
8.6.2.	Preservation of product	35
8.6.3.	Post-delivery activities	35
8.6.4.	Release of products.....	35
8.6.5.	Control of nonconforming process outputs and products	35
9.	Performance Evaluation	37
9.1.	Monitoring	37
9.2.	Internal audit.....	37
9.3.	Management review	37
10.	Improvement	39
10.1.	Nonconformity and corrective action.....	39
10.2.	Continual improvement	39

1. Introduction

The FAMI-QS Code of Practice provides guidance for implementing measures necessary to ensure feed safety and quality of products manufactured by processes, as defined by FAMI-QS. The text of the Code is designed to set out general requirements and to be used as a tool for Operators to develop their specific procedures.

The Code covers guidance on Good Manufacturing Practices and HACCP plans and suggestions on continuous improvements to the design, management of operations and risks with a goal of maintaining feed safety and quality.

A set of Process Documents are provided as add-ons to the FAMI-QS Code. These are auditable documents, established in line with *Codex Alimentarius* (including HACCP) principles, for each process described in the Scope Chapter (see Chapter 2 of this document). The Process Documents are meant to check for specific risks per process and to provide information on how to deal with particular issues in a more detailed and practical way. These documents will be submitted to periodical review, in line with emerging relevant technological, scientific and legislative developments or statutory modification in the sector.

The ultimate goal of this Code of Practice is to ensure feed safety by minimizing the risk of unsafe ingredients entering the food chain. Feed is considered unsafe for its intended use if it is likely to pose a risk to (has adverse effect on) human or animal health, or if the food derived from food-producing animals is unsafe for human consumption.

Compliance with FAMI-QS does not exonerate the Operator from meeting statutory or regulatory requirements including:

- a) in the country where the Operator is based;
- b) in the country where the final product coming from a FAMI-QS certified process is placed.

The FAMI-QS Code of Practice is a public document and its contents can be followed freely by any Operator. Participation in the FAMI-QS auditable system is voluntary.

2. Scope

This chapter helps operators identify their products, according to the definitions within the scope of this Code of Practice.

Operators wishing to get FAMI-QS certification or to enlarge the scope of already existing FAMI-QS certification, must follow the procedure described in the Rules for Operators.

2.1. FAMI-QS Scope

The Scope of FAMI-QS is Specialty Feed Ingredients. A specialty feed ingredient is defined as 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*).

Specialty feed ingredients can be obtained via the following production processes or their combination:

- **Chemical** – 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/or gas could be inserted into the process. After the synthesis the final product can be purified by e.g. distillation/ crystallization/ filtration and dried.
- **Bioprocessing** – The process uses biological material or its components to obtain the desired product. Bioprocessing is mainly based on upstream processes to produce biological material (cell culture, fermentation) and downstream processes which include recovery, separation/purification of the desired material/ intermediate products, and possible preservations steps such as drying/ freeze drying and formulation.
- **Mining** – Mining is the extraction of valuable minerals or other geological materials from the earth. Mineral processing is mainly based on various mechanical means of crushing, grinding, washing, precipitating, etc. that enable the separation of valuable minerals from the source.
- **Extraction** – Extraction mainly is executed either by aqueous solution or by using organic solvents, or by a combination of both. The distinctive characteristics of such production methods are the combination of a series of dissolution and precipitation steps, pH, temperature and moisture adjustments, in order to isolate the molecule from its organic matrix and further refine it to the desired properties.
The down-stream process(es) usual comprise of the removal of the solvent agent, distillation, temperature treatment to inactivate potentially harmful substances, drying, granulation, formulating, sieving and packaging.
- **Mixing** – Dry or liquid mixtures of one or more speciality feed ingredients with or without a carrier. These mixtures are not intended for direct feeding to animals or can be combined with the daily ration and must perform specific, technological, sensory, zootechnical or other functions related to the specialty feed ingredients.
- **Formulations/ preparations** – 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.

Specialty feed ingredients shall be defined and labelled with clear directions of use, according to the applicable animal feed legislation of the intended market. The regulatory status of the products will be under the responsibility of the Operator. The Operator must ensure that the products confirm with all necessary legal requirements including:

- being legally produced in the country of origin and
- meeting the regulatory requirements of the country of destination.

The Feed Chain Activities covered by FAMI-QS are the following:

- Production – The processes and methods used to transform tangible inputs (raw materials, semi-finished goods) and intangible inputs (information, data) into goods. Resources are used in this process to create an output that is suitable for use or has exchange value.
- Trade – The action of buying, handling, storage and selling goods and services.

2.2. Exclusions to the Scope

- 1) Complete feedingstuffs, e.g., mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration (*Article 2(c) of Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition*) are not covered within the scope.
- 2) Any substance or combination of substances presented for treating or preventing disease in animals, which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals (*e.g. Veterinary medicinal products as defined in Article 1 of Council Directive 2001/82/EC on the Community code relating to veterinary medicinal products*), are not covered within the scope, with the exception of coccidiostats and histomonostats used as, for example, feed additives in the EU.

3. Terms and Definitions

The following terms and definitions are used in this Code and associated documents:

Adequate: The terminologies “adequate”, “where appropriate”, “where necessary”, or “sufficient” mean that it is up to the business Operator in first instance to decide whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives of the Code. 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)*

Authorised personnel: Persons who have skills, permission and purpose as specified by job descriptions, process descriptions or management.

Batch: Unit of production from a single plant 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 themselves. *(COM(2008)124 final & Regulation 767/2009/EC and adapted)*

Carry-over: Contamination of a material or product with another material or product that originates from previous use of equipment and would alter the quality and safety beyond the established specifications.

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)*

Compound feed: Mixture of feed materials, whether or not containing feed additives, for oral animal feeding in the form of complete or complementary feed. *(COM(2008)124 final & Regulation 767/2009/EC)*

Contaminant: Any biological or chemical agent, foreign matter, or other substances not intentionally added to food or feed which may compromise food and/or feed safety or suitability. *(Codex Alimentarius and adapted)*

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)*

Contract Manufacturer: A contract manufacturer is an external service provider performing (parts of) productions processes leading to feed products or their mixtures on behalf of the Operator.

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: Action to eliminate the cause of a detected nonconformity or other undesirable situation. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. *(ISO 22000:2005)*

Crisis: An event that represents an immediate and significant threat to animal and/or human health resulting from the production or supply of unsafe or illegal product; where the product has left the immediate control of the Operator. *(Synopses from articles 15 & 19, Regulation 178/2002/EC)*

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 to reduce it to an acceptable level. *(Codex Alimentarius and adapted)*

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

Defect: Nonconformity related to an intended or specified use. *(ISO 9001:2015)*

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)*

Establishment: Any unit of a feed business that carries out the manufacture/production and/or the placing on the market of products covered by FAMI-QS scope. *(Regulation 183/2005/EC and adapted)*

External provider: An external provider can be a service provider, a contract manufacturer or a supplier of raw materials etc.

