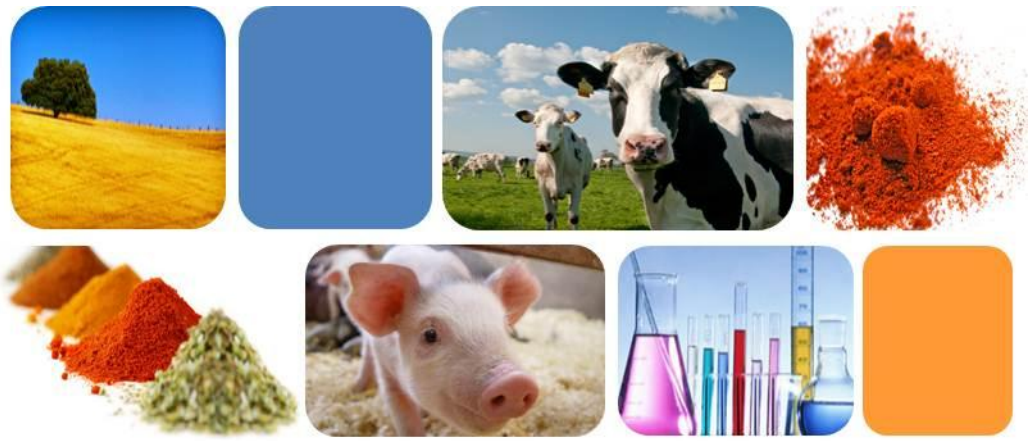
EUROPEAN CODE OF GOOD PRACTICE FOR FEED ADDITIVES AND PREMIXTURES OPERATORS



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EUROPEAN CODE OF PRACTICE
FOR FEED ADDITIVES AND PREMIXTURES OPERATORS

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1 INTRODUCTION

This European Code of Practice for Animal Feed Ingredients Operators ('**Code**') is in line with the Regulation of the European Parliament and the Council laying down requirements for feed hygiene, (Regulation 183/2005/EC), in particular articles 20 to 22 which encourage the development of guides to good practice on hygiene and the application of HACCP principles.

Implementation of the Code aims to encourage measures to be put in place to ensure the safety and quality of products covered by FAMI-QS scope; the operation of businesses in accordance with European feed hygiene requirements, and improved traceability. The Code applies equally to import from third countries of these products.

The combination of the above principles provides guidance for feed business Operators in implementing the measures necessary to ensure feed safety in European and International manufacturing and trade.

In the exceptional case, where a direct or indirect risk to human or animal health is related to a product manufactured and marketed under the Code, the information and recall procedures (including the rapid alert system) defined in Regulation (EC) 178/2002 shall apply.

The text of the Code is designed to set out general requirements and to be used by Operators as a tool to develop their own procedures.

A compilation of Guidance is provided as annex to the Code. This covers topics of special importance. While the requirements of the Code are mandatory for every Operator, the Guidance provides information on how to deal with specific issues in a more detailed and practical way and may serve as further supporting information to the Code. If the Operator decides to follow the procedures described in the Guidance, this will become a part of its Feed Safety Management System. In case that, for good reasons, different procedures are used, the Operator must be able to provide evidence upon request that they comply with the requirements of the Code as well.

Both the Code and Guidance will be submitted to periodical review in line with emerging/new relevant technological, scientific and legislative developments or statutory modification in the sector.

The aim of this European Code of Practice is to ensure feed safety by:

- minimizing the risk that unsafe ingredient(s) enter the feed/food chain;
- enabling an Operator to implement the objectives of the Feed Hygiene Regulation (Regulation (EC) 183/2005); and
- providing measures to ensure that other feed safety regulatory requirements are met.

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.

This Code shall apply to Operators at all stages of feed production from the first placing on the market based on current EU legislation. Therefore it also applies to the placing on the market after import from third countries.

Compliance with FAMI-QS does not exonerate the Operator from meeting the statutory or regulatory requirements in each country in which the Operator is active. The regulatory status of feed additives can be checked on the Register of Feed Additives published and frequently updated by the European Commission:

http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives_1831-03.pdf

Note: FAMI-QS Code of Practice is a public document and its contents can be freely followed by any Feed Business Operator.

Running side by side with the Code, FAMI-QS Asbl has developed a parallel and independent certification system that is described in the Rules for Certification documents (Rules for Certification Bodies – Rules for Operators). Participation in the FAMI-QS auditable system is based on voluntary commitment.

Please, consult the FAMI-QS web-page www.fami-qs.org to have access to these documents and learn more about how to ensure compliance with this Code of Practice.

2 SCOPE

The FAMI-QS scope is described in the last version of the Scope Description Document P-SCD-01.

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).*

Agent: An individual or firm authorised to act on behalf of an Operator such as by executing commercial transactions without ever taking legal responsibility of the product and the way it is supplied and provided into the feed chain.

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 feed additive 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 (EC) 767/2009)*

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*)

CIP: Cleaning-in-place.

Code of Practice: Document identifying the principles of feed hygiene essential to ensure the safety of feed for animals and in turn the safety of animal products intended for human consumption.

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 (EC) 767/2009)*

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)*

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 non-conformity or other undesirable situation. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. *(ISO 22000:2005)*

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

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 feed business Operator. *(synopses from articles 15 & 19, Regulation (EC) 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)*

Critical Limit: a criterion that separates acceptability from unacceptability *(Codex Alimentarius)*.

EC: European Commission

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).*

Export: The release for free circulation of a product or the intention to release a product for free circulation into a non EU member state, which is manufactured in an EU member state.

Feed: Any substance or product, including feed additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals *(Regulation 178/2002)*.

Feed additives: Substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions *(Regulation 1831/2003/EC and Regulation 183/2005/EC)*:

- favourably affect the characteristics of feed;
- favourably affect the characteristics of animal products;
- favourably affect the colour of ornamental fish and birds;
- satisfy the nutritional needs of animals;
- favourably affect the environmental consequences of animal production;
- favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs; or
- have a coccidiostatic or histomonostatic effect.

Feed business: Any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer manufacturing, processing or storing feed for feeding to animals on his own holding. *(Regulation178/2002/EC and adapted).* See '*Stages of production, processing and distribution*'

Feed business 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. *(Regulation178/2002/EC and adapted).* See '*Feed business*'.

