

European Code of Practice For Feed Additive and Premixture Operators

INTRODUCTION

This European Code of Practice for Animal Feed Additive and Premixture Operators ('Code') responds to the Regulation of the European Parliament and the Council laying down requirements for feed hygiene, (183/2005/EC), articles 20 to 22 of which encourage the development of guides to good practice for hygiene and the application of HACCP principles.

Implementation of the code aims to ensure the safety of feed additives and premixtures, the operation of businesses in accordance with feed hygiene requirements harmonised on a European level, and improved traceability.

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:

- EN ISO 9001:2000, Quality Management Systems
- The European Commission's White Paper on Food Safety (COM (1999) 719 final)
- European Council Directives 95/69/EEC and 98/51/EEC. (Laying down conditions and arrangements for approving and registering establishments and intermediaries in the animal feed sector).
- Regulation of the European Parliament and of the Council on additives for use in animal nutrition. (1831/2003/EC)
- Regulation 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. (178/2002/EC)
- Regulation of the European Parliament and of the Council laying down requirements for feed hygiene. (183/2005/EC)
- The relevant codes of practice of the Codex Alimentarius.
- 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/>.
- Management systems developed by associations in different Member States, for instance; Code of Practice (FEFAC, EU), FEMAS (AIC, UK), GMP (OVOCOM, B), GMP+ (PDV, NI), Q+S (DVT, D).

The combination of the above principles provides guidance for feed additive and premixture 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 178/2002/EC shall apply.

The text of the Code is designed to set out general requirements. Questionnaires are included in order to further detail the requirements. In addition it can be used as a tool for detailed guidance of the operators and in auditing operators.

A compilation of guidance is provided as annex to the Code. These are covering topics of special importance in a more detailed and practical way and may serve as additional assistance for the operator to implement the required methods. They are updated in parallel as need may be.

The FAMI-QS document 'FAMI-QS Certification Process Description', explains the certification process.

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Annexes: Guidance on implementation

Annex 1: Guidance on the implementation of HACCP

Annex 2: Guidance on the implementation of basic hygiene rules

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Annex 4: Guidance on transport

Annex 5: Guidance on homogeneity

Annex 6: Guidance on carryover

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Annex 8: Guidance on microbiology

1 Scope

This European Code of Practice shall apply to feed additives and premixture operators at all stages from the first placing on the market of feed additives and premixtures. Therefore it also applies to the placing on the market of feed additives and premixtures after import from third countries.

The aim of this Code of Practice is to:

- establish an industrial standard to reduce risk related to adulterated feed additives and premixtures entering the feed chain;
- enable an operator to implement the objectives of the feed hygiene regulation (1831/2003/EC); and.
- provide measures to ensure that other applicable feed safety regulatory requirements are met.

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

2 Terms and definitions

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

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.

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 beyond the established specifications.

Check/control: Monitor and measure processes and product against policies, objectives and requirements for the product and report results

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.

Contamination: The undesired introduction of impurities of a chemical or microbiological nature or of foreign matter, into or onto a raw material, intermediate, feed additive or premixture during production, sampling, packaging or repackaging, storage or transport.

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

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:

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

Feed hygiene: The measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed additive or a premixture, taking into account its intended use.

Feed material: Various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof. Organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures.

Feed Safety: High level of assurance that the feed (feedingstuff) will neither cause harm to the farm animals when prepared or consumed according to the intended use, nor to the final consumer.

First placing on the market: The initial placing on the European Union market of an additive or premixture after its manufacture or the import of an additive or premixture. (See placing on the market).

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

Hazard: Property of a biological, chemical or physical agent in the feed chain with the potential to cause an adverse health effect for animals or consumers.

Incoming material: A general term used to denote raw materials (starting materials, reagents, solvents) and process aids.

Intermediate: Any material which has been processed by the operator and not yet been labelled as a final commercial product.

Lot Number: A combination of numbers, letters, and/or symbols which identify a lot and from which the production and distribution history can be determined.

Lot: A specific quantity of material produced in a process or series of processes, that it is expected to be homogeneous within specified limits. In the case of continuous production, a lot may correspond to a defined fraction of the production. A lot size may be defined either by a fixed quantity or the amount produced in a fixed time interval.

