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NOTE: Although this Standard may be translated into various languages for the convenience of users, the English version remains the definitive reference document in the event of any dispute.

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SECTION 1 INTRODUCTION

1.1 Scope

This FEMAS standard has been designed to cover the assurance requirements for all feed ingredients used in the production of animal feed, whether they are the primary products *of a production system* or by-products and regardless of their country of origin. This standard is intended for use with all feed ingredients, including micro-ingredients such as flavours, vitamins and enzymes.

1.2 The Principles of FEMAS

This standard has been developed to provide assurance to purchasers of feed ingredients that the feed ingredients they buy are safe and will meet the quality criteria specified. The **FEMAS International Core Standard** is designed for application in all countries where feed ingredients are produced and application for certification is open to feed ingredients suppliers in all countries.

The main aims of this FEMAS standard are:

- i) The protection of health: both of the animals that consume the feed ingredients certificated under this standard and of the humans consuming the livestock products derived from those animals in the form of meat, milk, eggs and fish.
- ii) To ensure that the feed ingredients certificated under FEMAS meet the quality expectations required by this standard and the purchaser.

To comply with this standard, participants will need to apply the principles of Hazard Analysis (HACCP) and Good Operating Practice. Participants certificated to the FEMAS Standard will have demonstrated that they have rigorous controls at each stage of the supply chain that meet standards currently recognised as international “good practice” and which maintain the safety and specification of the feed ingredients supplied.

Where a participant owns or operates multiple sites, each site must be assessed for compliance against the FEMAS requirements in its own right.

FEMAS is a product certification programme, consequently each feed ingredient supplied by a participant will be assessed on its own merits and any certificates of compliance issued will specify the feed ingredients for which compliance is being certificated.

This FEMAS standard encompasses all the operations and activities of a participant that may have a bearing on the safety and specification of the feed ingredients

supplied, from raw material procurement and supplier approval, through to the point at which any feed ingredients produced are transferred to a third party.

Assessments will therefore include:

- i) The original selection and sourcing of raw materials by participants
- ii) All transport to and from the participants premises or designated store
- iii) The process by which feed ingredients are produced
- iv) The storage of both raw materials and feed ingredients.

Although FEMAS represents 'good practice', compliance with this standard does not in itself absolve or diminish obligations that may be incumbent upon a participant as a result of any client, statutory or regulatory requirements. In addition to the requirements of this standard, participants must ensure that all feed ingredients they supply meet the current legislative requirements of both the country in which the participant is operating and the countries to which they supply feed ingredients.

1.3 The FEMAS 'Non-GM' Module

An additional Module has been produced for the application of FEMAS to non-GM feed ingredients, where specific additional controls are required beyond those detailed in this Standard. Participants seeking certification to FEMAS for the supply of non-GM feed ingredients must demonstrate compliance with the **FEMAS Non-GM Module**, in addition to compliance with this **FEMAS International Core Standard**.

The **FEMAS Non-GM Module** applies to:

- i) All participants making non-GM claims for their feed ingredients.
and
- ii) Those participants who market feed ingredients within / into the EU derived from organisms for which there is a commercially available GM alternative, but who do not label these feed ingredients as containing GM under the EU GM Regulations 1830/2003.

1.4 Sector Notes

A number of Sector Notes have been produced to assist both assessors and participants in interpreting the requirements of the **FEMAS** for specific industrial sectors supplying feed ingredients. *Copies of the various Sector Notes* are available from the Agricultural Industries Confederation (AIC) website: www.agindustries.org.uk

1.5 Country Notes

Country Notes provide the links to integrate the **FEMAS** into industry-wide assurance programmes within a specified country and can be produced on request in co-operation with National Bodies. Where such Country Notes exist, compliance with any requirements contained within them is necessary for FEMAS certification to be achieved by feed ingredients producers in the country concerned. *Copies of the various Country Notes* are available from the AIC website: www.agindustries.org.uk

1.6 Claims Associated with FEMAS Certification

Participants who achieve successful certification against this FEMAS standard are reminded that FEMAS is a product certification programme. Claims of FEMAS certification may only be made in relation to those products included within the scope of the FEMAS Certificate of Conformity.

