



## 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 European feed hygiene requirements, and improved traceability. The code also applies to import from third countries of feed additives and premixtures.

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:

- The European Commission's White Paper on Food Safety (COM (1999) 719 final)  
[http://europa.eu.int/comm/dgs/health\\_consumer/library/pub/pub06\\_en.pdf](http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub06_en.pdf)
- 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conditions and arrangements for approving and registering establishments and intermediaries in the animal feed sector (repealed by Regulation 183/2005).  
[http://www.europa.eu.int/comm/food/food/animalnutrition/approval/approval01\\_en.pdf](http://www.europa.eu.int/comm/food/food/animalnutrition/approval/approval01_en.pdf)  
[http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l\\_208/l\\_20819980724en00430048.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_208/l_20819980724en00430048.pdf)
- Regulation of the European Parliament and of the Council on additives for use in animal nutrition. (1831/2003/EC).  
[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_268/l\\_26820031018en00290043.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00290043.pdf)
- 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).  
[http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l\\_031/l\\_03120020201en00010024.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf)
- Regulation of the European Parliament and of the Council laying down requirements for feed hygiene. (183/2005/EC).  
[http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l\\_035/l\\_03520050208en00010022.pdf](http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_035/l_03520050208en00010022.pdf)
- 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/>.

- o Management systems developed by associations in different Member States, for instance:

Code of Practice (FEFAC, EU)

<http://www.fefac.org/code.aspx?EntryID=265> )

FEMAS (AIC, UK)

<http://www.agindustries.org.uk/content.template/30/30/Home/Home/Home.msp>x)

GMP (OVOCOM, B)

[http://www.ovocom.be/intro\\_fr.htm](http://www.ovocom.be/intro_fr.htm)

GMP+ (PDV, NI)

[http://www.pdv.nl/index\\_eng.php?switch=1](http://www.pdv.nl/index_eng.php?switch=1)

Q+S (DVT, D).

<http://www.q-s.info/>

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 order to facilitate implementation of the Code, the structure of ISO 9001:2000, Quality Management Systems, is used.

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 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. These are covering topics of special importance. While the requirements of the Code are mandatory for every operator, the Guidance papers provide information in a more detailed and practical way and if applicable may serve as additional assistance. If the operator decides to follow the procedures described in the Guidance, this will become a part of its Safety System. In case that, for good reasons, he uses different procedures, he must be able to provide evidence upon request that he is complying with the requirements of the Code as well.

Both the Code and Guidance will be submitted to periodical revision in case of relevant technological, scientific and legislative developments or statutory modification in the sector.

Note: FAMI-QS Code of Practice is a public document and its contents can be freely followed by any feed additive or premixture operator.

Running side by side FAMI-QS Asbl has developed a parallel and independent certification system that is described in the Process Description document. Participation in the FAMI-QS auditable system is based on voluntary commitment.

*Please, consult the FAMI-QS web-page [www.fami-qs.org](http://www.fami-qs.org) to have access to these documents and learn more about how to ensure compliance with this Code of Practice.*

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## Annexes

- Annex 1: Guidance on the implementation of HACCP
- Annex 2: Guidance on the implementation of basic hygiene rules
- Annex 3: Guidance on the implementation of a complaint handling system
- Annex 4: Guidance on transport
- Annex 5: Guidance on homogeneity
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- Annex 7: Guidance on sampling
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- Annex 10: Guidance on carriers for premixtures
- Annex 11: Guidance on risk assessment in production
  - . 11a: Production of feed additives by fermentation processes
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  - . 11c: Production of feed additives by mixing (premixes)
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  - . 11e: Production of feed additives by extraction processes
- Annex 12: Guidance on product recall
- Annex 13: Tables of cross references between FAMI-QS requirements and EU legislation

## 1 Scope

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

- minimizing the risk, that adulterated feed additives and premixtures enter the feed chain;
- enabling an operator to implement the objectives of the feed hygiene regulation (1831/2005/EC); and
- providing measures to ensure that other applicable feed safety regulatory requirements are met.

Feed is considered unsafe for its intended use if it 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 feed additives and premixture operators at all stages from the first placing on the market of feed additives and premixtures based on current EU legislation. Therefore it also applies to the placing on the market of feed additives and premixtures 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. A tool for checking the regulatory status of feed additives is the Register of Feed Additives:

([http://europa.eu.int/comm/food/food/animalnutrition/feedadditives/registeradditives\\_en.htm](http://europa.eu.int/comm/food/food/animalnutrition/feedadditives/registeradditives_en.htm))

that has been published by the European Commission and is periodically updated.