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

Operator: Any unit producing or manufacturing feed additives, premixtures prepared from additives, or products covered by Directive 82/471/EEC and any person other than the manufacturer or the person producing for the exclusive requirements of his holding, who holds additives, premixtures prepared from additives, or one of the products covered by Directive 82/471/EEC (amino acids and analogues) or any unit of feed additives or premixtures business (including traders and importers).

Placing on the market: Holding products for the purposes of sale, including offering for sale or for the purposes of any other form of transfer, whether or not free of charge, to third parties, and the sale and other forms of transfer themselves. (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 to direct feeding to animals.

Procedure: Operations to be performed, precautions to be taken and measures to be applied directly or indirectly related to the manufacturing of a material, feed additive or premixture.

Raw material: Any material which enters the manufacturing process of the feed additive and/or premixture.

Record: Written documents containing actual data.

Reworking: Any appropriate manipulation steps in order to ensure a feed additive or premixture will conform to specifications.

Risk: Exposure to a hazard related to food and feed safety

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.

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.

Verification: Application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with a requirement.

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.

3 Quality Management System (QMS)

3.1. General requirements

The operator shall establish, document, implement and maintain a quality management system in accordance with the requirements of this Code.

The QMS shall be continually adapted to consider regulatory developments.

The structure of the quality management system shall be specific to the organisation of the operator and includes policies, requirements and process documents that reflect the best practice of the operator.

The QMS 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. ISO standards as well as other approaches may be used to define the QMS.

3.1	Questionnaire	Remark
	List other quality standards the operator may comply with:	

3.2. Quality Management Principles

Operators should be able to demonstrate the awareness of all employees of their contribution to feed safety.

Each operator shall perform and record the evaluation of risks and subsequently define controls to be applied to the manufacturing process based on HACCP principles.

All quality related activities shall be recorded directly after they are performed.

Effective change control and investigation procedures shall be implemented to manage deviations from planned procedure.

Procedures shall exist for the timely notification of the appropriate management of occurrences that pose a threat to product safety or quality. (Such situations may include complaints, product recall, audit findings).

3.2	Questionnaire	YES	NO	Remark
	Do documents exist which give evidence that employees are involved in quality and feed safety?			
	Are HACCP principles applied?			
	Is an effective process change control system implemented?			
	Is a system in place to inform management of threats to product safety or quality?			
	Does the operator have a system in place to ensure that management is kept up-dated on all relevant legislation, feed and food safety issues, and relevant quality guidelines?			

3.3. 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 principles as part of a quality control plan.

Records shall contain all relevant data that will permit investigation of any non-conformance or deviation from planned procedure.

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

QMS documentation should include:

- a) a written quality 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.

Document control. Documents should

- 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.

Minimum documents required are:

- 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).

The Quality Policy should:

- a) be appropriate to the purpose of the operator;
- b) provide a framework for establishing and reviewing quality objectives; and
- c) be communicated and understood throughout the organisation.

The Quality Manual should include:

- a) the scope of the QMS, including details of and justification for any exclusion;
- b) documented procedures established as part of the QMS, or reference to them; and
- c) a description of the interaction between the processes of the QMS.

3.3	Questionnaire	YES	NO	Remark
	Does a quality management system exist?			
	Is a quality manual: <input type="checkbox"/> In place <input type="checkbox"/> Approved and signed by authorised persons? <input type="checkbox"/> Dated <input type="checkbox"/> And updated?			
	Does a written quality policy exist?			

3.3	Questionnaire	YES	NO	Remark
	Does the QMS state the operator's intention to meet its obligations to produce and market safe products?			
	Does the QMS state the operator's responsibility to its customers?			
	Is the QMS manual readily available to relevant staff?			
	Is a traceable document control system in place?			
	Does the QMS system include specifications on: <input type="checkbox"/> raw materials <input type="checkbox"/> finished products			
	Is a label control system in place to ensure that each label meets legislative requirements?			
	Do master formulae exist for all relevant products?			
	Do written controlled operating instructions and batch process records for each product exist?			
	Are Standard Operating Procedures (SOPs) available and adequate to ensure controlled production?			

4 Management Responsibility

4.1. Management commitment

Management shall be committed to the implementation of the Code in order to ensure feed quality and safety.