1.7 The FEMAS Working Group

The FEMAS assurance programme is governed by the FEMAS Working Group, which reviews and updates the documented FEMAS standards, ensures the requirements of FEMAS continue to be met and liaises with the authorised Certification Body. Members of the Working Group are selected for their expertise, provide their services on a voluntary basis and represent a cross-section of the food and feed industries. Participants wishing to be considered for membership of the FEMAS Working Group should contact the FEMAS Secretariat at:

*AIC Services
Confederation House
East of England Showground
Peterborough
PE2 6XE
United Kingdom*

1.8 Application For Certification and The Assessment Process

1.8.1 Application For FEMAS Certification

Suppliers of feed ingredients (the 'participant') must apply for certification against the FEMAS International Core Standard to the authorised FEMAS Certification Body. *Details of the authorised Certification Body* are available from the AIC website: www.agindustries.org.uk

1.8.2 The Assessment Process

Participants are required to undergo an assessment process to ensure that their operations comply with the requirements of FEMAS, before a Certificate of Conformity can be issued.

The assessment process comprises:

- i) **Pre-Assessment** – (Mandatory for new participants wishing to supply markets that accept only feed ingredients that are certified as feed safe – optional for other participants). Pre-assessments will evaluate new participants' ability to meet the main criteria of FEMAS in order to achieve 'applied' status. Participants who sign a Certification Agreement with *the authorised Certification Body*, pay any fees due and undergo a successful pre-assessment will be authorised to trade for a maximum of 6 months prior to full FEMAS certification and their company name will be added to the FEMAS Register as 'Applied'. At *the authorised Certification Body's* discretion, pre-assessments will involve either an on-site or 'desk top' audit that key feed safety controls are in place. After a maximum of 6 months from the application date, participants must undergo a FEMAS initial assessment and achieve full certification to FEMAS for all products for which certification is being sought, or their company name will be removed from the FEMAS register.
- ii) **Initial Assessment** – A formal (mandatory), in-depth, on-site assessment to confirm that participants comply with the requirements of FEMAS. The duration of initial assessments is dictated by the time required to fully assess the systems and procedures of the participant. The number of days required will be indicated prior to assessment, but may be extended if circumstances require this. Certificates of Conformity are only issued on satisfactory completion of all Action Points identified at Initial Assessment. The details and scope of certification for certified sites will be added to the FEMAS Register.
- iii) **Surveillance Assessment** – A formal (mandatory) on-site assessment of certified sites, scheduled annually to ensure that the requirements of FEMAS continue to be met and that any amendments / updates to the FEMAS Standard have been implemented.
- iv) **Unscheduled Assessment** – A number of unscheduled assessments will be undertaken each year under the FEMAS Programme. These will not affect all certified sites each year, but *the authorised Certification Body* retains the right to undertake unscheduled assessments of any and all FEMAS certified sites at its discretion. The appointed assessor will advise certified sites subject to unscheduled assessment two days prior to the assessment taking place. The unscheduled assessment programme will be funded from a small levy included in the cost of all

initial assessments and no additional charges will be made for unscheduled assessments.

- v) FEMAS assessments are not of fixed duration and quotations will be provided on a case-by-case basis, prior to work commencing. *The authorised Certification Body* administers the programme and in most cases will perform the on-site assessment. However, the participant may select, if they wish, an alternative organisation to carry out the on-site assessment activity from a list of approved and qualified Inspection Bodies appointed by *the authorised Certification Body* for this purpose. The list of approved Inspection Bodies is available from *the authorised Certification Body*.

1.9 The FEMAS Register

Those companies that achieve FEMAS certification are listed on the FEMAS Register. The Register includes details of the scope under which FEMAS certificates have been granted. Interested parties may view the Register via the Feed and Assurance links of the Agricultural Industries Confederation website at:

www.agindustries.org.uk

1.10 Updates to the Standard

As an aid to users, each revision of this standard will be published with the areas of significant change highlighted in *blue italics*.