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

Feed material: Various products of vegetable or animal origin,whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the

industrial processing thereof. Organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal feeding either directly as such, or after processing, or in the preparation of compound feed, or as carriers of premixtures. *(Regulation 767/2009/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 Code, the word '*Safety*' is taken to have the same meaning as '*Feed Safety*'.

First placing on the market: The initial placing on the European Union market of feed ingredient(s), an additive, premixture or products covered by FAMI-QS scope after its manufacture or the import of an additive or premixture. See '*placing on the market*'. *(Regulation 1831/2003/EC and adapted)*

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

HACCP (Hazard Analysis and Critical Control Point): A system which identifies, evaluates, and controls hazards to feed 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 shall be addressed in the HACCP plan. *(Codex Alimentarius)*

Hazard: Biological, chemical or physical agent in the feed chain with the potential to cause an adverse health effect for animals or consumers. *(Regulation178/2002/EC)*

Homogeneity: The degree to which a property or a constituent is uniformly distributed throughout a quantity of material. *(PAC; 1990)*

Import: The release for free circulation of a product or the intention to release a product for free circulation into an EU member state, which is manufactured in a non EU member state. *(Regulation 882/2004/EC and modified)*

Incoming material: A general term used to denote raw materials delivered at the beginning of the production chain (*e.g.* reagents, solvents, processing aids, feed materials, feed additives, premixtures and products covered by FAMI-QS scope).

Intermediate (product): Any material which has been 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*).

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

Minerals: Feed materials may include minerals mentioned in Annex Part B, chapter 11, of Directive 96/25/EC *(amended by Directive 98/67/EC)*.

MS: Management System

Operator: See '*feed business Operator*'.

Placing on the market: Holding products for the purposes of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of

transfer themselves. *(Regulation178/2002/EC)* (See '*first placing on the market*').

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

Premixtures: Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals. *(Regulation 1831/2003/EC).*

Prerequisite Programs (PRPs): Basic conditions and activities which are necessary to maintain a hygienic environment throughout the feed/food chain suitable for the production, handling and provision of safe end products. Specified procedure(s) or instruction(s), specific to the nature and size of the operation, that enhance and/or maintain operational conditions to enable more effective control of feed safety hazards, and/or that control the likelihood of introducing feed safety hazards to and their contamination or proliferation in the product(s) and product processing environment. Alternative terms for PRPs may be used. For instance, the terms Good Manufacturing Practice (GMP), Good Agricultural Practice (GAP) and Good Hygienic Practice (GHP). *(ISO 22000:2005 and adapted)*

Preventive Action: Action to eliminate the cause of a potential non-conformity 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)*

Processing aids: Any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technological unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have any adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed. *(Regulation 1831/2003/EC)*

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

Quality Manual: Document specifying the quality management system of an organisation. *(ISO 9000:2005)*

Raw material: Any material which enters the manufacturing process of the feed additive and/or premixture and/or products covered by the FAMI-QS scope. See '*Incoming Material*'.

Recall: Any measure aimed at achieving the return of a an unsafe feed that has already placed on the market by a feed business 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 No 2001/95/EC and Regulation 178/2002)*

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

Requirement: need or expectation that is stated, generally implied or obligatory. (*ISO 9000:2005*)

Reworking / rework: Any appropriate manipulation steps in order to ensure that a product covered by FAMI-QS scope will conform to specifications. Action on a non-conforming 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*'.

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

Shall: Compliance with a requirement which is mandatory for compliance with this standard (Obligation to follow the exact requirement as stated by this Code).

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).

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

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 shall 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*).

Subcontractor / Subcontracting: The delivery of a service, pertaining to the product, provided by a third party to the Operator where no change in ownership of the product takes place.

Sufficient: See "*Adequate*".

Stages of production, processing and distribution: Any stage, including import, from and including the primary production of a food, 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)*

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*".

Written documents: Paper printed documents. These may be substituted by electronic, photographic, or other data processing systems provided that the data will be appropriately stored during the anticipated period of storage (archive) and can be made readily available in a legible form.

4 MANAGEMENT SYSTEM (MS)

4.1. General requirements

The Operator shall establish, document, implement and maintain a management system (MS) in accordance with the requirements of this Code.

The MS shall be continually adapted in line with regulatory developments and customer requirements.

The structure of the MS shall be specific to the organisation of the Operator and shall includes policies, requirements and process documents that reflect commitment to feed safety.

The MS shall ensure that all activities carried out by the Operator that could impact on the quality and feed safety of the product are consistently defined, implemented and maintained at all levels in the organisation.

The MS shall include quality procedures to ensure that the product consistently conforms to the authorisation of the feed additive and the specification of the premixture(s) as the other products covered by FAMI-QS scope thereof.

Ensure that:

- *A documented MS is in place;*
- *The MS includes regulatory, safety and customer requirements;*
- *The MS is covering all the Operator's activities;*
- *Other activities are not conflicting with the feed safety requirements.*

4.2. Management Principles

Operators shall be able to demonstrate that its employees are aware of their contribution to feed safety and relevant EU legislation associated to their various tasks.

Each Operator shall perform and record the evaluation of risks associated with processes within his operations and subsequently define controls to be applied to these based on HACCP principles.

Effective change control and investigative procedures shall be in place to manage product history and deviations from planned procedure.

Procedures shall exist for the timely notification of the appropriate management of occurrences that might pose a threat to product quality and safety. These include for example, complaints, product recall, and audit findings.

Ensure that:

- *Employees commitment to feed safety and quality can be demonstrated;*
- *HACCP principles are applied;*
- *An effective change control system is implemented;*
- *Management are informed in case of threats to product quality and feed safety;*
- *A system is in place to ensure that management is kept up-dated on all relevant legislation, feed and food safety issues, and other relevant requirements and guidelines.*

4.3. General documentation requirements

The Operator shall have a system of documentation which reflects all aspects of this Code. The system of documentation shall reflect in particular the application of HACCP plan.

Records shall contain all relevant data to permit investigation of any non-conformance or deviation(s) from planned procedure(s).

All quality and safety related activities shall be recorded immediately after they have been performed.

The design and nature of use of records is at the discretion of the Operator.