Documentation shall be provided to evidence this.

4.1	Questionnaire	YES	NO	Remark
	Does the management show commitment to quality and safety?			
	Is evidence documented to show this commitment?			

4.2. Quality and safety policy

Management shall:

- a) establish a quality and safety policy and ensure that objectives are established;
- b) define the scope of the HACCP system, by identifying the products/product categories and production sites which are covered by the system and ensuring that safety objectives are established as part of the system; and
- c) ensure that these objectives and policies are in compliance with business goals of the operator, statutory and regulatory requirements, and any specific additional safety requirements from customers.

4.2	Questionnaire	YES	NO	Remark
	Does the quality and safety policy specify objectives?			
	Are the requirements appropriate to the operator's activities and business goals?			
	Is the HACCP scope defined in the HACCP program?			
	Is the HACCP scope communicated to all involved persons?			

4.3. Responsibility, authority and communication

Management shall ensure that responsibility and authority are defined, in written form, and communicated within the organisation.

Staff appointed by senior management should have defined responsibility and authority to:

- a) identify and record any problems with regard to product quality, safety and the operator's HACCP system;
- b) initiate remedial measures and control of any such problems;
- c) initiate action to prevent the occurrence of nonconformities relating to product quality and safety; and
- d) appoint a HACCP team and team leader.
 - o The operator shall provide adequate resources for the implementation and control of the quality and HACCP systems. (Further information on HACCP is found in section 6.2).

4.3	Questionnaire	YES	NO	Remark
	Do function descriptions exist for each individual or group of individuals?			
	Is responsibility and authority defined?			
	Are function descriptions updated?			
	Is legal information communicated throughout the organisation?			

4.4. Management representative

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

- ensuring that processes needed for the quality management and HACCP systems are established, implemented and maintained;
- reporting to top management on the performance of the quality and product safety management systems and any need for improvement; and
- ensuring the promotion of awareness of customer requirements throughout the operator.

4.4	Questionnaire	YES	NO	Remark
	Is a management representative with responsibility for quality and safety issues appointed?			
	Does the manager report to the operator's top management?			
	Does the responsibility include the promotion of awareness of customer requirements?			

4.5. Management review

The management shall review, at defined intervals, the continuing suitability and effectiveness of quality and safety management systems.

Review shall include the assessment of opportunities for improvement and the need for changes to the quality and safety management systems.

4.5	Questionnaire	YES	NO	Remark
	Does a documented procedure exist for management review of the suitability and effectiveness of the QMS?			
	Does the review include: <input type="checkbox"/> Product quality? <input type="checkbox"/> Product safety? <input type="checkbox"/> Complaints? <input type="checkbox"/> Other? (Please give details)			
	How often is the review: <input type="checkbox"/> Annually? <input type="checkbox"/> Biannually? <input type="checkbox"/> Quarterly? <input type="checkbox"/> Bimonthly? <input type="checkbox"/> Monthly?			
	Are conclusions drawn and actions to be taken documented as part of the review process?			

5 Resource management

5.1. Provision of resources

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

To accomplish this, management shall:

- a) provide sufficient and appropriately designed equipment & premises;
- b) employ sufficient numbers of appropriately trained staff; and
- c) clearly assign the responsibility and authority for ensuring compliance with regulatory requirements and industry codes of practice to competent persons. Issue, maintain and make available to the operator and external bodies an organisational chart and job descriptions.

5.1	Questionnaire	YES	NO	Remark
	Does the operator have sufficient equipment?			
	Is equipment appropriately designed?			
	Does the operator have sufficient staff?			
	Are staff skilled to comply with expected tasks and requirements?			
	Has the operator assigned responsibilities to appropriate persons to comply with external requirements?			
	Does the operator have an organisational chart?			
	Is the organisational chart updated?			
	Are job descriptions available?			

5.2. Human resources

Employees and managers shall have the necessary skills, competencies, qualifications training and awareness to be able to execute their respective tasks, thereby ensuring the conformity of product and feed quality and safety

In particular:

- a) staff shall be adequately educated and trained in the appropriate procedures;
- b) education and training shall be documented and maintained; and
- c) staff shall be trained in appropriate standards of hygienic behaviour in order to contribute to overall feed safety, as part of the food chain.