1.11 Definitions

For the purposes of this standard, the following definitions apply:

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.

Check: Monitoring and measuring of processes and products against policies, objectives and requirements for the product, with the reporting of results.

Contamination: The undesired introduction of impurities of a chemical or microbiological nature or of foreign matter during production, sampling, packaging or repackaging, storage or transport.

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

Corrective Action: Any action to eliminate a non-conformity.

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

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

Critical Limit: A criterion that separates acceptability from unacceptability. (Codex)

Feed (or Animal Feed): Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals. (Regulation (EC) No 178/2002)

Feed Additives: Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has a nutritional value, which affects the characteristics of feed or animal products. (Codex)

Feed Ingredients: A component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, animal or aquatic origin, or other organic or inorganic substances. (Codex)

Flow Diagram: A systematic representation of the sequence of steps or operations used in the production or processing of a particular feed ingredient. (Codex adapted)

Food (or Foodstuffs): Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.

'Food' shall not include: feed; live animals unless they are prepared for placing on the market for human consumption; plants prior to harvesting; medicinal products; cosmetics; tobacco and tobacco products; narcotic or psychotropic substances; residues and contaminants. (Regulation (EC) No 178/2002)

GMP: Good Manufacturing Practice. Series of procedures in a branch or sector in which the standard of conduct is laid down (often with respect to hygiene and safety).

HACCP (Hazard Analysis & Critical Control Points): A system that identifies, evaluates and controls hazards that are significant for food / feed safety. (Codex adapted)

HACCP Plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food / feed safety in the sector of the feed chain under consideration. (Codex adapted)

Hazard: A biological, chemical or physical agent in, or condition of, food / feed with the potential to cause an adverse health effect. (Codex adapted)

Hazard Analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food / feed safety and therefore should be addressed in the HACCP plan. (Codex adapted)

Litter: Cans, wrappers, bottles, plastic, paper and cardboard packaging or other items discarded after the foodstuffs, cigarettes or other consumables they were originally associated with have been consumed.

Monitor: The act of conducting a planned sequence of observations or measurements to assess whether an expected outcome is being achieved. (Codex adapted)

Participant: A producer or processor seeking certification against this standard for the production and supply of feed ingredients intended for feeding to livestock (from which products will be derived for human consumption) or to companion animals.

Process Aid: Any substance not consumed as a feeding stuff by itself, intentionally used in the processing of feeding stuffs or feed ingredients to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed. (Regulation (EC) No 1831/2003)

Purchaser: The party supplied with the feed ingredient by the participant.

Quality Control: A system based upon sampling and testing, with the intention of ensuring compliance with specification and identifying non-conforming products.

Quality Management System: An organised system of documented procedures, controls and practices with the specific purpose of ensuring that the standards of food / feed safety and quality intended by the company are met during the course of its activities.

Raw Materials: All materials used by participants for manufacturing, processing or blending into feed ingredients.

Record: A document providing evidence of a necessary action having been carried out.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard. (Regulation (EC) No 178/2002)

Safe: Feed ingredients shall be deemed to be safe if they do not have an adverse effect on human or animal health and do not make the food derived from food-producing animals injurious to health or unfit for human consumption when the feed ingredient concerned is used as intended and in accordance with normal industry or feeding practice (Regulation (EC) No 178/2002; adapted).

In addition, safe procedures and practices shall ensure the maintenance of those quality parameters that if breached *may cause harm to a target class of livestock, or to humans subsequently consuming affected livestock products, through the excess or deficit of critical nutrients or the presence of anti-nutrients not expected under normal circumstances nor declared by the participant to the purchaser.*

Site: Factories / buildings sharing the same premises, under the same senior management control and involved in various stages of the same continuous process.

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 should 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.

Standard: The document containing the essential principles of assurance, compliance with which will confirm adherence to the requirements of the *FEMAS Programme*.

Step: A point, procedure, operation or stage in the food / feed chain including raw materials, from primary production to final consumption. (Codex adapted)

Supplier: The external organisation(s) or person(s) that provides the raw materials (from which the participant will produce feed ingredients) and services related to feed ingredient production, processing, *transport and storage*.