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 Fraud: The intentional and economically motivated adulteration of feed. *(USP Guidance on Food Fraud Mitigation Guidance and adapted)*

Feed Safety: Concept that feed will not cause harm to animals and/or lead to contamination. *(Codex Alimentarius and adapted)*

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)*

Good Manufacturing Practice (GMP): Processes and actions taken to maintain hygienic conditions throughout the food chain that provide the foundation for the HACCP system. *(ISO 22000:2005)*

HACCP (Hazard Analysis and Critical Control Point): A system which identifies, evaluates, and controls hazards which are significant for feed safety.

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 plan. *(Codex Alimentarius)*

Incoming material: A general term used to denote raw materials delivered at the beginning of the production chain.

Intermediate (product): Any material processed by the Operator before the final product is obtained. Substance that is manufactured for, and consumed in, or used for chemical processing, in order to be transformed into another substance. *(REACH Article 3(15))*.

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 organization to establish policies and objectives and processes to achieve those objectives. *(ISO 9001:2015)*

Manual: One document or a series of documents. *(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 Code).

Nonconformity: Non-fulfilment of a requirement. *(ISO 9001:2015)*

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)*

Plan: To establish the objectives and processes necessary to deliver results in accordance with the Operator's policies regarding quality and safety.

Policy: Intentions and direction of an organisation, as formally expressed by its top management. *(ISO 9001:2015)*

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. See 'Incoming Material'.

Recall: Any measure aimed at achieving the return of an unsafe feed that has already placed on the market by an Operator. Feed is considered unsafe if it has an adverse effect on human or animal health and/or will make the food

derived from food-producing animals unsafe for human consumption. (*adaptation of the definitions in Directive 2001/95/EC and Regulation 178/2002/EC*)

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*)

Risk assessment: Means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk Characterisation. (*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 Code by appropriate means).

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

Sign / signature: Confirmation of an authorised person in writing or by electronic means with controlled access.

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 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*)

Stages of production, processing and distribution: Any stage, including import, from and including the primary production of a feed, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the import, production, manufacture, storage, transport, distribution, sale and supply of feed. (*Regulation 178/2002/EC*)

Statutory requirement: Obligatory requirement specified by a legislative body. (*ISO 9000:2015*)

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: Confirmation, through the provision of objective evidence that specified requirements have been fulfilled. (ISO 22000:2005)

Where appropriate: See “Adequate”.

Where necessary: See “Adequate”.

4. Context of the Operator

4.1. Understanding the Operator and its context

The Operator must determine the external and internal risks that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its Feed Safety and Quality Management System. The Operator must monitor, review and record the information about these external and internal risks.

NOTE 1: Understanding the external context can be facilitated by considering risks arising from legal, regulatory, technological, market, cultural, and economic environments, whether international, national, regional or local.

NOTE 2: Understanding the internal context can be facilitated by considering risks related to values, culture, knowledge and performance of the Operator.

4.2. Understanding the needs and expectations of interested parties

FAMI-QS Certified Operator is part of the global feed and food chain. Due the impact or potential impact of the interested parties on the Operator's ability to consistently provide speciality feed ingredients that meet customer and applicable statutory and regulatory requirements, the Operator must determine the following:

- a) interested parties that are relevant to the Feed Safety and Quality Management System;
- b) requirements of those interested parties that are relevant to the Feed Safety and Quality Management System. The Operator must monitor and review the information about these interested parties and their relevant requirements;
- c) regulatory requirements and ensure they are met;
- d) risks and opportunities that can affect conformity of products and the ability to enhance customer satisfaction and ensure all these are addressed;
- e) and focus on consistently providing products that meet customer and applicable regulatory requirements and ensure they are maintained.

4.3. Feed Safety and Quality Management System and its processes

The Operator must establish, implement, maintain and continually improve a Feed Safety and Quality Management System, including the processes needed and their interactions, in accordance with the requirements of the FAMI-QS Code.

The Operator must determine:

- a) the processes needed for the Feed Safety and Quality Management System and their application;
- b) the inputs required and the outputs expected from these processes;
- c) the sequence and interaction of these processes;
- d) the criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of these processes;
- e) the resources needed and how they are ensured;
- f) the risks and opportunities in accordance with the requirements, and plan and implement the appropriate actions to address them;

- g) the methods for monitoring, measuring, as appropriate, evaluating processes and, if needed, changes to processes to ensure that they achieve intended results;
- h) the opportunities for improvement of the processes and the Feed Safety and Quality Management System;
- i) and assign responsibilities and authorities for the processes.

The Feed Safety and Quality Management System must ensure that all activities carried out by the Operator that could impact the feed safety and quality of the product are consistently defined, implemented and maintained at all levels.

The Feed Safety and Quality Management System must include documented information that the product consistently conforms to the regulatory requirements of the country of production (where statutorily required) and destination.

4.4. Feed Safety and Quality Management System Documentation

The Operator must have a documented management system which reflects all the aspects of this Code.

Records must contain all relevant data to permit investigation of any nonconformity or deviation(s) from planned procedure(s).

All quality and safety related activities must be recorded immediately after they have been performed. The design and nature of use of records is at the discretion of the Operator.

The Operator's Feed Safety and Quality Management System must include:

- a) Feed Safety and Quality Manual compliant with the FAMI-QS Code Requirements;
- b) documented information determined by the Operator as being necessary for the effectiveness of the Feed Safety and Quality Management System;
- c) a written Feed Safety and Quality Policy;
- d) documented procedures, records and information needed by the Operator to ensure the effective planning, operation and control of its processes and information, including HACCP plans and reviews and product crisis management procedure;
- e) reference(s) to the risk assessments where applicable according to the FAMI-QS requirements addressed in this code.

The Feed Safety and Quality Manual must include quality and feed safety procedures or references in support of the HACCP programme.

The documented information must:

- f) have unambiguous contents: the title, nature and purpose must be clearly stated;
- g) be approved, signed (written or electronically) and dated by appropriate authorised persons. No document must be changed without authorisation and all changes must be recorded;
- h) be controlled and kept up to date;
- i) be available and suitable for use, where and when it is needed;
- j) be adequately protected (e.g. confidentiality status, improper use, or loss of integrity).

Documented information of external origin, determined by the Operator to be necessary for the planning and operation of the Feed Safety and Quality Management System, must be identified, as appropriate, maintained with suitable access rights and controlled.

Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

4.5. Determining the scope of the Feed Safety and Quality Management System

The Operator must determine the boundaries and applicability of the Feed Safety and Quality Management System to establish the concerned scope. The scope must specify the process, the products or product categories and production sites that are covered and addressed by the Feed Safety and Quality Management System.

The scope must not exclude any activities, processes or products when those activities, processes or products are essential and can have an influence on the feed safety and quality of the end products. When exclusions are made, the scope of the Feed Safety and Quality Management System must justify them.

The scope must be available and be maintained as an integral part of the Feed Safety and Quality Manual.