MS documentation shall include*:*

a) a written quality and safety policy;

b) a Quality Manual;

c) documented procedures and records; and

d) information needed by the Operator to ensure the effective planning, operation, and control of its processes.

The Quality Manual shall include:

a) the scope of the MS, including details of and justification for any exclusion;

b) quality procedures established as part of the MS, or reference to them;

c) quality procedures or references in support of the HACCP programme;

d) HACCP procedures or references to ensure feed safety.

Minimum documents required include:

a) specifications and testing procedures for incoming materials and finished product;

b) master formulae and operating instructions for each product or group of products;

c) batch processing records for each product; and

d) Standard Operating Procedures (SOPs).

Documents shall:

a) have unambiguous contents: the title, nature and purpose shall be clearly stated;

b) be approved, signed and dated by appropriate authorised persons. No document shall be changed without authorisation; and

c) be kept up to date.

Ensure that:

- *A written quality and safety policy exists;*
- *A Quality Manual is in place;*
- *Documented procedures and records are available;*
- *The scope of the MS is defined;*
- *Quality procedures are established as part of the MS;*
- *Quality procedures cover the prerequisite program in support of the HACCP program;*
- *HACCP procedures are sufficient to ensure feed safety;*
- *Specifications and testing procedures for incoming materials and finished products are documented;*
- *Master formulae and operating instructions for each product or group of products are in place;*
- *Processing records for each batch of product are available;*
- *Standard Operating Procedures (SOPs) for all activities under the scope of the MS are documented;*
- *Documents are unambiguous and include title, nature and purpose;*
- *Documents are approved, signed and dated by appropriate authorised persons;*
- *All documents are kept up to date.*

5 MANAGEMENT RESPONSIBILITY

5.1. Management commitment

Management shall be committed to the implementation of the Code and the Operators own specific quality requirements in order to ensure feed safety and predefined quality of products

Ensure that:

- *Management commitment to feed safety and quality can be demonstrated.*

5.2. Quality and safety policy

Management shall:

a) establish a quality and safety policy, ensure that objectives are established, clearly state the companies obligation to produce safe and legal feed products covered by FAMI-QS scope and to respect their customers requirements;

b) communicate this policy throughout the organisation, which shall be understood by all staff involved in the production of products covered by FAMI-QS scope.

c) provide the necessary resources for the fulfilment of the quality and safety policy;

d) ensure that all key aspects of the Management and HACCP systems are documented, reviewed, updated and communicated to key staff as frequently as might be necessary.

Ensure that:

- *The quality and safety policy specifies the Operators objectives including regulatory and customer requirements;*
- *The policy is adequately communicated;*
- *The Operator has the basic resources necessary to fulfil the stated objectives;*
- *Management and HACCP systems are documented, reviewed, updated and communicated to key staff.*

5.3. Responsibility, authority and communication

Management shall:

a) appoint a HACCP team and team leader;

b) define the scope of the HACCP system, by identifying the product(s) categorie(s) and production sites, which are covered by the system and ensuring that safety objectives are established as part of the system;

c) ensure that job descriptions are available to clearly define the responsibilities of all staff involved in the production of products covered by FAMI-QS scope;

d) identify and record any problems and corrective actions with regard to product quality, safety and the Operator's management system;

e) initiate action(s) to prevent the occurrence of non-conformities relating to product quality and safety, the Operator shall provide adequate resources for the implementation, management and control of the HACCP systems; (Further details on HACCP requirements can be found in section 7.2).

f) assign responsibility and authority to ensure compliance with regulatory requirements and industry codes of practice to clearly identified competent persons;

g) issue, maintain and make available to the operation's staff and external bodies an organisational chart of the operation including job descriptions.

Ensure that:

- *A suitably qualified HACCP team leader is appointed;*
- *The scope of the HACCP system is clearly defined;*
- *Job descriptions exist for each individual or group of individuals;*
- *A system is in place to identify and correct problems within the management and HACCP systems;*
- *A suitably qualified person is appointed to ensure compliance with regulatory requirements;*
- *An organisational chart is available.*

5.4. Management representative

Senior management shall appoint a member of management who shall have responsibility and authority that includes:

a) ensuring that processes needed for the management and HACCP systems are established, implemented and maintained;

b) reporting to top management on the performance of the management systems and any need for improvement; and

c) ensuring the promotion of awareness of customer requirements throughout the Operators organisation.

Ensure that:

- *A management representative with responsibility for quality and safety is appointed;*
- *The management representative reports to top management;*
- *The responsibility includes promotion of awareness towards customer requirements.*

5.5. Management review

Management shall review the effectiveness of the Management and HACCP systems at regular defined intervals:

a) records of this review shall be maintained;

b) the need to update or change the Management and HACCP systems shall be evaluated at these reviews;

c) results from external and internal audits shall be reviewed;

d) customer complaints and requests shall be reviewed;

e) internal problems and changes to the operation processes must be reviewed;

f) decisions to change any aspect of the Management and HACCP systems shall be communicated to key staff;

g) Management shall ensure that a system is in place to audit the Management and HACCP systems.

Ensure that:

- *A documented procedure exists for management to review the suitability and effectiveness of the MS and HACCP;*
- *Records of this review are available;*
- *The review is done periodically at predefined intervals;*
- *Conclusions drawn and actions taken are documented as part of the review;*
- *Any actions are communicated to key personnel within the organisation.*

6 RESOURCE MANAGEMENT

6.1. Provision of resources

Management shall identify and provide the necessary resources in order that the manufacture, processing, storage and transport of products are carried out in an efficient and safe manner.

Feed businesses must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the products concerned.

Management shall provide sufficient and appropriately designed infrastructure, work environment facilities, production areas and equipment.

Provide water of a suitable quality, *e.g*. potable water, so that the product complies with feed safety requirements.

Ensure that:

- *An organisational chart exists and is updated;*
- *Appropriate persons have been assigned responsibilities to comply with external requirements;*
- *The design is appropriate.*

6.2. Human resources

6.2.1. Competence, awareness and training

Employees and managers shall have the necessary skills, competencies, qualifications, training and awareness to be able to effectively execute their respective tasks, thereby ensuring the conformity of product(s) to the expected quality and feed safety (specifically the HACCP team).

Education and training of personnel shall be documented and maintained.

In particular, the team must be properly trained and rehearsed with the appropriate procedures.