Technological Additives: Any substance added to feed ingredients for a technological purpose, i.e. preservatives, antioxidants, emulsifiers, stabilisers, thickeners, gelling agents, binders, substances for the control of radionuclide contamination, anti-caking agents, acidity regulators, denaturants. (Regulation (EC) No 1831/2003)

Traceability: The ability to trace and follow a substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution. (Regulation (EC) No 178/2002)

Undesirable Substances: Any substance or product, with the exception of pathogenic agents, which is present in and / or on the product intended for animal feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production. (Directive 2002/32/EC)

Validation: Obtaining evidence of effectiveness. (Codex adapted)

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance. (Codex adapted)

Waste: Those substances or objects that fall out of the commercial cycle or out of the chain of utility. Waste is a substance or object which:

- a) Someone wants to get rid of and cannot be used for any other purpose,
- b) Is destined for dumping / land filling,
- c) Is not intended for re-use, recovery or recycling as animal feed,
- d) Cannot be used for any other purpose.

SECTION 2 QUALITY MANAGEMENT SYSTEM

2.1 General Requirements

The participant must achieve standards of feed safety that both reflect the importance of feed ingredients within the human food chain and meet contractual and legal obligations.

2.1.1 The participant must establish, document, implement and maintain a Quality Management System (QMS) in accordance with the requirements of this standard. The QMS must be adapted to regulatory and other safety related developments, as they occur.

2.1.2 The structure of the QMS must be specific to the organisation of the participant and include policies, requirements and documented procedures that maintain feed ingredient safety.

2.1.3 The QMS must ensure that all those activities that could impact on the safety of the feed ingredients produced / processed are consistently defined, implemented and maintained in the organisation.

2.2 Management Responsibilities

Management must be committed to the implementation of this standard and the operation of effective feed safety and quality systems. Documentary evidence must be provided to demonstrate this.

2.2.1 Management must:

- i) Establish a documented Quality Policy and ensure that feed safety objectives are established. The Quality Policy must include, as a minimum, confirmation of compliance with regulatory requirements and the requirements of customers;
- ii) Define the scope of the QMS, by identifying the products / product categories and production sites which are covered by the system and ensuring that the feed safety objectives are established;
- iii) Provide adequate resources for the implementation and control of the QMS;
- iv) Review at least annually, the continuing suitability and effectiveness of feed safety and quality management systems. This review must include assessing opportunities for improvement and the need for changes to the safety and quality management systems. Management reviews must be recorded.

2.3 Quality Management Structure

The responsibility and authority of personnel performing feed safety related tasks must be documented.

2.3.1 Participants must have a nominated person responsible for feed safety matters ('Quality Manager'). The *Quality Manager* may be known by another title and also have other duties and responsibilities. The Quality Manager must have appropriate authority to carry out the function effectively.

2.3.2 All personnel involved in feed safety related tasks must be suitably experienced, trained and qualified such that they are competent for the tasks that they undertake. Records of the participant's evaluation of the competence of personnel must be retained and kept updated.

2.4 Documentation Requirements

Participants must produce and implement their own set of operating procedures that incorporate the requirements of this standard.

2.4.1 The QMS documentation must include:

- i) The documented Quality Policy, including feed safety objectives.
- ii) The Quality Manual, covering:
 - The scope of the QMS, including details of and justification for any exclusion
 - The documented procedures established for the QMS or reference to them
 - Documented procedures and records required by this standard
 - Documents required by the HACCP system (see Section 5 of this standard and Codex Alimentarius Commission of the World Health Organisation 'Recommended International Code of Practice General Principles of Food Hygiene – CAC/RCP 1- 1969, Rev. 4 – 2003', Principle 7)

2.4.2 Documented procedures may form part of a structured and certificated feed safety and quality management system, or be part of a national, industry or company scheme that delivers equivalent controls. Independently certified HACCP or quality systems are not a pre-requisite for certification against this standard. However, where this standard does require procedures it requires them to be documented and:

- i) Be reviewed at least annually, approved, dated, and signed by an authorised person;
- ii) Be readily available and understood by those required to operate to the requirements of the procedure;
- iii) Be revised to reflect any significant changes that have an effect on the operations of the participant and ensure the content of procedures remain current and accurate.