4.6. Feed Safety and Quality Policy

Top management must establish, implement and maintain a Feed Safety and Quality Policy that:

- a) is suitable for the purpose of the operation and the scope;
- b) includes a commitment to provide safe specialty feed ingredients;
- c) includes a commitment to satisfy applicable regulatory requirements;
- d) includes a commitment towards continuous improvement of the Feed Safety and Quality Management System;
- e) includes a commitment to take the necessary actions for preventing fraud/ adulteration;
- f) provides a framework for setting and reviewing feed safety and management objectives.

The Feed Safety and Quality Policy must be:

- g) available as documented information;
- h) communicated within by the Operator in appropriate language;
- i) available to interested parties, as appropriate;
- j) communicated, implemented and maintained at all levels within the organisation;
- k) reviewed at planned intervals (at least yearly), to ensure its continuing suitability, adequacy and effectiveness. Records of this review must be maintained.

5. Leadership

5.1. Leadership commitment and responsibilities

Top management must demonstrate leadership and commitment with respect to Feed Safety and Quality Management System by ensuring that:

- a) the Feed Safety and Quality Policy and Objectives are established for the Feed Safety and Quality Management System and are compatible with the strategic direction and the context of the Operator;
- b) the resources needed for the Feed Safety and Quality Management System are available;
- c) the Feed Safety and Quality Management System achieves its intended result(s);
- d) the Feed Safety and Quality Policy and Objectives direct and support persons to contribute to the effectiveness of the Feed Safety and Quality Management System;
- e) the Feed Safety and Quality Policy and Objectives promote continual improvement;
- f) the Feed Safety and Quality Policy and Objectives support other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility;
- g) the Feed Safety and Quality Policy is communicated, understood and applied by all internal and external parties concerned with the operation(s).

Top Management must ensure that the responsibilities and authorisations for relevant roles within the Feed Safety and Quality Management System are assigned, communicated and understood within the organisation.

The Operator must ensure that:

- h) an organisational chart of the organisation is maintained and made available to the Operator's staff and relevant external bodies;
- i) the job descriptions are available to clearly define the responsibilities of all staff involved in the production, handling, storage and distribution of products covered by the Feed Safety and Quality Management System scope;
- j) responsibility and authority is assigned to ensure compliance with regulatory requirements;
- k) responsibility is assigned in case of a feed safety incident;
- l) adequate resources are provided for the implementation, management and control of the HACCP systems;
- m) a HACCP team leader is appointed;
- n) the problems with regard to the Feed Safety and Quality Management System are identified and corrective actions undertaken;
- o) actions are initiated to prevent the (re-)occurrence of nonconformities related to product's quality and safety.

6. Planning

6.1. Actions to address risks and opportunities

The Operator must monitor and review the information about the external and internal risks and determine the risks and opportunities that need to be addressed, and must plan actions to address these risks and opportunities. The actions must be proportionate to the context of the Operator and the requirements of interested parties. The actions must include the development and implementation of:

- a) good Manufacturing Practices;
- b) HACCP plan and reviews;
- c) emergency preparedness and response plan.

6.2. Feed safety and Quality objectives and planning to achieve them

The Operator must establish Feed Safety and Quality objectives at relevant functions and for relevant processes, throughout the organisation.

The Feed Safety and Quality objectives must:

- a) be consistent with the Feed Safety and Quality Policy;
- b) be measurable, if practicable;
- c) take into account applicable regulatory or contractual requirements;
- d) be monitored in a timely manner;
- e) be communicated;
- f) be updated and revised as appropriate.

Documents relating to the monitoring efforts must be retained.

6.3. Planning of Changes

Where the Operator determines the need for change in the Feed Safety and Quality Management System, the change must be carried out in a planned and systematic manner, according to written procedures. Changes must be approved by authorised personnel.

The Operator must consider:

- a) the purpose of the change and any of its potential consequences;
- b) the integrity of the Feed Safety and Quality Management System;
- c) the availability of resources;
- d) the allocation or reallocation of responsibilities, accesses and authorisations.

7. Good Manufacturing Practices

Where applicable, Good Manufacturing Practices (GMP) must be established and designed before proceeding to the hazard analysis. The Operator must maintain Good Manufacturing Practices to control:

- a) the likelihood of introducing contaminants to the product through the work environment;
- b) the biological, chemical and physical contamination of products, including cross contamination between them;
- c) the levels of contaminants in the final products and processing environment.

The Good Manufacturing Practices must be:

- d) appropriate to the organisation and its context with regard to feed safety;
- e) appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled;
- f) implemented across the entire production system, either as general programmes or as specific programmes for a particular product or operational line.

7.1. Establishment

Establishments must be designed, constructed and maintained in a manner that:

- a) facilitates satisfactory performance of all operations;
- b) eliminates or minimizes to acceptable levels the feed safety hazards associated with those operations;
- c) prevents contamination from the surroundings.

Establishments must be maintained in good order. Establishments must be designed, constructed and maintained to allow adequate drainage and cleaning.

The establishment boundaries must be defined and documented. Access to the establishment must be managed to address feed safety hazards. Access by non-employees must be controlled in a manner depending on the risk to feed safety. Where it is not feasible to control access to the establishment, measures to prevent contamination must be taken.

Access points to bulk material receiving lines must be identified and secured from unintended use, intrusion and contamination.

The Operator must provide appropriate work environment, in line with local regulations, including to achieve product conformity.

The Operator must assess if feed safety hazards may be expected to occur by potential acts of sabotage, vandalism or terrorism and must put in place adequate protective measures.

7.1.1. Local plant environment

Potential sources of contamination from the local plant environment (such as air pollution, contaminated water, soil pollution, dust exposure) must be identified and assessed. Measures taken to protect against potential sources of contamination must be documented and reviewed for effectiveness.

Vegetation must be tended, removed or otherwise managed to address feed safety hazards where relevant.

7.1.2. Layout and workspace

Processes and workspaces must be designed, constructed and maintained to prevent and control feed safety hazards. The establishment must be designed so the movement of materials, end-products and people must not contribute to contamination or hinder feed safety.

Testing areas and laboratories must be designed, located and operated so as to prevent contamination. The lay-out, design, construction of the facilities and equipment must permit adequate cleaning and/or disinfection and be in such way to minimise the risk of error and to avoid contamination, cross-contamination and any generally adverse effects on the safety and quality of the feed.

7.1.3. Internal structures and fittings

Where applicable, process area walls, floors and floor–wall junctions must be cleanable. Structural materials must be resistant to the cleaning system applied. Standing water must be prevented and/or removed.

Openings must be managed to prevent entry of foreign matter, precipitation and pests. This includes external openings for the transfer of materials within the establishment. Roofs in manufacturing and storage locations must be adequately drained and must not leak.

Ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation. Growth of undesirable microorganisms and the shedding of particles that can affect the safety and quality of feed must be kept under control.

Ventilation systems and devices must be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceiling. If necessary to keep rooms free of excessive steam and condensation, mechanical ventilation of sufficient capacity must be provided. If necessary, heating, cooling or air-conditioning systems must be designed and installed so that air-intake or exhaust vents do not cause contamination of products, equipment or utensils.

7.2. Equipment

Equipment must be designed and located to permit access for operation, cleaning and maintenance.

Manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of the products concerned.