5.2	Questionnaire	YES	NO	Remark
	Are qualifications documented?			
	Are staff trained in appropriate disciplines: <input type="checkbox"/> Feed safety? <input type="checkbox"/> HACCP principles? <input type="checkbox"/> Hygiene?			

5.2	Questionnaire	YES	NO	Remark
	<input type="checkbox"/> Quality? <input type="checkbox"/> Health and safety? <input type="checkbox"/> Environment?			
	Is training documented and maintained?			

5.3. Infrastructure

The operator shall provide applicable production conditions to the degree of necessity.

In particular this should include:

- a) adequate buildings;
- b) adequate utilities; and
- c) adequate process equipment.

The facilities and manufacturing equipment should be located, designed, constructed and maintained to suit the manufacture of the products concerned.

The lay-out, design and operation of the facilities and equipment should minimise the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination, carry over and any adverse effects generally on the quality of the products.

Any waste materials shall be clearly identifiable and disposed of in accordance with local regulations and feed safety.

5.3	Questionnaire	YES	NO	Remark
	Does the building seem to be adequate?			
	Are the buildings built of durable materials?			
	Are the building well maintained?			
	Are necessary utilities installed? <input type="checkbox"/> Water <input type="checkbox"/> Steam <input type="checkbox"/> Pressured air <input type="checkbox"/> Heating system <input type="checkbox"/> Extraction units <input type="checkbox"/> Others:			
	Are waste materials properly identified to avoid mix-up with other materials?			
	Is waste labelled and handled properly to avoid risks for workers or environment? <input type="checkbox"/> Internally <input type="checkbox"/> Externally			

5.4. Work environment

Where applicable, the operator shall provide adequate work environment in accordance with local regulations to achieve product conformity. For example:

- a) adequate ventilation;
- b) adequate control of humidity;
- c) adequate control of temperature;
- d) adequate lighting; and/or
- e) adequate hygienic design of plants and equipment.

5.4	Questionnaire	YES	NO	Remark
	<p>Does the operator seem to have established adequate work environment to maintain product conformity:</p> <p><input type="checkbox"/> Ventilation <input type="checkbox"/> Humidity control <input type="checkbox"/> Temperature control</p> <p><input type="checkbox"/> Lighting <input type="checkbox"/> Hygienic design</p> <p><input type="checkbox"/> Others:</p>			

6 Product realisation

6.1. Product requirements

6.1.1. 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.

	Questionnaire	YES	NO	Remark
	Does the operator have a system to identify external requirements?			
	Does the operator comply with external requirements?			
	Is compliance documented?			
	If there are requirements specified by customers is there a system to control their implementation?			
	Are other requirements identified and controlled?			

6.1.2. 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 of the EU and which cannot, from a regulatory point of view, be placed on the EU market, is described in the operator's QMS.
The operator should maintain a list of products in and out of the FAMI-QS certification scope.

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 6.3.2).

6.1.2	Questionnaire	YES	NO	Remark
	Are procedures in place to check the ability of the operator to comply with the identified requirements?			

6.1.3. 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.

6.1.3	Questionnaire	YES	NO	Remark
	Does the operator have in place relevant product information? (e.g. technical product information, specifications, material safety data sheets).			
	Is a system in place to communicate this information to the customers?			
	Is a system in place to receive and process information provided by the customers?			

6.2. HACCP Program

In the hazard analysis a survey is to be conducted to identify all potential hazards. Based on this analysis, hazards shall be classified according to risk.

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

It is recommended that operators follow the guidance for application of HACCP as documented in the Codex Alimentarius Guidelines.

Other requirements related the HACCP system can be found in sections 3.2, 4.2, 4.3, 4.4, 6.3.1, 6.4.1, 6.5.1 and 6.9.

6.2	Questionnaire	YES	NO	Remark
	Does the operator have a HACCP program in place?			
	Does the operator have a multidisciplinary HACCP team?			
	Does the operator have an appointed team leader?			
	Do the team members have adequate training and experience?			
	Is the HACCP system based on an adequate prerequisite quality system?			
	Are the following basic principles considered:			
	- Is the HACCP analysis performed and documented?			
	- Are the Critical Control Points (CCPs) identified?			
	- Are critical limits for the CCPs specified?			
	- Is a monitoring procedure specified?			
	- Are deviation procedures established and documented?			
	- Are verification procedures established and implemented?			
	- Are all procedures and records archived?			
	Does the HACCP plan consider all possible biological, physical and chemical hazards?			