Staff shall be trained in appropriate standards of hygienic behaviour in order to contribute to the overall feed safety part of the food chain.

Ensure that:

- *The staff is sufficient and skilled to comply with expected tasks and requirements;*
- *Job descriptions are available and updated.*

6.2.2. Personal Hygiene

The management shall:

a) ensure that personnel hygiene facilities are clearly and suitably designated, located and maintained;

b) provide appropriate work wear such as protective clothing, safety footwear and maintain them in hygienic conditions;

If gloves are worn, control is needed to ensure that there is no risk of contamination of the finished product from them.

c) establish clear rules on smoking and eating/drinking on site. If necessary, separate facilities for these activities shall be provided;

d) ensure that visitors and contractors respect the hygiene requirements when visiting/working on the site.

Ensure that:

- *Necessary competence are available in disciplines concerning:*
  - *Feed safety;*
  - *HACCP (see 7.2 HACCP program);*
  - *Hygiene;*
  - *Quality;*
  - *Health and safety;*
  - *Environment;*
- *Level of competence is documented and maintained;*
- *There is a sufficient level on personal hygiene facilities and personnel hygiene.*

6.3. Infrastructure

6.3.1. Basic requirements

Where applicable, the Operator shall provide appropriate work environment in line with local Regulations to achieve product conformity.

Adequate ventilation, controlable humidity, temperature setting, lighting and hygienic design of plants and equipment shall be provided.

6.3.2. Requirements for facilities, production areas and equipment

The lay-out, design, construction and size of the facilities and equipment shall:

a) permit adequate cleaning and/or disinfection;

b) be such as to minimise the risk of error and to avoid contamination, cross-contamination and any generally adverse effects on the safety and quality of the feeds.

6.3.3. Facilities & production Areas

Where necessary, 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 shall be kept under control.

Ventilation systems and devices shall 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 shall be provided.

If necessary, heating, cooling or air-conditioning systems shall be designed and installed so that air-intake or exhaust vents do not cause contamination of products, equipment or utensils.

Lighting must be of sufficient intensity to ensure that hygienic 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.

Water used in feed manufacture shall be of suitable quality.

It shall be ensured that drainage lines and sewage systems are watertight and of sufficient capacity.

Drainage facilities must be adequate for the purpose intended, they must be designed and constructed to avoid the risk of contamination.

6.3.4. Equipment

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

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.

Ensure that:

- *The facility is designed to facilitate a good environment as described in 6.3.3;*
- *The facility is designed to make it easy to clean;*
- *The facility is suitable to minimize feed safety risks;*
- *Necessary utilities are available, e.g:*
  - *Potable water or other water quality;*
  - *Steam;*
  - *Pressured air;*
  - *Heating system;*
  - *Extraction units;*
  - *Other relevant utility systems.*

6.4. Maintenance and control of monitoring and measuring devices

A documented maintenance programme for manufacturing operations shall be implemented.

Records shall be kept of work carried out.

The Operator shall establish processes to ensure that monitoring and measurement can be carried out in a manner consistent with documented procedures.

All scales and metering devices used in the manufacture of feed shall be appropriate for the range of weights or volumes to be measured and shall be tested for accuracy regularly according to the risks.

Where necessary to ensure valid results, measuring equipment shall:

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 shall be recorded;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable the calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result; and

e) be protected from damage and deterioration during handling, maintenance and storage.

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

Ensure that:

- *A formal calibration system is in place;*
- *This includes items to be calibrated;*
- *Appropriate calibration intervals are defined;*
- *Calibration results are documented;*
- *A formal preventive maintenance system exists;*
- *Appropriate maintenance intervals are defined;*
- *Maintenance work is documented;*
- *Maintenance work does not interfere with product safety.*

6.5. Cleaning

A cleaning and inspection programme shall be introduced and documented. The effectiveness of the programme shall be demonstrated.

All indoor and outdoor areas, buildings, facilities and other equipment must be kept clean and in good state to function as intended, to prevent contamination.

Containers and equipment used for the transport, storage, conveying, handling and weighing of feed shall be kept clean.

A schedule shall be implemented with methods, agents used and frequency of cleaning including responsibilities for the tasks.

Cleaning can be carried out by *e.g.* physical methods like scrubbing and vacuum cleaning or chemical methods using alkaline or acidic agents and methods without the use of water.

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

Cleaning agents shall be used and stored according to the manufacturer's instruction(s), 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 shall be dry enough for the next production.

Ensure that:

- *A formal cleaning program exists, covering:*
  - *Daily house-keeping;*
  - *Periodic deep cleaning;*
  - *Cleaning after maintenance;*
- *The program defines responsibility;*
- *Post evaluation is covered;*
- *Cleaning records are filled-in daily;*
- *Procedures on cleaning of equipment exist, and support hygiene and feed safety;*
- *Employees are trained in cleaning procedures and the training is documented.*

6.6. Pest control

There shall be a written plan for pest control including description of periodic inspections and their results. Effectiveness of the plan shall be demonstrated.

A schedule shall be implemented with areas, facilities and equipment to be inspected including frequency, details of pesticides, fumigation agents or traps used as well as responsibilities for these tasks.

Pesticides, fumigation agents or traps used shall be suitable and comply with local regulations for the purpose concerned. They shall be used and stored according to the manufacturer's instruction, clearly marked and separately stored from raw materials and finished products and applied properly to avoid contamination of raw materials and finished products.

The positions of traps and bait stations shall be mapped.

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

Spoilage and dust shall be controlled to prevent pest invasion.

The results of the pest control shall be part of the yearly management review.

Windows and other openings must, where necessary, be proof against pests. Doors must be close-fitting and proof against pests when closed.

Ensure that:

- *A formal (documented) preventive pest control system is in place;*
- *The responsibility - In-house or contracted – are defined;*
- *Relevant preventive measures are taken:*
  - *Rodents, outside and inside;*
  - *Insects, flying and crawling;*
  - *Birds;*
  - *Other relevant pests;*
- *A map or schematics exist showing the locations of preventive measures and are updated;*
- *Pest activities are documented;*
- *Applied pesticides/chemicals are suitable for the purpose (Product Data Sheet);*
- *pesticides/chemicals are legal;*
- *The plant is maintained reasonably clear of infestation.*

6.7. Waste control

Waste and materials not suitable as feed should be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed of in an appropriate way and not used as feed:

a) waste is clearly identified and disposed in a manner which avoids contamination of raw materials and finished products;

b) waste is stored in closed or covered containers at defined waste accumulating areas;

c) waste accumulating areas are cleaned regularly;

d) waste containers shall be clearly marked and designated for that purpose only;

e) Sewage, waste and rainwater shall 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.