## 2 Terms and definitions

The following terms and definitions do not only cover this guide but also the annexes:

**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 Regulation. In determining whether a requirement is adequate, appropriate, necessary, or sufficient, account should be taken of 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 authorized 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.

**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 and safety 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.

**Establishment:** Any unit of a feed business that carries out the manufacture/production and/or the placing on the market of feed additives and premixtures (*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 a EU member state.

**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:

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 gastrointestinal flora or digestibility of feedingstuffs; or

have a coccidiostatic or histomonostatic effect.

*(Regulation 1831/2003/EC and Regulation 183/2005/EC)*

**Feed business:** Any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing or distribution of feed additives and premixtures. *(Regulation 178/2002/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 law are met within the feed business under their control. *(Regulation 178/2002/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 additive or a premixture, taking into account its intended use. *(Regulation 183/2005/EC)*.

**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. *(Regulation 1831/2003/EC)*

**Feed Safety:** High level of assurance that the feed (feedingstuff, feed additive, or premixture) will neither cause harm to the farm animals when prepared or consumed according to the intended use, or 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 an additive or premixture after its manufacture or the import of an additive or premixture. (See placing on the market). *(Regulation 1831/2003/EC)*

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

**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.

**Hazard:** Biological, chemical or physical agent in the feed chain with the potential to cause an adverse health effect for animals or consumers. *(Regulation 178/2002/EC)*

**Import:** The release for free circulation of a product or the intention to release a product for free circulation into a 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 and premixtures).

**Intermediate:** Any material which has been processed by the operator before the final product is obtained.

**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.

**Minerals:** Feed materials may include minerals mentioned in Annex Part B, chapter 11, of Directive 96/25/EC.

**Operator:** See feed business operator.

**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. (*Regulation 178/2002/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 to direct feeding to animals. (*Regulation 1831/2003/EC*)

**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.

**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*)

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

**Safety:** See feed safety.

**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.

**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 importation, 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)*

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

**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.

### 3 Management System (MS)

#### 3.1. General requirements

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

The MS shall be continually adapted to consider regulatory developments.

The structure of the MS shall be specific to the organisation of the operator and 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 authorization of the feed additive and the specification of the premixture.

**Ensure that:**

- *The MS is covering all the operator's activities.*
- *Other activities are not conflicting with the feed safety requirements.*

#### 3.2. 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 and safety related activities shall be recorded directly after they are performed.

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

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

For more detailed information on the relevant legislation on feed additives and premixtures see Annex 9 "Guidance on compliance with the EU legislation on feed additives and premixtures for product realisation".

**Ensure that:**

- *employees are committed to quality and feed safety*
- *HACCP principles are applied*
- *An effective change control system is implemented*
- *Information of management 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 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.

*MS documentation should include:*

- a) a written quality and safety policy, re. section 4.2;
- 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 Manual should 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 to cover the prerequisite program in support of the HACCP program
- d) HACCP procedures to ensure feed safety.

**Ensure that:**

- *A management system exists.*
- *The quality manual is*
  - *In place*
  - *Approved and signed by responsible person/persons*
  - *Dated and updated*
- *That a quality and safety policy exists.*
- *The MS include the operator's intention to meet obligations the produce and market safe products.*
- *The MS includes the operator's responsibility to its customers.*
- *The MS manual is readily available to relevant staff.*
- *The document control system is traceable.*
- *Specifications on raw materials and finished products exist.*
- *The label system in place meets legislative requirements.*
- *Master formulae exist on all products.*
- *Controlled operating instructions and batch process records for each product exist.*
- *Standard Operating Procedures (SOPs) are available.*

## 4 Management Responsibility

### 4.1. Management commitment

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

Documentation shall be provided to evidence this.

**Ensure that:**

- *Management shows commitment to quality and feed safety*
- *Evidence of commitment is documented.*

### 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.

**Ensure that:**

- *The quality and safety policy specifies the objectives.*
- *The requirements are appropriate to the business goals.*
- *The scope of the HACCP program is defined.*
- *The HACCP scope is 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.

The operator shall provide adequate resources for the implementation and control of the HACCP systems. Further details on HACCP requirements are found in section 6.2.

**Ensure that:**

- *Function descriptions exist for each individual or group of individuals.*
- *Responsibility is included.*
- *Function descriptions are updated.*
- *Legal information is communicated throughout the organisation.*

#### **4.4. Management representative**

Senior management should 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 operator.