Where applicable the equipment must be designed to facilitate manual or *Cleaning In Place* (CIP) and/or disinfection by having surfaces that are smooth, free of sharp angles, corners, crevices and with smooth welds.

Where applicable, equipment must be placed away from walls to allow easy access for cleaning and to prevent pest infestation.

Mobile structures and equipment including those which are used temporarily must be managed to prevent contamination.

7.3. Storage

All storage activities, including owned and contracted storage services, must be controlled. Control measures for the storage must be adequate and documented.

A storage management system must be in place. Deliveries into and loads out of each storage area/bin must be recorded. Where possible, stock rotation systems must be applied (e.g. First In - First Out (FIFO) or First Expired - First Out (FEFO)).

Storage conditions must be appropriate for the intended use of the material. Temperature and humidity and other environmental conditions must be controlled, where necessary.

Storage must provide protection from dust, condensation, waste, pests and other sources of contamination.

Dedicated storage areas for materials that have to be kept dry and appropriately ventilated must be provided. Storing materials directly on the floor must be avoided, if potential contamination is relevant.

Sufficient space (risk based) must be maintained between packaged materials and walls to allow cleaning, inspection and pest control activities to be carried out. Packaging must be fit for purpose.

For bulk – flat stores capable of storing more than one type of feed – bays must be identified and there must be a floor plan of the storage areas.

Materials (i.e. feed, waste materials and hazardous chemicals, pharmaceutical products) with the potential to introduce a hazard must be separated during storage and secured based on suitable risk assessment and management procedure. Nonconforming materials must be identified and separated in a manner to prevent unintended use.

Area for defective or customer returned products must be identified and separated.

Storage areas/bins must be cleaned at planned intervals.

Dispatch area must be secured from material theft, uncontrolled access and contamination.

NOTE: Separation can be managed physically and/or electronically, as appropriate.

7.4. Utilities

The provision and distribution routes for utilities, to and around processing and storage areas, must be designed to prevent contamination.

7.4.1. Water supply

All forms of water, used as a product ingredient or that comes into direct contact with feed or product contact surfaces, must be assessed on potential feed safety hazards.

Facilities for storage and distribution of water must be designed to meet specified water quality requirements.

Use of reclaimed or recycled water must be justified by a risk assessment. Reclaimed or recycled water must have a separate supply system, identified and not connected to, or otherwise prevented from, refluxing into the primary or potable water systems.

7.4.2. Ventilation

Production and storage areas must be appropriately ventilated to prevent contamination. Measures must be taken to remove excess humidity and to facilitate drying after wet cleaning. Ventilation systems, including intake ports and filters, must be inspected and maintained.

7.4.3. Compressed air and other gases

Air and gases that come into direct contact with feed, including those used for transferring, blowing or drying, must be suitable, for example, to prevent contamination.

Gases from combustion intended for direct contact with feed must not be a source of contamination. The fuel used as the combustion source must be fit for purpose.

Oils used in compressors must not compromise product integrity (for example should be of appropriate technical grade, *e.g.* food, if possibility of contact with product could occur).

7.4.4. Lighting

Lighting must be of sufficient intensity to ensure that sanitary conditions can be maintained throughout the production and storage areas, as well as where equipment and utensils are cleaned including hand-washing areas and toilets.

Light fixtures must be designed in such a way to prevent contamination in the case of breakages. Lights must be shatterproof and provisions for glass/brittle registry must be in place.

7.5. Waste disposal

7.5.1. Waste control

Containers for waste must be closed and:

- a) clearly identified for their intended use, marked and designated for that purpose only;
- b) located in a designated area;
- c) designed to be regularly and effectively emptied.

Provision must be made for the segregation, storage and removal of waste. Removal frequencies from production areas must be managed to avoid accumulations. Waste accumulation in general must be limited as it poses a risk of pest infestation. Waste must be managed in a manner that prevents attraction and harbouring of pests.

Materials (bulk or packaged) designated as waste must be disposed of in a manner that prevents unauthorised use. Waste and materials not suitable as feed should be isolated and identified. Any such materials including those containing hazardous levels of veterinary drugs, contaminants or other hazards must be disposed of in an appropriate way and not used as feed.

7.5.2. Drains and drainage

Drains must be designed, constructed and maintained so that contamination is prevented. Drains must flow freely and have sufficient capacity to handle expected loads.

Drains should not leak and be located in such a way that materials would not be contaminated if a leak occurred. Drainage direction must not be from a contaminated area to a clean area.

Sewage, waste and rainwater must be disposed of according to local regulations and in a manner which ensures that equipment and the safety and quality of feed is not affected.

7.6. Equipment suitability

7.6.1. Measuring devices (calibration)

All measuring, metering and dosing devices used in the manufacture of specialty feed ingredients must be fit for purpose.

The Operator must establish processes to ensure that monitoring and measurement can be carried out in a manner consistent with documented procedures and must retain appropriate documented information as evidence of fitness for purpose of monitoring and measurement resources.

Measuring and dosing devices essential to feed safety must be identified and must meet the following conditions:

- a) be calibrated or verified, at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards. Where no standards exist, the basis for calibration or verification must be recorded;
- b) be adjusted or re-adjusted as necessary;
- c) be identified to show the calibration status;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

In case of external calibration the laboratory must be accredited against ISO/IEC 17025 or equivalent. In case of internal calibration all the reference materials must be certified.

In addition, the Operator must assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The Operator must take appropriate action on the equipment and any product that might have been affected. Records of the results of calibration and verification must be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application should be verified. This verification should be undertaken prior to initial use and reconfirmed if necessary. For existing software, verification can be based on legacy data/performance.

If a computer software is used to control a CCP, its ability to satisfy the intended application should be validated.

7.6.2. Maintenance

A documented preventive maintenance programme must be in place and must include manufacturing equipment, and all devices used to monitor and/or control feed safety hazards.

Sanitary requirements must apply to maintenance activities. Maintenance personnel must be trained in the feed hazards associated with their activities.

Maintenance requirements that affect product safety must be given priority. Maintenance activities must be performed in a manner that prevents contamination. Maintenance activities in process areas must be recorded.

A procedure of the release of the equipment under maintenance must exist and must specify cleaning and pre-use inspection measures.

Temporary fixes must not put feed safety at risk. A request for replacement by a permanent repair must be included in the maintenance schedule.

Lubricants and heat transfer fluids must be fit for purpose and meet appropriate statutory requirements, where relevant, wherever there is a risk of direct or indirect contact with feed.

7.7. Measures for prevention of cross-contamination

Programmes must be in place to prevent, control and detect potential cross-contamination.

Where appropriate, a zoning plan (e.g. different levels of sanitation requirements) must be implemented.

Based on risk assessment(s), procedures to prevent potential physical, chemical and/or biological cross-contamination must be implemented. Cross-contamination must be prevented or controlled by use of dedicated lines, cleaning, line changeover practices (such as flushing) and/or product sequencing. Effectiveness of procedures must be verified. Verification that procedures are followed as well as validation studies must be recorded.