Ensure that:

- *Waste materials are properly identified to avoid mix-up with production materials;*
- *Waste is handled properly to avoid risks for workers or environment, both internally and externally.*

7 PRODUCT REALISATION

7.1. Product requirements

7.1.1. Determination of requirements related to the product

The Operator shall determine:

a) statutory and regulatory requirements related to the product;

b) requirements specified by the customer, including requirements related to delivery and post-delivery activities; and

c) requirements not stated by the customer but necessary for specified or intended use, where known.

Ensure that:

- *A system to identify external requirements is implemented;*
- *The external requirements are communicated and complied with;*
- *Requirements and compliance are documented;*
- *Requirements specified by customers are controlled and implemented.*

7.1.2. Compliance of the product to the requirements

The Operator shall monitor the compliance of products with the relevant product requirements and shall ensure that:

a) product requirements are defined;

b) the Operator has the ability to meet the defined requirements; and

c) the existence and handling of products for export outside the EU and which cannot, from a regulatory point of view, be placed on the EU market, is described in the Operator's MS. If the Operator markets such non-EU compliant products, the Operator should maintain a list of products which may be marketed in the EU and those which may be marketed outside the EU only.

Should product requirements change, the Operator shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. (See also section 7.3.2).

Ensure that:

- *Procedures are in place to comply with identified requirements.*

7.1.3. Customer communication

The Operator shall determine and implement effective arrangements for communicating with customers in relation to:

a) product information;

b) enquiries, contracts or order handling, including amendments; and

c) customer feedback, including complaints.

Ensure that:

- *Relevant product information is in place;*
- *The information is communicated to the customer;*
- *Information provided by customers are received and implemented.*

7.2. HACCP Programme

The purpose of the HACCP programme is to ensure feed safety in a controlled manner based on a systematic procedure. The programme comprises any activities and process steps ranging from purchase of raw materials to transport of the finished products.

In the hazard analysis, a survey shall be conducted to identify all potential hazards. Based on this analysis, hazards shall be classified according to risk and possible Critical Control Points (CCP's) shall be identified and control procedures established.

Special attention shall be paid to hazards requiring specific control measures.

It is recommended that Operators follow the guidance for application of HACCP provided in the Codex Alimentarius Guidelines, which are based on 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 system are working effectively;
7. document all procedures and records to demonstrate that the HACCP system is working effectively.

Among the risks to be considered during a HACCP analysis are issues such as homogeneity and/or microbiology (biological hazards).

Further requirements on HACCP can be found in the following sections of the Code:

3 Terms and definitions;

4.2 Management principles;

4.3 General documentation requirements;

5.2 Quality and safety policy;

5.3 Responsibility, authority and communication;

5.4 Management representative;

5.5 Management review;

6.2.1 Competence, awareness and training;

6.5 Cleaning;

6.6 Pest control;

7.3.1 Development of new products and processes;

7.4.1 Sourcing of incoming materials;

7.5.1 Quality control and production;

7.5.2 Verification of processes for production;

7.6.1 Transport. General requirements;

9.1 Control of nonconforming products. General requirements.

7.3. Design and development

7.3.1. Development of new products and processes

The Operator shall plan and control the design and development of products or processes related to safety.

The safety of products covered by FAMI-QS scope shall be assured during the developmental stages of a new product through application of HACCP principles.

Ensure that:

- *Development plans are issued prior to relevant phases of the development process;*
- *The development plan considers risks related to safety;*
- *HACCP is considered.*

7.3.2. Change control

Design and development changes shall be identified and corresponding records maintained.

All changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.

The review of design and development changes shall include evaluation of the effect of the changes on product safety.

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

Ensure that:

- *A formal change control procedure exists;*
- *Changes are approved before implementation;*
- *Changes are monitored and documented;*
- *Changes are revised, verified, validated and resulting documents are archived;*
- *Safety, quality, legal requirements are taken into account in the change control procedure.*

7.4. Handling of incoming materials

7.4.1. Sourcing of incoming materials

The approval of good quality suppliers and the selection of excellent ingredients is a key aspect of any Operators quality and safety management system(s). Poor raw materials can result in the production of poor quality finished product and may also compromise the safety of the Operator's entire process. All Operators shall therefore put special emphasis on ensuring that their suppliers and ingredients are of the required quality and standard.

7.4.1.1 Management requirements

a) Purchasing information shall describe the product to be purchased, including, where appropriate, requirements for approval of purchased product.

b) Selection and approval of all raw materials shall include their origin, transport, storage, processing and handling.

c) Any potential hazard associated with a raw material shall be documented.

d) Each raw material shall have a written specification, including quality agreement, which is amended when change of documented parameters takes place.

e) In addition to the analytical characteristics of the raw material, the specification shall include, where appropriate, details of any undesirable substance with which the raw material may typically be associated, and any other hazards or limitations associated with the raw material which have been considered in the Operator's HACCP system.

f) Where appropriate, requirements for analytical monitoring shall be defined.

g) In case the material is a product (which is covered by FAMI-QS certificate) imported from outside the European Union, a written confirmation of its compliance with the current EU feed regulations issued by the supplier is needed. Documentation is required that these products covered by FAMI-QS certificate are produced in compliance with EU legislation.

h) There shall be a list of internally approved suppliers and each supplier shall be subject to periodical review.

i) The Operator shall evaluate and select suppliers based on their ability to supply products in accordance with the Operator's requirements. Criteria for selection, evaluation and re-evaluation shall be established.

j) Records of any relevant analytical and monitoring results and records of the evaluations on the supplier and necessary actions arising from that evaluation shall be maintained.

7.4.1.2 Realization requirements

k) Every raw material shall be evaluated to assess any potential hazard associated with it; this shall be carried out according to HACCP principles for all materials falling under the scope of the Regulation (EC) No 183/2005 on Feed Hygiene.

l) There shall be a check that these products covered by FAMI-QS are being produced in compliance with the requirements of this Code and with the EU legislation.