6.3. Design and development

6.3.1. 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 feed additives shall be taken into account during the development process of a new product by applying HACCP principles.

6.3.1	Questionnaire	YES	NO	Remark
	Are development plans issued prior to relevant phases of the developments process?			
	Does the development plans consider risks related to safety?			
	Is HACCP considered?			

6.3.2. *Change control*

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

All changes should 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.

6.3.2	Questionnaire	YES	NO	Remark
	Does a formal change control procedure exist?			
	Are changes approved before implementation?			
	Are changes controlled and documented?			
	Are implemented changes reviewed?			
	Are implemented changes verified?			
	Are changes archived in a proper manner?			
	Are the following items included in the change control procedure <input type="checkbox"/> Safety? (Feed, workers, environment) <input type="checkbox"/> Regulatory requirements? <input type="checkbox"/> Quality?			

6.4. *Handling of incoming materials*

6.4.1. *Sourcing of incoming materials*

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

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

Every raw material shall be evaluated to assess any potential hazard associated with it.

Each raw material shall have a written specification which is amended when any change takes place. In addition to the analytical characteristics of the product, the specification should include, where appropriate, details of any undesirable substance with which the product may typically be associated, and any other hazards or limitations associated with the product which have been considered in the operator's HACCP system.

In case the material is a feed additive or premixture imported from outside the European Union, a written confirmation of the compliance with the EU current feed regulations issued by the supplier is needed. Feed additives and premixtures imported from outside the EU should only be supplied by FAMI-QS certified operators.

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

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.

Records of the results of evaluations and necessary actions arising from the evaluation shall be maintained.

6.4.1	Questionnaire	YES	NO	Remark
	Is there an approval process for new suppliers?			
	Is there an up-to-date list of approved suppliers?			
	Are approved suppliers reviewed and re-evaluated?			
	How often does review of approved suppliers take place? <input type="checkbox"/> Annually? <input type="checkbox"/> Biannually? <input type="checkbox"/> Other:.....			
	Does each purchased incoming material have an agreed upon specification?			
	Do specifications consider compliance with feed safety and legislative requirements?			

6.4.2. Verification of incoming materials

Each lot entering the site shall be uniquely registered by means of a lot 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.

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

Handling of incoming product should 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.

If incoming materials are rejected and not incorporated for any reason related to product quality or safety, their disposal, destination, or return to supplier shall be recorded.

6.4.2	Questionnaire	YES	NO	Remark
	Does a formal written procedure on handling of incoming materials exist?			
	Are incoming materials registered uniquely according to: <input type="checkbox"/> Supplier's name/lot/batch number? <input type="checkbox"/> Operator's lot/batch number? <input type="checkbox"/> Name of material? <input type="checkbox"/> Quantity received? <input type="checkbox"/> Date of receipt? <input type="checkbox"/> Expiry date?			
	Are incoming materials inspected? <input type="checkbox"/> Before unloading? <input type="checkbox"/> During unloading? <input type="checkbox"/> After unloading?			

6.4.2	Questionnaire	YES	NO	Remark
	Does the inspection include: <input type="checkbox"/> Pest infestation? <input type="checkbox"/> Documentation of findings?			
	Are non-conformities recorded?			
	Are records of inspection results documented and maintained?			
	Are records of supplier guarantees or certifications maintained?			
	Are incoming materials released before being used?			
	In the event that product is returned to a supplier, is documentation maintained to reflect that?			