7.8. Cleaning and sanitation

7.8.1. Cleaning and sanitizing programmes

Cleaning programmes must be established to maintain sanitary conditions and documented.

Where identified in the risk assessment, sanitizing programmes must be established and documented. Programmes must be monitored for continuing suitability and effectiveness.

Facilities and equipment must be maintained in a condition which facilitates wet or dry cleaning and/or sanitation.

Cleaning, and when applicable, sanitizing programmes must specify, as a minimum:

- a) areas, items of equipment and tools to be cleaned and/or sanitized;
- b) responsibility for the tasks specified;

- c) cleaning/sanitizing agents;
- d) method and frequency;
- e) monitoring and verification.

7.8.2. Cleaning agents and tools

Cleaning agents must be used and stored according to the manufacturer's instructions, clearly labelled, separately stored from raw materials and finished products and applied properly to avoid contamination of raw materials and finished products.

After a wet cleaning procedure, the machinery coming into contact with feed must be dry enough for the next production.

Where appropriate, disinfection may be necessary after cleaning, but traces of detergents and disinfectants must be minimised.

Chemicals that are strongly scented or could give rise to taint and odour contamination must not be used.

Materials and equipment used for cleaning toilets must be segregated from those used elsewhere.

7.9. Pest control

Sanitation, cleaning, incoming materials inspection, storage and monitoring procedures must be designed and implemented to avoid creating an environment conducive to pest activity.

Feed production and storage buildings must be maintained in a manner to prevent pest access. Windows and other openings must, where necessary, be proofed against pests. Doors must be close-fitting and proofed against pests when closed.

Storage and material handling practices must be designed to avoid the availability of feed and water to pests. Spilled materials and waste must be efficiently managed to prevent availability to pests.

A preventive pest control programme must be maintained at manufacturing, storage and transport facilities under the Operator's control. Pest control programme must have description of periodic reviews including physical inspections and their frequency of inspections must be determined by risk assessment and must be documented. The pest control programmes must be clearly defined and reflect the activities of the site, targeted pests, preventive plans to control and control procedures for prevention. The pest control programme must be reviewed for effectiveness.

The HACCP plan must consider the risk of contamination due to infestation or use of pesticides.

The results of the pest control must be regularly reviewed and necessary actions taken.

Pest monitoring programmes must include the placing of pest control devices in key locations to identify pest activity. A map of pest control devices must be maintained. Pest control devices must be designed and located so as to prevent potential contamination of materials, products, equipment or facilities.

Control and/or eradication measures must be put in place immediately after evidence of infestation is reported. Pesticide use and application must be restricted to trained staff and must be controlled to avoid feed safety hazards.

Records of pesticide use must be maintained to show the type, quantity and concentrations used, where, when and how applied, and the target pest.

7.10. Personnel hygiene

Requirements for personal hygiene and behaviour must be established and documented. All personnel, visitors and contractors must be required to comply with the documented requirements.

7.10.1. Personal behaviour and cleanliness

A documented procedure must describe required personal behaviour. The procedure must, as a minimum, cover:

- a) permissibility of eating, drinking, gum chewing and tobacco use in designated areas. All human food must be stored, prepared and consumed in designated areas;
- b) control measures to avoid hazards presented by jewellery and other items carried by a person;
- c) staff hygiene, sanitary facilities and toilets must be available, clearly designated and maintained;
- d) permissibility of personal items, such as smoking materials and medicines, in designated areas;
- e) availability of separate lockers for private cloths and working cloths to avoid a contamination. Maintenance of the personal lockers so that they are kept free from rubbish and in an acceptable state;
- f) instructions on unacceptable behaviour. These include sneezing or coughing over open product or product contact surfaces and no spitting allowed. Fingernails must be kept clean and trimmed.

Staff in feed production and storage areas must maintain personal hygiene to prevent contamination. Hand washing must be conducted before starting any working shift, after using the toilet and immediately after handling different products and or potential contaminants that could lead to a feed safety risk.

7.10.2. Clothing and protective equipment

The Operator must provide staff who work in areas where feed is handled, with appropriate workwear such as protective clothing, safety footwear and other protective equipment that does not pose a feed safety risk. If gloves are worn, control is needed to ensure that there is no risk of contamination of the finished product from them. Clothing and protective equipment must be maintained in hygienic conditions.

The Operator must define appropriate dress code for visitors and contractors.

7.10.3. Health status

Operator must have a written procedure regarding management of illness and open wounds of staff.

Where permitted by law, staff must inform the Operator of any condition, disease or illness that may be transmissible through feed, in order to possibly be prevented from handling feed and production contact surfaces.

The Operator must inform visitors and contractors about hygiene and health requirements before being allowed into feed production and storage areas.

7.11. Transport

An Operator must include the below stated requirements in their communication with the transporters.

7.11.1. Driver Responsibility

The haulier must ensure that the driver in charge of transport:

- a) is aware of her/his responsibility in terms of product preservation during cleaning, loading, transport and unloading activities;
- b) if necessary, takes preventive actions to avoid any kind of contamination during cleaning, loading, transport and unloading activities;

- c) informs the Operator as agreed, directly or via own organisation, of any nonconformity that could compromise the safety of the goods.

The haulier must document and maintain evidence of education and training of driver personnel.

7.11.2. Transport of packed goods

Transports should be fit for purpose. Products must not be transported, even if sealed, with goods that might compromise the safety of the raw material or the finished product. The chosen transport vehicle must be designed to protect the packaged goods against adverse effects (e.g. humidity, scratches in package).

The transport vehicle must be designed to avoid any risk of cross-contamination with impurities coming from other goods loaded on the same vehicle at the same time or in a previous loading.

7.11.3. Transport of bulk products

1) Prerequisites

The haulier must ensure that the containers for transport:

- a) can be effectively cleaned and maintained to avoid contamination of the feed. This applies in particular to materials and surfaces which come into direct contact with feed;
- b) are in good technical condition;
- c) are appropriate for the intended use and function;

When transport requirements are changed, the haulier must ensure that:

- d) relevant documents are amended;
- e) relevant persons, including the Operator's representative, are made aware of the changes made to documents and associated requirements.

2) Cleanliness and contamination prevention

Before loading takes place, the container must be: empty, clean, odourless and dry (especially where solid or powdery product(s) is/are to be loaded). Preload restrictions must be observed.

The discharge equipment must be clean and this includes piping, hoses and pumps on vehicles, where applicable.

NOTE: Four basic principles can be distinguished with respect to cleaning and disinfection: dry cleaning, cleaning with water, cleaning with water and cleansing agent and disinfection immediately or after one of the previous cleaning regimes. The choice of a minimum necessary cleaning regime is established on the basis of the characteristics of the previous product. If the loading compartment is not clean after the chosen cleaning regime, additional cleaning must take place and the choice of cleaning regime must be reconsidered.

3) Traceability of containers and loads

For each delivery the haulier must:

- a) record the previous load-product information, including associated container identification, as well as any associated cleaning operations;

- b) record the loaded product information, including associated container identification;
- c) keep the recorded information available for an appropriate period of time.