Ensure that:

- *New suppliers are covered by an approval process;*
- *Approved suppliers are documented, reviewed, re-evaluated and the documentation is up-to-date;*
- *The review is done periodically at a predetermined interval;*
- *Purchased incoming material has an agreed specification;*
- *Specifications comply with feed safety topics and legislative requirements.*

7.4.2. Verification of incoming materials

Each batch entering the site shall be uniquely registered by means of a batch number, full name of product, date of receipt and quantity received. Any damage shall be reported to an appropriate responsible unit, *e.g.* the quality control unit.

If the incoming material is delivered in bulk, a receipt and storage procedure must be in place. If silos are emptied, this shall be recorded and cleaning must be evaluated.

Incoming materials shall be checked and formally approved prior to use according to written procedures. Samples of these materials shall be retained. Where appropriate, a retained sample shall be available for at least the shelf life of the material, either at the suppliers or the Operators.

Handling of incoming product shall be in accordance with its status. For example, a received product which is deemed unfit for use must be identified as such and segregated from those products released for use. In the same light, perishable materials should be treated as appropriate to ensure their wholesomeness before use.

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

Ensure that:

- *A written procedure on handling of incoming materials exists;*
- *Incoming materials are registered uniquely and include:*
  - *Supplier's name and lot/batch number;*
  - *Operator's lot/batch number;*
  - *Name of material;*
  - *Quantity and date of receipt;*
  - *Possible expiry date;*
- *Incoming bulk materials are stored according to adequate separation procedures;*
- *Materials are inspected before, during and after unloading;*
- *The inspection includes contamination, pest infestation and documentation of findings;*
- *Non-conformities are recorded;*
- *Records of inspection results are documented and archived;*
- *Records of supplier guarantees and other relevant supplier documentation kept;*
- *Incoming materials are released before use;*
- *Documentation is maintained in case a product is returned to the supplier.*

7.5. Production of finished goods

7.5.1. Quality Control and Production

The Operator shall plan and carry out production and service provision under controlled conditions. Production areas shall be controlled so that access for non-authorised personnel can be prevented.

Controlled conditions shall include, as applicable:

a) The availability of information that describes the characteristics of the finished product.

- Each product shall have a written specification, which is amended when any change takes place.
- Each product shall have a unique name or code.
- Details of packaging and labelling shall be available. Product labelling shall be in accordance with the relevant EU feed legislation.
- Each package shall be labelled by a unique identifier (which can be a combination of codes) in order that the batch to which it belongs can subsequently be identified and traced.
- All finished product shall be inspected prior to dispatch, in accordance with written procedures, to ensure it meets specification. A retention sample of adequate size shall be taken of each batch and held, as a minimum, for a time equivalent to the defined shelf life of the product. The samples must be sealed and labelled, stored in a manner that shall prevent abnormal change, and kept at the disposal of the authorities for a period appropriate to the use.

- If products are rejected and thus not put into circulation for any reason related to product quality and safety, their disposal, destination, or return to supplier shall be recorded.

b) The availability of work instructions:

- The different stages of production shall be carried out according to written procedures aimed at defining, controlling and monitoring the critical points in the manufacturing process.
- These shall include procedures to address the risk of carry-over.

c) Rules governing packaging:

- Where products are packaged, care shall be taken to avoid contamination and cross-contamination during the packaging process, and to ensure that packaged products are correctly identified and labelled in compliance with the provisions of relevant feed regulations.
- Packaging shall be appropriate to product type, with the objective of maintaining the contents for its intended shelf life. Packaging shall be considered under HACCP analysis.
- Pallets shall be serviceable, clean and dry. All pallets which are returned after a particular use shall be inspected and if necessary cleaned before re-use.

d) Rules controlling storage:

- Finished products shall be clearly identified and stored in clean dry conditions. Access to these materials shall be restricted to authorised personnel only.
- Incoming materials, active substances, carrier substances, products which meet the specifications – and those which do not – shall be stored in suitable designed places , adapted and maintained, in order to ensure appropriate storage conditions which manage the risks of contamination and possible infestation by harmful organisms. Packed materials shall be stored in appropriate packaging.
- Materials shall be stored in a manner which enables easy identification, avoids cross-contamination and prevents deterioration. A stock rotation system shall be in place.
- The storage environment shall be set up in a manner which minimises the risk of damage to packaging and spillage of material.

e) Rules concerning loading and delivery:

- Products shall be delivered with the protection of animal and human health as prime considerations in mind.
- Containers and equipment used for transport, storage, conveying, handling and weighing shall be kept clean. Cleaning procedures shall consider such containers and equipment.
- A final inspection shall take place to ensure delivery of safe and high quality product.

Ensure that:

- *Production areas are accessible to authorised personnel only;*
- *Production is run according to formal production planning;*
- *The production plan is distributed to relevant persons;*
- *Production records are kept to prove compliance with master formula;*
- *Cross-contamination is prevented or controlled;*
- *Each product has a specification, unique name and/or code;*
- *Each product has a predefined label;*
- *Finished products are clearly marked and identified;*
- *Each product has a predefined packaging instruction;*
- *The packaging process is controlled to avoid contamination and mix-up;*
- *Deliveries are inspected prior to dispatch;*
- *This inspection is documented;*
- *Non-conforming products are segregated and stored in a manner to prevent failures;*
- *Storage facilities are adequate to the purpose;*
- *Storage facilities are operated in a manner to prevent failures during handling;*
- *Storage facilities are suitable to the purpose, e.g. cleanliness, ventilation, dry, and temperature controlled;*
- *A defined stock rotation system is in place, e.g. FIFO "First In, First Out";*
- *Outdated stock is controlled and segregated.*
- *Loose bulk materials are controlled and segregated from other loose bulk material.*

7.5.2. Verification of processes for production

The Operator shall verify any processes for production. This includes any processes where deficiencies become apparent only after the product is in use or has been delivered.

Verification shall demonstrate the ability of these processes to achieve expected results. Frequency of verifications shall be considered under the Operator's HACCP system. Particular attention shall be given to carry-over and homogeneity.

The Operator shall establish arrangements for these processes including:

a) defined criteria for review and approval of the manufacturing processes;

b) approval of equipment;

c) qualification of personnel;

d) use of specific methods and procedures; and

e) requirements for records.