6.5. Production of finished goods

6.5.1. 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 should include, as applicable:

- a) The availability of information that describes the characteristics of the finished product.
 - o Each product shall have a written specification, which is amended when any change takes place.
 - o Each product shall have a unique name or code.
 - o Details of packaging and labelling shall be available.
 - o 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.
 - o All finished product should be inspected prior to dispatch, in accordance with written procedures, to ensure it meets specification. A retention sample shall be taken of each batch and held, as a minimum, for a time equivalent to the defined shelf life of the product.
 - o If products are rejected and not put into circulation for any reason related to product quality or safety, their disposal, destination, or return to supplier shall be recorded. Further details are found in section 8. (Control of non-conforming products).
- b) The availability of work instructions
 - o 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 include procedures surrounding the precautions necessary to avoid cross-contamination and errors.
 - o Records shall be kept which confirm that procedures are followed and/or identify any deviation from them. Procedures shall be subject to regular critical appraisal to ensure that they continue to be effective.
- c) Rules governing packaging
 - o Where products are packaged, care shall be taken to avoid 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 being to maintain contents for their intended shelf life. Packaging shall be considered under HACCP analysis.
 - Pallets shall be serviceable, clean and dry. All pallets which are returned shall be inspected and if necessary cleaned before re-use.
- d) Rules controlling storage
- Finished product shall be clearly identified and stored in clean dry conditions. Access to these materials should 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 places designed, adapted and maintained, in order to ensure appropriate storage conditions which manage the risks of contamination and the presence of harmful organisms. Packed materials shall be stored in appropriate packaging.
 - Materials should be stored in a manner which enables easy identification, avoids cross-contamination and prevents deterioration. A stock rotation system should be in place.
 - The storage environment should 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.
 - Containers and equipment used for internal transport, storage, conveying handling and weighing shall be kept clean. Cleaning procedures should consider such containers and equipment.
 - A final inspection shall take place to ensure delivery of correct product.

6.5.1	Questionnaire	YES	NO	Remark
	Are the production areas accessible to authorised personnel only?			
	Is production run according to formal production planning?			
	Is the plan distributed to the relevant persons?			
	Does the operator keep records on production in order to demonstrate that production has been followed according to planned methods?			
	Are there any systems to prevent or control cross-contamination?			
	Does each product have a specification?			
	Does each product have a unique name and/or code?			
	Does each product have a predefined label?			
	Are finished products clearly marked and identified?			
	Does each product have a predefined packaging instruction?			
	Do packaging specifications exist?			
	Is the packaging process controlled to avoid contamination and ensure proper labelling?			
	Are all deliveries inspected prior to dispatch?			
	Is this inspection documented?			
	Are non-conforming products stored segregated and in a manner to prevent			

6.5.1	Questionnaire	YES	NO	Remark
	failures?			
	Are the storage facilities adequate?			
	Are storage facilities operated in a suitable manner with separation between various purchased materials?			
	Are appropriate storage facilities available? <input type="checkbox"/> Clean areas/rooms? <input type="checkbox"/> Ventilated? <input type="checkbox"/> Dry? <input type="checkbox"/> Temperature controlled?			
	Is a stock rotation system in place?			
	Is outdated stock controlled and segregated?			
	Are loose bulk materials controlled and segregated efficiently from other loose bulk materials?			

6.5.2. Verification of processes for production

The operator shall verify any processes for production where the resulting output cannot be controlled by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or has been delivered.

Verification should demonstrate the ability of these processes to achieve planned results.

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.

6.5.2	Questionnaire	YES	NO	Remark
	Is a written verification procedure in place?			
	Does recent verification show that the equipment is able to ensure proper operation?			
	Does this show the process will result in material complying with predetermined requirements?			

6.5.3. 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, additives or of intermediaries. Incoming materials shall be verified according to section 6.4.2.
 - the nature and quantity of the additives and premixes produced, 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 name and

addresses of the intermediaries or manufacturers or users to whom the additives or premixes have been delivered.

6.5.3	Questionnaire	YES	NO	Remark
	Is a traceability system in place?			
	Can traceability be shown by examples?			
	Can supplied incoming materials be traced to suppliers?			
	Do records allow tracing back from the final product through quality control data and batch records to the raw materials used?			
	Can deliveries be traced to customers?			
	Is name of customer related to delivered batch and amount?			

6.5.4. Preservation of product

The operator shall establish the shelf life of a product and preserve the conformity of 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.

6.5.4	Questionnaire	YES	NO	Remark
	Is a stability program installed?			
	Is product environment controlled during storage to preserve conformance with quality requirements?			