7.12. Feed packaging information and customer communication

Information on content and intended use of feed products must be communicated to customers (via label or any other written document accompanying the goods) to ensure proper and safe use. Procedures must be in place detailing the correct labelling of products. Nonconforming or expired labels must be managed in a manner to prevent unauthorised use.

Label must fulfil the legal requirements of the country of the destination. A process to obtain the necessary documented information for the content of the label must be in place.

7.13. Competence and training

The Operator must:

- a) determine the necessary competence of staff involved in feed safety and quality management and the general operations;
- b) ensure that the staff is competent on the basis of appropriate education, training, periodic retraining or experience and, where necessary, evaluate the effectiveness of any training undertaken;
- c) ensure that the staff is trained in the relevant policies and procedures of the Feed Safety and Quality Management System;
- d) document, maintain and retain appropriate documented information as evidence of competence.

7.14. Awareness

Relevant staff must be aware of:

- a) their contribution to the effectiveness of the Feed Safety and Quality Management System, including the benefits of improved safety performance;
- b) the implications of not conforming with the Feed Safety and Quality Management System requirements.

7.15. Communication

The Operator must consider the need for both internal and external communications relevant to the Feed Safety and Quality Management System. Responsibility for communication must be established.

7.16. Complaint handling system

A formalised documented procedure on complaint handling must:

- a) allocate responsibility for controlling and adequate follow up of complaints;
- b) unequivocal tracking of each complaint;
- c) record name of complaining customer;
- d) record product name and identification code;
- e) reason for complaint;
- f) identify and record each complaint;

- g) reply to the complaining customer;
- h) identify if other customers could be involved.

Corrective actions must be carried out in a timely and effective manner, with consideration given to the frequency and seriousness of complaints.

Where possible, complaint information must be used to avoid recurrence and implement ongoing improvements.

7.16.1. Feed Safety Incident Communication (Crisis Management)

If an Operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the defined feed safety or statutory requirements, it must immediately initiate procedures to recall the feed in question from the market and inform the competent authorities, if applicable. It is required that:

- a) the crisis management procedure is documented and meets the requirements of the FAMI-QS Feed Safety Incident Procedure;
- b) the responsibility is defined for notifying customers and regulatory authorities (where applicable);
- c) the responsibility within the operation for product recall(s) is defined;
- d) the test of the Feed Safety Incident Communication is performed at regular intervals, defined by the company, and documented.

NOTE 1: A crisis may result in a Rapid Alert situation (RASFF or equivalent) or originate from such.

7.16.2. Recall procedures

Systems must be in place in such way that products failing to meet the required Feed Safety standards can be identified, located and removed from all necessary points of the supply chain. A documented product recall programme must be established and maintained, including a list of internal and external key contacts.

Where products are withdrawn due to immediate health hazards, the safety of other products produced under the same conditions must be evaluated. The need for public warnings, notification of customers, and/or regulatory authorities must be considered.

The product recall programme must be evaluated periodically to ensure effectiveness. Records must be maintained.

8. Operation

8.1. Operational planning and control

The Operator must plan, implement and control the processes needed to meet requirements, and to implement the actions determined in the Feed Safety and Quality Management System, by:

- a) establishing criteria for the processes;
- b) implementing control of the processes in accordance with the criteria;
- c) keeping documented information, to the extent necessary, to have confidence that the processes have been carried out as planned.

The Operator must control planned changes, including relevant updates of the HACCP programme, and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

8.2. Determination of requirements for products

The Operator must determine:

- a) the statutory and regulatory requirements related to the product;
- b) the requirements specified by the customer, including requirements related to delivery and post-delivery activities;
- c) the requirements not stated by the customer but necessary for specified or intended use, where known;
- d) the contract or order requirements differing from those previously expressed.

The Operator must determine and implement effective arrangements for communicating with customers in relation to product information, enquiries, contracts or order handling, customer feedback, including complaints, and crisis management.

A review must be conducted prior to the Operator's commitment to supply products to the customer and must ensure contract or order requirements differing from those previously defined are resolved.

Where requirements for products are changed, the Operator must ensure that relevant documented information is amended and that relevant staff is made aware of the changed requirements.

8.3. Design and development of products

The Operator must establish, implement and maintain a design and development process. A design and development process must be established also in the case that the already existing requirements of the product change.

The safety of products must be assured during the developmental stages of a new product through application of HACCP principles.

The Operator must plan and control the design and development of products or processes, with clearly identified requirements. The development plan must consider risks related to feed safety and quality. The Operator must ensure new developments are fit for intended purpose and their safe and proper use, and conforms to specified requirements. Design and development process is applied to any new ingredient/product or any change to an existing ingredient/product.

The Operator must retain the documented information resulting from the design and development process.

8.3.1. Design and development planning

In determining the stages and controls for design and development, the Operator must consider:

- a) the nature, duration and complexity of the design and development activities;
- b) the requirements that specify particular process stages, including applicable design and development reviews;
- c) the required design and development verification and validation;
- d) the responsibilities and authorities involved in the design and development process;
- e) the need to control interfaces between individuals and parties involved in the design and development process;
- f) the need for involvement of customer and user groups in the design and development process;
- g) the necessary documented information to confirm that design and development requirements have been met.

8.3.2. Design and development Inputs

The Operator must determine:

- a) requirements essential for the specific type of products and services being designed and developed, including, as applicable, functional and performance requirements;
- b) applicable statutory and regulatory requirements;
- c) standards or codes of practice that the Operator has committed to implement;
- d) internal and external resource needs for the design and development of products and services;
- e) the potential consequences of failure, due to the nature of the products and services;
- f) the level of control expected of the design and development process by customers and other relevant interested parties.

Inputs must be adequate for design and development purposes, complete, and unambiguous.
Conflicts among inputs must be resolved.

8.3.3. Design and development controls

The controls applied to the design and development process must ensure that:

- a) the results to be achieved by the design and development activities are clearly defined;
- b) design and development reviews are conducted as planned;
- c) verification is conducted to ensure that the design and development outputs have met the design and development input requirements;
- d) validation is conducted to ensure that the resulting products are capable of meeting the requirements for the specified application or intended use (when known).

8.3.4. Design and development outputs

The Operator must ensure that design and development outputs:

- a) meet the input requirements for design and development;
- b) are adequate for the subsequent processes for the provision of products and services;
- c) include or reference monitoring and measuring requirements, and acceptance criteria, as applicable;
- d) ensure products to be produced, or services to be provided, are fit for intended purpose and their safe and proper use.

The Operator must retain the documented information resulting from the design and development process.

8.4. Change control

Any change after the development process and the placing of the product on the market must be reviewed, controlled and approved before implementation, to ensure that there is no adverse impact on product safety and conformity to requirements.

Following the establishment of the Good Manufacturing Practice (GMP) and HACCP plan, the Operator must update these documents with following information, if necessary, in case of a change:

- a) characteristics of raw materials, ingredients and product-contact materials;
- b) characteristics of end products;
- c) intended use;
- d) flow diagrams, process steps and control measures.

Records of the results of the review and any necessary actions must be maintained.