Ensure that:

- *A written verification procedure is in place;*
- *Verification data demonstrates that all production processes achieve planned results;*
- *Verification data of production demonstrates that carry-over is controlled.*

7.5.3. Identification and traceability

To ensure traceability, the Operator shall:

a) identify and record the product by suitable means throughout product realisation; and

b) maintain a register, that contains:

- the names and addresses of manufacturers of incoming materials, feed additives, functional feed ingredients or of intermediates. Incoming materials shall be verified according to section 7.4.2.
- the nature and quantity of the products produced covered by FAMI-QS scope,
- the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacturing, and
- the names and addresses of the intermediaries, manufacturers or users to whom the products covered by FAMI-QS scope have been delivered.

Ensure that:

- *A traceability system is in place, including tracing back from the final product through quality control data and batch records to the raw materials used and the suppliers;*
- *Deliveries can be traced to customers, including customer name, date, batch and amount.*

7.5.4. Preservation of product

The Operator shall establish the shelf life of a product and preserve the conformity of the product during processing and delivery to the intended destination.

Preservation measures shall include product identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

Ensure that:

- *a preservation programme is implemented to ensure stability of the product ;*
- *the product environment is controlled during storage in order to maintain compliance of the quality and safety requirements.*

7.6. Transport

7.6.1. General requirements

Transportation of raw material and finished products are critical points in the process. Impurities that are hazardous to humans or animals may get in contact with the final product. Measures must be taken to ensure that the transportation of raw material and finished products is adequate in order to minimize the risk of contamination.

Two categories of finished products have to be considered: *transportation of packed goods* and *transportation of bulk materials*, either liquid or solid.

Where distribution or transport is performed by a subcontractor, the transporter shall be selected on the basis that it can satisfy product safety and reliability criteria.

The Operators' HACCP programme shall take transport into consideration when formulating the requirements on suppliers and transporters.

The Operator must communicate its requirements on transportation to the transporter. These requirements shall be documented and verified regularly.

The Operator's evaluation of the performance of the transporter shall confirm the effectiveness of the transporter's actions to meet the requirements.

When transport of finished products is arranged and the buyer takes responsibility for the transport, it is the Operator's responsibility to communicate, to the buyer, that the requirements in this Code will be applied on the transport before and during loading and during transportation/delivery.

Ensure that:

- *Agreements with subcontracted transporters are documented;*
- *Selection of transporters takes into consideration their ability to fulfill the Operators requirements as certified by this Code;*
- *Transporters are controlled, evaluated and meet expected quality and safety requirements;*
- *Requirements in this Code are applied by the Operator also to transports arranged by the buyer.*

7.6.2. Transport of packaged goods

Products covered by FAMI-QS certificate shall not be transported, even if sealed, with goods that compromise the safety of the raw material or the finished product.

The package for the raw material or the finished product shall provide adequate protection against deterioration or contamination that may occur during transportation.

Ensure that:

- *Procedures are in place to ensure product integrity during transport;*
- *Packaging provides adequate protection for the raw material or finshed goods.*

7.6.3. Transport of bulk products

A system shall be in place to safeguard against contaminants which may compromise the integrity of products covered by FAMI-QS certificate according to applicable existing regulations.

The Operator shall ensure that the transporter of bulk products has sufficient knowledge about handling products covered by the FAMI-QS scope. In the best case, this shall be proven by a transporter's certification to a recognized standard.

Valid information about the product to be loaded must be given by the Operator to the transporter. The transporter can then define the suitable container to provide the best protection.

If cleaning of a container is required, the cleaning method shall be chosen to clean possible contaminants from the previous loads

The transporter shall provide cleaning certificate(s) with the following information:

a) information that enables container traceability;

b) previous load(s);

c) method of cleaning;

d) cleaning company;

e) if applicable, information about the cleaning of discharge/unloading equipment.

After cleaning, the efficiency of the cleaning operation must be checked and recorded.

Exceptions from the requirement on cleanliness may be done if the previous load does not compromise the safety of the one to be loaded.

Ensure that:

- *Procedures are in place to control all relevant risks found in the Operators HACCP plan;*
- *If cleaning is required, the cleaning certificates shall include all relevant information needed to evaluate if the supplied container is suitable for loading;*
- *Procedures are in place to safeguard against unwanted or forbidden contaminants.*

8 SYSTEM REVIEW

8.1. General requirements

The Operator shall document measures taken to ensure that the MS is working efficiently. This may include planning, implementing and monitoring processes which demonstrate product conformity. Monitoring processes shall include collection of measurements, analysis of data, conclusions and if relevant, issuing of procedures which improve the MS.

Ensure that:

- *A formal review system exists;*
- *The system includes collection of data;*
- *The system includes analysis of the data;*
- *The system includes conclusions;*
- *The system includes actions for improvement originating from the conclusion;*
- *Time scales for improvements are defined and maintained.*

8.2. Internal audits

The Operator shall ensure that internal audits are performed to verify that the MS is:

a) effectively implemented and maintained;

b) in compliance with regulatory and other defined requirements;

c) the scope of the audits is defined and their frequency are scheduled in relation to the risk associated with the activity to be audited; and

d) covering that auditors shall be trained, competent and independent.

Internal audits may also be used to identify potential opportunities for improvements.

Corrective actions shall be scheduled and verified when completed.

The schedule for conducting internal audits shall be documented and include planning, reports and details of suggested improvements. The detailed audit programme shall, as a minimum, include:

a) preparation and issue of audit plans;

b) methods used to conduct the audits;

c) reporting of findings;

d) scope of the audit;

e) distribution of reports.

Ensure that:

- *A scheduled audit program is in place;*
- *Internal audits are carried out;*
- *The scope of audits are defined;*
- *Feed safety issues are included in the scope;*
- *The frequency of audits are defined;*
- *The auditors are experienced and suitably trained;*
- *Audits and non-conformities are reported and documented;*
- *Reports are distributed to key staff;*
- *A formal follow-up of non-conformities is reported;*
- *Corrected non-conformities are verified.*

9 CONTROL OF NON-CONFORMING PRODUCTS

9.1. General requirements

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

The procedure shall include:

a) identification of product and batch code;

b) documentation of any non-conformance, corrective action(s) and verification steps;

c) evaluation of the cause of the non-conformance;

d) segregation of affected batch or batches;

e) provision for disposal of products where appropriate;

f) recording of internal information of relevant parties.