**Ensure that:**

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

#### **4.5. Management review**

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

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

**Ensure that:**

- *A documented procedure exist for management to review the suitability and effectiveness of the MS.*
- *That the revies include topics like:*
  - *Product quality and safety*
  - *Complaints*
- *The review is done periodically at a predefined interval.*
- *Conclusions drawn and actions taken are documented as part of the review.*

## 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.
- d) provide water of a suitable quality, e.g. potable water, so that the product complies with feed safety requirements.

**Ensure that:**

- *That the equipment suits its purpose.*
- *The design is appropriate.*
- *The staffs is sufficient and skilled to comply with expected tasks and requirements.*
- *Appropriate persons have adequate responsibilities to comply with external requirements.*
- *An organisational chart exists and updated.*
- *Job descriptions are available and updated.*

### 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 quality and feed 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.

**Ensure that:**

- *Qualifications are documented*
- *Necessary disciplines are available like*
  - *Feed safety*
  - *HACCP competencies*
  - *Hygienic knowledge*
  - *Quality competencies*
  - *Health and safety*
  - *Environment*
- *Training files are documented and maintained*

**5.3. Infrastructure**

The operator shall provide applicable production conditions to the degree of necessity to ensure feed safety of the products.

In particular this should include:

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

This means that,

- 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 and safety of the products.

For more detailed information on how carry-over can be dealt with see the “Guidance on carry-over” (Annex 6).

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

**Ensure that:**

- *The building is suitable for the purpose to minimize risks.*
- *The building is durable to minimize maintenance and food safety risks.*
- *The building is well maintained by a preventive maintenance program.*
- *Necessary utilities are available, e.g.*
  - *Potable water or other water quality*
  - *Steam*
  - *Pressured air*
  - *Heating system*
  - *Extraction units*
  - *Other relevant utility system*
- *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.*

**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;

Ventilation systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceiling.

## b) Adequate control of humidity;

If necessary to keep rooms free of excessive steam and condensation, mechanical ventilation of sufficient capacity shall be provided.

## c) Adequate control of temperature;

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.

## d) Adequate lighting; and/or

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

## e) Adequate hygienic design of plants and equipment.

The plant must be designed to be durable to the processes and permit cleaning in order to prevent built-up of dirt and dust.

The equipment must be designed to facilitate manual or CIP cleaning and/or disinfection by having surfaces that are smooth, free of sharp angles, corners, crevices, smooth welds.

**Ensure that:**

- *Product conformity is maintained by adequate work environment, like*
  - *Ventilation*
  - *Humidity control*
  - *Temperature control*
  - *Lighting*
  - *Hygienic design*

## 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.

**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.*

#### 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 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 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 6.3.2).

**Ensure that:**

- *Procedures are in place to comply with 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.

**Ensure that:**

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

## 6.2. HACCP Program

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

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, 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 procedure and records to demonstrate the HACCP system is working effectively.

For more detailed information on how HACCP principles can be applied see the "Guidance on the implementation of HACCP" (Annex 1).

Among the risks to be considered during a HACCP analysis are issues such as homogeneity or microbiology. For more information see the "Guidance on homogeneity" (Annex 5) and the "Guidance on microbiology" (Annex 8).

For an HACCP analysis to study the risks associated to various production processes, see the "Guidance on risk assessment in production" (Annexes 11 a-e)

Due to HACCP requirements being integrated in the MS and the Quality Manual, other specific requirements are mentioned in the following sections of this Code:

- 3.2 Management principles
- 3.3 General documentation requirements
- 4.2 Quality and safety policy
- 4.3 Responsibility, authority and communication
- 4.4 Management representative
- 5.2 Human resources
- 6.3.1 Development of new products and processes
- 6.4.1 Sourcing of incoming materials
- 6.5.1 Quality control and production
- 6.8 Cleaning
- 6.9 Pest control
- 8.1 General requirements, non-conforming products

For more detailed information on how basic hygiene can be achieved see the “Guidance on the implementation of basic hygiene rules” (Annex 2).

**Ensure that:**

- *A HACCP program is developed and maintained.*
- *A multidisciplinary HACCP team is announced.*
- *A competent team leader is appointed.*
- *Adequate training of the HACCP team members is supplied.*
- *An adequate prerequisite quality program exists.*
- *A HACCP analysis is performed and documented.*
  - *The Critical Control Points (CCPs) are identified.*
  - *Critical limits are specified.*
  - *Monitoring is provided.*
  - *A deviation procedure is established and implemented.*
  - *Verification procedures are established and implemented.*
  - *All procedures and records are archived.*
- *Possible biological, physical and chemical hazards are considered.*

### **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.

**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,*

#### *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.

**Ensure that:**

- *A formal change control procedure exists.*
- *Changes are approved before implementation.*
- *Changes are controlled and documented.*
- *Changes implemented are reviewed, verified and archived.*
- *Safety, quality and regulatory requirements covered by the change control procedure.*

### **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.

These feed additives and premixtures should be produced in compliance with the requirements of this code, see Annex 9 "Guidance on compliance with the EU legislation on feed additives and premixtures for product realisation".