6.6. Transport

Where third party distribution or haulage is used, this shall be selected on the basis that the haulier can satisfy safety and reliability criteria. Special attention shall be paid to vehicle hygiene and cleanliness, correct loading and avoidance of contamination and cross-contamination. This shall be verified by visual inspection prior to loading.

In respect of bulk deliveries, the transportation agent shall provide information about at least the last previous load. In cases where the last previous load consisted of product/s which may compromise the safety of the final product, or are products not permitted for inclusion in feedingstuffs according to existing regulations, the transportation agent shall provide a cleaning certificate, information about the means of cleaning and drying and guarantee that a clean, empty, dry and odourless cargo compartment and discharge equipment is made available.

6.6	Questionnaire	YES	NO	Remark
	Are third party transporters used?			
	Are these evaluated and do they meet current (feed) quality requirements?			
	Do procedures make provision for a check of the previous load carried by bulk hauliers?			
	Where the previous load presents a risk to the operator's product, does the system ensure a check that the bulk transporters provide cleaning certificates for the cargo			

6.6	Questionnaire	YES	NO	Remark
	compartment and discharge equipment?			
	Where a cleaning check is implemented, does it include a check of the cargo compartment and discharge equipment?			
	Does a final inspection take place before shipping, and is this inspection documented?			

6.7. Control of monitoring and measuring devices

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

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 affected. Records of the results of calibration and verification shall be maintained.

A documented plant maintenance program shall be in operation. A record shall be kept of work carried out.

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 as necessary.

6.7	Questionnaire	YES	NO	Remark
	Is a formal calibration system in place?			
	Does this include identification of items to be calibrated?			
	Are appropriate calibration periods defined based on evidence?			
	Is calibration recorded?			
	Does a formal preventive maintenance program exist?			
	Are maintenance intervals defined?			
	Is maintenance work documented?			
	Is the safety of products ensured during maintenance work?			

6.8. Cleaning

Both inspection and cleaning shall be documented. This shall be addressed as part of the HACCP system.

6.8	Questionnaire	YES	NO	Remark
	Does a formal cleaning program exist?			
	Does the cleaning program include cleaning at appropriate frequencies? <input type="checkbox"/> Periodic deep cleaning <input type="checkbox"/> Maintenance cleaning <input type="checkbox"/> Daily house-keeping			
	Does the cleaning program define responsibility?			
	Does the cleaning program describe post-evaluation?			
	Are cleaning records up-to-date?			
	Do detailed procedures on cleaning of equipment exist?			
	Do the cleaning procedures appear to support hygiene and feed safety efficiently?			
	Are employees trained in cleaning procedures?			
	Is training on cleaning procedures documented?			
	Does the plant appear in a clean state?			

6.9. Pest control

There should be a written plan for pest control including description of periodic inspections. Results of such inspections shall be recorded. Details of any fumigation or use of chemicals such as pesticides shall be recorded.

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

6.9	Questionnaire	YES	NO	Remark
	Is a formal, (documented) preventative pest control system in place?			
	Is the program undertaken <input type="checkbox"/> In-house? <input type="checkbox"/> Outside contractor? Name (if contracted):			
	Are preventive measures on place for: <input type="checkbox"/> Rodents, outside? <input type="checkbox"/> Rodents, inside? <input type="checkbox"/> Birds? <input type="checkbox"/> Flying insects? <input type="checkbox"/> Crawling insects? <input type="checkbox"/> Other, describe:			
	Do maps or schematics showing the locations of the preventive measures exist?			
	Are pest activities documented?			
	Are pesticide/chemicals applied and their suitability documented?			
	Does the usage of the suitable pesticides / chemicals comply with local regulations?			

6.9	Questionnaire	YES	NO	Remark
	Does the plant seem to be reasonably cleared to prevent infestation?			

7 System Review

7.1. General requirements

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

7.1	Questionnaire	YES	NO	Remark
	Does a formal review system exist?			
	Does the system include collection of data?			
	Does the system include analysis of data?			
	Does the system include conclusions?			
	Does the system include improvements based on conclusions?			

7.2. Internal audits

The operator shall ensure that internal audits are performed to verify that the quality management system is:

- a) effectively implemented and maintained; and
- b) in compliance with regulatory and other defined requirements.