Responsibility for review and disposal of the non-conforming product shall be defined.

A non-conforming product shall be reviewed in accordance with documented procedures and action to be taken in one of the following ways:

a) rework;

b) reclassification or dispensation/dispatch; or

c) rejection and subsequent destruction or disposal.

Records of all non-conformances must be maintained in accordance with document control procedures and archived for an appropriate time.

The approval and use of reworks (*e.g.* from rejects, customer returns or spillage) shall be considered within the HACCP system. Potential reworks which are not approved become waste material and shall be dealt with according to waste disposal procedures.

Ensure that:

- *A formal system on how to handle non-conforming products exists;*
- *The procedure covers:*
  - *Product Identification;*
  - *Documentation of non-conformities;*
  - *Evaluation of root causes;*
  - *Documentation of corrective actions and verification steps;*
  - *Segregation, handling and assessment of non-conforming product, including:*
    - *Rejected materials;*
    - *Accepted materials with restrictions;*
    - *Justification of potential alternative use within feed safety requirements;*
- *The staff is aware of these procedures;*
- *A clear marking or other means of controlling non-conforming products exists;*
- *Records of non-conformities are maintained.*

9.2. Complaint handling system

A formalised documented procedure on complaint handling shall exist and shall include requirements to:

a) allocate responsibility for controlling complaints;

b) record name of complaining customer;

c) record product name and identification code;

d) reason for complaint - identify and record each complaint; and

e) reply to the complaining customer.

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

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

Ensure that:

- *A formal customer complaint handling system exists;*
- *Responsibility for controlling complaints is defined;*
- *The system includes sufficient customer and product information;*
- *The complaints are evaluated according to:*
  - *Cause;*
  - *Seriousness;*
  - *Customer;*
  - *Other relevant topics;*
- *The complaint topics are used to prevent reoccurrence;*
- *The related corrective actions are carried through;*
- *Operator's feedback is given to the customer.*

9.3. Recall

A formal recall procedure shall be documented so that customers can be informed immediately of any irregularities that may compromise feed safety. The recall procedure shall be regularly reviewed to ensure conformance with the quality manual and regulatory requirements and the Operator's organization.

The recall procedure shall include requirements to:

a) define and allocate responsibility for the recall process;

b) identify each batch of non-conforming product including consequences to other product batches or raw materials throughout the entire process;

c) identify the destination of affected batches;

d) notify customers of affected batches and coordinate product return;

e) describe procedures for the handling and reassessment and/or disposal of recalled product(s) including segregation from other products and materials;

f) maintain records of product recall(s) and components from production and/or distribution to the affected customers.

Simultaneously with the above listed action points, it is important to limit recurrence by:

- ensuring immediate corrective and preventive actions are undertaken;
- verifying that corrective and preventative actions are effective.

Operators may also remove products from the market for reasons other than feed safety. These cases shall be handled in the same manner described here.

The recall procedure shall be tested at least annually to ensure functionality. Such tests shall be documented and evaluated for improvements.

Ensure that:

- *A formal recall procedure exists;*
- *Responsibility is assigned to an appropriate person;*
- *The recall process is adequately described;*
- *The recall procedure includes handling, reassessment and/or disposal of recalled product;*
- *Effective corrective and preventive actions are implemented;*
- *Any recall is recorded;*
- *The recall procedure is tested regularly;*
- *The test recalls are documented;*
- *The outcomes of the test recalls are evaluated.*

9.4. Crisis Management

If a feed business Operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it must immediately initiate procedures to recall the feed in question from the market and inform the competent authorities thereof. In such cases the last version of the "*Feed Safety Incident and Crisis Management Procedure for Operators and CBs*" (P-CM-01) of the Code must be applied.

a) The crisis management procedure shall be documented.

b) Responsibility shall be defined for notifying customers and regulatory authorities.

c) Responsibility within the operation for product recall(s) shall be defined.

It is important to emphasize that a crisis may result in a Rapid Alert situation (RASFF) or originate from such.

Ensure that:

- *A crisis management procedure exists;*
- *Responsibility for notifying customers and regulatory authorities is defined;*
- *Responsibility for conduction a product recall is defined.*

10 STATISTICAL TECHNIQUES

The Operator shall, where appropriate, evaluate and identify the need for the use of statistical techniques.

Where statistical techniques are applied, the need for these techniques shall be demonstrated.

The adequacy of these techniques shall be demonstrated:

a) standard error shall be calculated and documented;

b) standard error must be of an appropriate level to sufficiently ensure feed safety;

c) data exceeding standard error and trends shall be monitored;

d) Corrective actions shall be specified in the event of a breach of error limits.

Ensure that:

- *The use of statistical techniques has been evaluated and defined;*
- *An overview of each statistical method is available;*
- *The applicability of methods is documented;*
- *The Operator possesses the necessary statistical competencies;*
- *Corrective actions are defined for results outside of the standard error.*

11 BIBLIOGRAPHY

In order to facilitate implementation of the Code, the structure of ISO 9001:2008, Quality Management Systems, is used.

In order to align the Code with current animal feed legislation and various activities on national, industrial and/or association levels, it takes into account the principles of feed and food safety as well as HACCP principles that are set out in various international documents further down and EC legislation, in particular:

- The European Commission's White Paper on Food Safety, COM (1999) 719 final.

  http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf

- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (and repealing Council Directive 95/69/EEC and Commission Directive 98/51/EEC (apart from article 6 on Interim measures), laying down conditions and arrangements for approving and registering establishments and intermediaries in the animal feed sector).

  http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_035/l_03520050208en00010022.pdf

- Directive 98/51/EC.

  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0051:EN:HTML

- Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition.

  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2003R1831:20100901:EN:PDF

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority.

  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002R0178:20090807:EN:PDF

- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

  http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_191/l_19120040528en00010052.pdf

Other documents:

- The relevant Codes of practice of the Codex Alimentarius.

  http://www.Codexalimentarius.net/.

- The principles of HACCP, re. Codex Alimentarius, General principles of Food Hygiene, (CAC/RCP 1-1969, Rev. 4-2003 Amd. (1999), Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application).

  http://www.Codexalimentarius.net/.

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