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.

**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,*

#### 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. For more detailed information on possible sampling procedures see the "Guidance on sampling" (Annex 7).

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 and safety, their disposal, destination, or return to supplier shall be recorded.

For more detailed information how safety of carriers for premixtures can be achieved see the “Guidance on carriers for premixtures” (Annex 10).

**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.*
- *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.*

## **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-authorized personnel can be prevented.

Controlled conditions should 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 should be inspected prior to dispatch, in accordance with written procedures, to ensure it meets specification. A retention sample 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 prevent abnormal change, and kept at the disposal of the authorities for a period appropriate to the use.

For more detailed information on possible sampling procedures see the "Guidance on sampling" (Annex 7).

- If products are rejected and not put into circulation for any reason related to product quality and 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:
- 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.
  - 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:
- 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.

**Ensure that:**

- *Production areas are accessible to authorized 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.*
- *Outdated stock is controlled and segregated.*
- *Loose bulk materials are controlled and segregated from other loose bulk material.*

### 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.

**Ensure that:**

- *A written verification procedure is in place.*

### 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.

**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.*

### 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.

**Ensure that:**

- *A stability program is defined and on-going.*
- *Product environment is controlled during storage to preserve conformance with quality and safety 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.

For more detailed information on transportation safety requirements see the “Guidance on transport” (Annex 4).

**Ensure that:**

- *Transporters are controlled, evaluated and meet expected quality and safety requirements.*
- *Procedures are in place to check for the previous load carried by bulk haulers.*
- *In case the previous load present a risk to the operator's product, perform a check that the bulk transporters provide cleaning certificates for the cargo compartments and discharge equipment.*
- *A final inspection takes place before shipping and the result is 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.

**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.*

**6.8. Cleaning**

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

**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 currently.*
- *Procedures on cleaning of equipment exist, and support hygiene and feed safety.*
- *Employees are trained in cleaning procedures and the training is documented.*

**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.

**Ensure that:**

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

## 7 System Review

### 7.1. 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 should 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 a conclusion.*
- *The system includes improvements originates from the conclusion.*

### 7.2. Internal audits

The operator shall ensure that internal audits are performed to verify that the 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.

**Ensure that:**

- *An audit system is in place.*
- *Internal audits are carried out.*
- *A scheduled audit program is in place.*
- *The auditors are suitably trained.*
- *Audits done are reported and documented.*
- *The audits contain a defined scope.*
- *Food safety issues are included in scope.*
- *Identified non-conformities are reported.*
- *A formal follow-up is reported.*
- *Corrected non-conformities are 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.
- d) 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 should be dealt with according to waste disposal procedures.

**Ensure that:**

- *A formal system on how to handle non-conforming products exists.*
- *The procedure covers*
  - *Work in progress*
  - *Finished products*
  - *Returned products*
- *The staff is aware of the*
- *A clear marking or other means of control of non-conforming products exist.*
- *Written procedures exist on how to handle*
  - *Rejected materials*
  - *Accepted materials with restrictions*
  - *Potential alternative use is justified and within feed safety*
- *Written procedures on how to handle rejected materials exist.*

## **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.

For more detailed information on how a complaint handling system can be installed see the "Guidance on the implementation of a complaint handling system" (Annex 3).

**Ensure that:**

- *A formal customer complaint handling system exists.*
- *The complaints are evaluated according to:*
  - *Cause*
  - *Seriousness*
  - *Customer*
  - *Environmental health and safety risks*
  - *Other relevant topics*
- *The complaint topics are used to prevent reoccurrence.*
- *The related corrective actions are carried through.*

## **8.3. Recall – Withdrawal**

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

See Annex 12 (Guidance on product recall) for a more detailed description of the process.

**Ensure that:**

- *A formal recall procedure exists.*
- *Responsibility is assigned to an appropriate person.*
- *The recall process is adequately described.*
- *Any recall is documented.*
- *The recall procedure is tested regularly.*
- *The test (mock) recalls are documented.*
- *The outcomes of the test (mock) recalls are evaluated.*
- *The recall procedure includes requirements on notification of the authorities.*

## 9 Statistical techniques

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

**Ensure that:**

- *The use of statistical techniques has been evaluated and defined*
- *An overview of statistical methods is available.*
- *The applicability of methods is documented.*
- *The operator possesses the necessary statistical competencies.*