8.5. Control of externally provided products and services

The Operator must identify externally provided processes, products, and services, which may have an impact on feed safety and quality, and ensure that they conform to specified requirements.

The Operator must communicate to external providers, applicable requirements related to the product, process or services and to the FAMI-QS Code. Those requirements must be mutually agreed, approved and documented.

The Operator must establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers based on their ability to provide processes or products and services in accordance with specified requirements, based on this document.

The Operator must retain appropriate documented information of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers.

8.5.1. Type and extent of control of external provision – Contract Manufacturers

Processes or functions of the Operator which have been outsourced to a contract manufacturer remain within the scope of the Operator's Feed Safety and Quality Management System. The Operator must define both the controls it intends to apply to the contract manufacturer and those it intends to apply to the resulting output.

The Operator has to demonstrate that it exercises sufficient control to ensure that the process is performed according to the relevant requirements of FAMI-QS, and any other requirements of the Operator's Feed Safety and Quality Management System.

There are two situations that frequently need to be considered when deciding the appropriate level of control of an outsourced process:

- a) When the Operator has the competence and ability to carry out a process, but chooses to outsource that process (for commercial or other reasons). In this situation the process control criteria must already have been defined, and can be transposed into requirements for the supplier of the outsourced process, if necessary.
- b) When the Operator does not have the competence to carry out the process itself, and chooses to outsource it. In this situation the Operator has to ensure that the controls proposed by the supplier of the outsourced

process are adequate. In some cases, it may be necessary to involve external specialists in making this evaluation.

If the contract manufacturer is not FAMI-QS certified or is not certified by any other recognized standard, the Operator must evaluate the risk associated to the Operator's product and perform an audit, in order to ensure that the contract manufacturer meets the FAMI-QS requirements.

Thus, the Operator must audit the establishment of the contract manufacturer against FAMI-QS requirements. The audit must be performed by an appropriately trained auditor. A report must be written and accessible.

During the Operator's certification and surveillance audits, the Certification Body must check the audit report of the contract manufacturer, and if deemed necessary also audit the external contract manufacturer.

If the contract manufacturer is certified according to FAMI-QS or to a recognized feed, food or pharmaceutical standard, no additional FAMI-QS audit by the Operator may be required, as long as the applicable product falls under the scope of that certification.

Note: Adequate training of auditor normally includes knowledge in the FAMI-QS code, auditing techniques and the scope of the external provider (process, product or service).

8.5.2. Purchased materials

Purchasing of materials must be managed in such a way that the suppliers used have the capability to meet specified feed safety and quality requirements.

The compliance of incoming materials to specified purchase requirements must be verified.

8.5.3. Selection and management of suppliers

The Operator must define a process for the selection, approval and monitoring of suppliers. The Operator must evaluate and select suppliers based on their ability to supply products in accordance with the Operator's requirements. The Operator must maintain a list of internally approved suppliers including the purchased raw material and their status as assured or non-assured.

If a supplier is not FAMI-QS certified or is not certified by any other recognized standard, it is considered a non-assured source. On the contrary, if it is FAMI-QS certified or certified by any other recognized standard, it is considered an assured source.

NOTE: To verify which standards are recognized by FAMI-QS, please consult the Document INF-SUP-01 (*under revision*).

Each supplier, either assured or non-assured, shall be subject to periodical review. The Operator must define the intervals for the supplier evaluation based on its own risk assessment.

The raw materials that enter the production process must be defined according to both their type and their use. The following information must be documented for each raw material:

- a) specification for the purchased product;
- b) product description;
- c) method of production;
- d) analytical characteristics;
- e) details of any undesirable substance with which the raw material may be typically associated, appropriate certification and any other hazards or limitations associated with the raw material, which have been considered in the Operator's HACCP system, etc.

Selection and approval of all raw materials shall also include their origin, transport, storage, processing and handling. Feed safety-related acceptance criteria or specifications of purchased materials and ingredients must be appropriate to their intended use.

The Operator must:

- f) record any relevant analytical and monitor results and records of the evaluations on the supplier and necessary actions arising from that evaluation;
- g) establish a process to provisionally qualify supplier in emergency situations.

In case the supplier is a non-assured source, an audit at the supplier's premises is required, in addition to the above requisites. In that case, the audit needs to be conducted at least within six months after the raw material's delivery. Operators shall present a realistic audit plan for their non-assured suppliers. They have to audit all their suppliers at least once, during the three years of the certification cycle.

As an alternative to the audit of a non-assured supplier, the Operator must perform a separate risk assessment based on the criteria described on this chapter (8.5.3 (a-g)), which must justify the use of the raw material, without a FAMI-QS audit, at the supplier's production location.

The auditor shall assess the implementation of the suppliers' audit programme and/or the risk assessment.

8.5.4. Verification of incoming materials

Each batch entering the site must be uniquely registered by means of a batch number, full name of product, date of receipt, quantity received as well as manufacturing and/or expiry date. Any damage must be reported to an appropriate responsible unit, e.g. the quality assurance and procurement unit.

Incoming materials must be checked and formally approved prior to use, according to written procedures. In case of hazardous raw materials used in the process, health and safety risks must be taken into consideration.

If the incoming material is delivered in bulk, a receipt and storage procedure must be in place and necessary checks performed before unloading.

Where appropriate, a retention sample of adequate size must be retained for the duration of the shelf life of the raw material concerned, either at the supplier or the Operator's facilities. The samples must be appropriately stored, in a manner that must maintain the integrity of the product.

Handling of incoming materials must be in accordance with its status and storage conditions. For example, a received material which is deemed unfit for use must be identified as such and segregated from those materials released for use.

If incoming materials are rejected and thus not incorporated because of noncompliance with the specification or for any reason related to product quality and safety, their disposal, destination or return to supplier must be recorded.

8.5.5. Production of finished goods

The Operator must, when appropriate, implement and document controlled conditions for production, including process validation, delivery and post-delivery activities. This must include the implementation of the HACCP plan for feed safety.

8.5.6. HACCP Programme

The Operator must establish, implement and maintain a HACCP plan.

The HACCP plan 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.

The Operator must use the guidance for application of HACCP provided in the *Codex Alimentarius* Guidelines.

The implementation of the HACCP must follow the applicable FAMI-QS Process Documents, depending the scope of the Feed Safety Management System.

Note: HACCP for Feed Safety must be approached from the perspective of animal and human health.

8.5.6.1. Determination of critical limits for critical control points and monitoring

Critical limits must be determined for the monitoring established for each CCP. 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.

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.

8.5.6.2. HACCP team leader

The HACCP team leader must:

- a) appoint 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 and suitability of the Feed Safety and Quality Management System.

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.

8.6. Control of Production

The Operator must plan and carry out production under controlled conditions.