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

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

- a) preparation and issue of audit plans;
- b) scope of audits;
- c) frequency of audits;
- d) methods used to conduct the audits;
- e) reporting of findings;
- f) distribution of reports;
- g) implementation of corrective actions and follow-up activities; and
- h) selection and training of competent auditors.

7.2	Questionnaire	YES	NO	Remark
	Does the company have an audit system in place?			
	Are internal audits carried out?			
	Which issues are included in the audits: <input type="checkbox"/> Product safety? <input type="checkbox"/> Regulatory requirements? <input type="checkbox"/> Quality? <input type="checkbox"/> Health and safety? <input type="checkbox"/> Environment?			

7.2	Questionnaire	YES	NO	Remark
	<input type="checkbox"/> Other, describe:			
	Does the operator have a scheduled audit program?			
	Are auditors suitably trained?			
	Are audits reported and documented?			
	Is the scope of each audit defined?			
	Are feed safety issues included in the audits?			
	Are non-conformities identified during the audit reported?			
	Is follow-up on non-conformities reported?			
	Are corrected non-conformities verified?			

8 Control of non-conforming products

8.1. General requirements

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

The procedure should 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; and
- 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 should be reviewed in accordance with documented procedures and actioned in one of the following ways:

- a) rework;
- b) reclassification or dispensation; or
- c) rejection and subsequent destruction or disposal.
 - o 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 quality rejects, customer returns or spillage) shall be considered within the HACCP system. Potential reworks which are not approved become waste material and should be dealt with according to waste disposal procedures.

8.1	Questionnaire	YES	NO	Remark
	Is a formal system in place to handle non-conforming products?			
	Do procedures consider the following: <input type="checkbox"/> work-in-progress? <input type="checkbox"/> finished products? <input type="checkbox"/> returned products?			
	Do staff seem to be aware of these procedures?			
	Do procedures include: <input type="checkbox"/> Clear marking of the non-conforming products?			
	Do procedures address control of the non-conforming batch/lot? <input type="checkbox"/> Disposition with rejection? <input type="checkbox"/> Acceptance with restrictions? <input type="checkbox"/> Potential for alternative use?			
	Do written procedures exist on how to handle rejected materials and products?			

8.2. Complaint handling system

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

- a) allocate responsibility for controlling complaints;
- b) record name of complaining customer;
- c) record product name and identification code;
- d) identify and record the cause of each complaint; and
- e) reply to the complaining customer.

Corrective actions should 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.

8.2	Questionnaire	YES	NO	Remark
	Does a formal customer complaint handling system exist?			
	Are complaints evaluated according to <input type="checkbox"/> ause of complaint? <input type="checkbox"/> Seriousness? <input type="checkbox"/> Customer? <input type="checkbox"/> Identification of environmental, health and safety risks? <input type="checkbox"/> Other, (please give details)			
	Are complaints used to prevent recurrence?			
	Are corrective actions initiated and carried through?			

8.3. Recall

A formal recall procedure shall be documented so that customers can be informed immediately of any irregularity which compromises product safety. The recall procedure shall be regularly reviewed to ensure conformance with the quality system and regulatory requirements.

The recall procedure should include requirements to:

- a) define and allocate responsibility for the recall process;
- b) identify the non-conforming product and batch, including consequences to other products, batches or raw materials;
- c) identify the destination of affected lots;
- d) describe procedures for disposal of returned product/s, including segregation from other products; and
- e) maintain registers of information tracing the product and its components from production to customers.

In case of a serious risk to human or animal health the recall procedure shall include requirements to notify local authorities, as defined in relevant legislation.

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

8.3	Questionnaire	YES	NO	Remark
	Does a formal recall procedure exist?			
	Does the recall procedure assign responsibility to an appropriate person?			
	Does the procedure adequately describe the recall process flow?			
	Are recalls documented?			
	Is the recall procedure tested regularly?			
	Are the test results documented?			
	Are the test results evaluated and used for improvement?			
	Does the recall procedure include requirements on notification of authorities?			

9 Statistical techniques

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

9	Questionnaire	YES	NO	Remark
	Are statistical techniques used?			
	Are the areas defined where the statistic tools are used?			
	Does an overview of statistical methods exist?			
	Is the applicability of the methods in use documented?			
	Does the operator possess statistic competencies?			