Controlled conditions must include, as applicable:

- a) the availability of information that describes the characteristics of the finished product;
- b) a written specification, which is amended when any change takes place for each product;
- c) a unique name or code for each product;
- d) details of packaging and labelling. Product labelling must be in accordance with the relevant feed legislation;
- e) for each packaged unit: labelling in order to allow traceability to the batch to which it belongs, if necessary, identified with a unique code (or combination of codes);
- f) production being carried out according to written procedures aimed at defining, controlling and monitoring the critical points in the manufacturing process. These must include procedures to address the risk of carry-over, if applicable;
- g) inspection of all finished products prior to dispatch, in accordance with written procedures, to ensure they meet specification;
- h) Retention sample must be kept for a minimum the shelf life of the product.

8.6.1. Identification and traceability

To ensure traceability, the Operator must:

- I. identify and record the process output by suitable means throughout product realisation;
- II. retain any documented information necessary to maintain traceability, including but not limited to:
 - a) the names and addresses of manufacturers of incoming materials, specialty feed ingredients or intermediates (including batch number information);
 - b) the flow of materials within its control in a manner which meets the objectives of the traceability system;
 - c) the nature and quantity of the products produced;
 - d) the respective dates of manufacture and, where appropriate, the number of the batch;
 - e) the names and addresses of the intermediaries, manufacturers or users to whom products have been delivered.

The Operator must identify the relevant regulatory and policy requirements (if applicable) to be met by its traceability system.

The traceability system must be verifiable and the Operator must establish a monitoring scheme for the traceability system.

NOTE 1: Process outputs are the results of any activities which are ready for delivery to the Operator's customer or to an internal customer (e.g. receiver of the inputs to the next process); they can include products, services, intermediate parts, components, etc.

NOTE 2: Operator must define the batch according to the specificity of his process (batch or continuous production).

8.6.2. Preservation of product

The Operator must establish the shelf life of a product and preserve the conformity of the product during production, to the extent necessary to maintain conformity to the requirements.

Preservation measures must include product identification, handling, packaging, storage and protection.

8.6.3. Post-delivery activities

The Operator must meet requirements for post-delivery activities associated with the products.

In determining the extent of post-delivery activities that are required, the Operator must consider:

- a) the risks associated with the products;
- b) the nature, use and intended lifetime of the products;
- c) customer feedback;
- d) statutory and regulatory requirements.

NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services and supplementary services such as recycling or final disposal.

8.6.4. Release of products

The Operator must implement the planned arrangements at appropriate stages to verify that product requirements have been met. Evidence of conformity with the acceptance criteria must be retained.

The release of products to the customer must not proceed until the planned arrangements for verification of conformity have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

Documented information must provide traceability to the person(s) authorising release of products for delivery to the customer.

If appropriate, an authorised document should be provided stating the compliance of the delivered batch with the agreed requirements, such as Certificate of Analysis.

8.6.5. Control of nonconforming process outputs and products

The Operator must ensure that process outputs/products that do not conform to the requirements are identified and controlled, to prevent their unintended use or delivery.

The Operator must establish a documented procedure for dealing with products which do not comply with intended requirements.

The procedure must include:

- a) identification of product and batch code;
- b) documentation of any nonconformity, corrective action(s) and verification steps;

- c) evaluation of the cause of the nonconformity, including other potentially affected batches;
- d) segregation of affected batch or batches;
- e) provision for disposal, reprocess or rework of products where appropriate;
- f) verification of conformity to the requirements after correction, if applicable;
- g) informing the customer and obtaining authorisation for release, following corrective actions, or release certain provisions, where applicable.

Responsibility for review and disposal of the nonconforming product must be defined.

The Operator must take appropriate corrective action based on the nature of the nonconformity and its impact on the conformity of products. This applies also to nonconforming products detected after delivery of the products.

The Operator must retain documented information of actions taken on nonconforming process outputs and products, including any concessions obtained and the person or authority that made the decision regarding dealing with the nonconformity.

8.6.5.1. Rework

The approval and use of reworks (e.g. from rejects, customer returns or spillage) must be considered within the HACCP plan.

Rework must be managed in such a way that feed safety, quality and traceability are not compromised. Rework management must include criteria and conditions for acceptance, storage, identification, traceability and processing. Product returned from distribution must be assessed for feed safety hazards and handled accordingly. Defective products must be stored separately and secured.

9. Performance Evaluation

9.1. Monitoring

The Operator must determine:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis, evaluation and verification, as applicable, to ensure validated results;
- c) when the monitoring and measuring must be performed;
- d) when the results from monitoring and measurement must be analysed and evaluated.

The Operator must retain appropriate documented information as evidence of the results.

9.2. Internal audit

The Operator must conduct internal audits, at planned intervals, to provide information on whether the Feed Safety and Quality Management System:

I. conforms to:

- a) the Operator's own requirements for its Feed Safety and Quality Management System;
- b) the requirements of the FAMI-QS Code;
- c) regulatory and other defined requirements.

II. is effectively implemented and maintained.

The Operator must:

- d) have a documented program that plans, establishes, implements and maintains an audit programme including the frequency, methods, responsibilities, planning requirements, scope & criteria and reporting, which must take into consideration the importance of the processes concerned and the results of previous audits. The audit programme may be used to identify potential opportunities for improvement;
- e) select trained, competent and independent auditors to conduct audits in order to ensure the objectivity and the impartiality of the audit process;
- f) ensure that corrective actions are scheduled and verified when completed;
- g) retain documented information as evidence of the implementation of the audit programme and the audit results.

9.3. Management review

Top management must review the Operator's Feed Safety and Quality Management System, at planned intervals (at least yearly), to ensure its continuing suitability, adequacy and effectiveness. Records of this review must be maintained.

The management review must take into consideration:

- a) the status of actions from previous management reviews;

- b) changes in the relevant external and internal risks and the need to update or change the Feed Safety and Quality Management;
- c) information on the Feed Safety and Quality Management System performance, including but not limited to trends in:
 - i. recalls, nonconformities, customer complaints and corrective actions;
 - ii. monitoring and measurement results;
 - iii. audit results;
- d) the opportunities for continual improvement;
- e) the need for updating the Feed Safety and Quality Policy.

The results of the management review must include decisions related to continual improvement opportunities and any need for changes to the Feed Safety and Quality Management System. Decisions to change any aspect of the Feed Safety and Quality Management System must be communicated to key staff.

The Operator must retain documented information as evidence of the results of management reviews.

10. Improvement

10.1. Nonconformity and corrective action

When a nonconformity occurs, the Operator must:

- a) react to the nonconformity as appropriate;
- b) evaluate the need for action to eliminate the immediate causes of the nonconformity, in order that it does not recur or occur elsewhere;
- c) implement any action needed, including short/ long term corrective and preventative actions, as well as changes to the Feed Safety and Quality System, where applicable;
- d) document any actions or solutions;
- e) communicate solution(s) internally and/or externally, if applicable;
- f) review the effectiveness of any corrective action(s) taken.

Corrective actions must be appropriate to the severity of the nonconformities encountered.

The Operator must retain documented information as evidence of actions taken and their effectiveness.

10.2. Continual improvement

The Operator must continually improve the suitability, adequacy and effectiveness of the Feed Safety and Quality Management System. This should not be limited to the Feed Safety and Quality objectives.

Evidence of continual improvement activities must also be documented to enable the revision by any relevant third parties.