2.5 Record Keeping

Participants must ensure that:

- i) All records required by this standard are kept for a minimum of two years, unless longer periods are required by legislation;
- ii) Storage facilities for records prevent any deterioration or damage to records under normal storage conditions;
- iii) Records are sorted and filed in such a way that information is complete and easily retrievable;
- iv) Records are legible.

2.6 Management Of Information Relating To Safety

Participants must demonstrate that they have systems and procedures in place that ensure they remain up-to-date with regulatory requirements and any food / feed safety issues relevant to the feed ingredients they supply.

2.6.1 Information relating to safety issues that may affect the operation of the organisation must be reliably and effectively transmitted to those personnel with responsibility for the areas involved. Any changes in practices or procedures necessitated by new information must be implemented effectively.

SECTION 3 RESOURCES AND GOOD HYGIENIC PRACTICES

3.1 General Requirements

Production, storage and handling must be carried out in conformity with this standard.

- 3.1.1** Facilities and equipment must be designed, constructed, maintained and managed to ensure that the safety of raw materials and feed ingredients is protected at all times. Consideration must be given to preventing both the malicious and accidental contamination of feed products. Access to processing facilities and storage areas must be restricted to personnel authorised by the participant.
- 3.1.2** Where the site location presents risks (for example adjacent to water courses that may flood or adjacent to other premises that may create hazards), participants must be able to demonstrate within the HACCP plan that appropriate controls are in place to manage these risks.
- 3.1.3** The participant's risk assessment study must consider the potential effect of all activities carried out on the site, with regard to the safety and suitability of feed ingredients. This includes identifying any locations where a significant possibility of contaminating feed ingredients may exist and taking specific measures to minimise any hazards identified.
- 3.1.4** Natural or artificial lighting must be adequate to ensure cleaning, processing and other activities important to raw material and feed ingredient safety can be undertaken effectively.
- 3.1.5** Ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, *to prevent* the growth of moulds and *to prevent* the shedding of particles that may adversely affect the safety of raw materials or feed ingredients.

3.2 Personnel

All personnel involved in the production, storage and handling of feed ingredients must have received appropriate training in safe and effective working practices that maintain the safety of feed ingredients. Such training must include an introduction to HACCP principles.

- 3.2.1** All personnel must be informed clearly in writing of their duties, responsibilities and powers with regards to the maintenance of safe raw materials and feed ingredients. This information must be updated in the event of any significant changes.
- 3.2.2** Accurate and up-to-date training records must confirm any relevant training that has taken place and that the participant has assessed personnel as competent to carry out the tasks that they undertake.

- 3.2.3** The participant must ensure that employees and visitors to the site have easy access to suitably equipped washing facilities and toilets.
- 3.2.4** Protective clothing must be worn wherever contamination of feed ingredients by personnel is identified as a risk by the risk assessment study. All clothing and equipment must be maintained in hygienic condition.
- 3.2.5** Clear policies on smoking and eating / drinking on site must be made known to employees and visitors and must prohibit eating, drinking and smoking in areas where these activities may adversely affect feed ingredients. If necessary, separate facilities must be provided.
- 3.2.6** Participants must ensure that appropriate hygiene training has been given to all personnel involved in the direct handling of feed ingredients and their packaging. No person known to be suffering from a disease, which may adversely affect the safety of feed ingredients, may handle feed ingredients or their packaging.
- 3.2.7** The participant must ensure that engineers and contractors working on site are controlled in such a way that maintenance and building works do not adversely affect either raw material or feed ingredient safety. There must be a procedure in place to ensure that appropriate cleaning and tidying has been completed prior to recommencing activities in that area.

3.3 Production / Processing Facilities & Equipment

Conditions within buildings must be suitable and must not adversely affect the safety of any feed ingredients either produced or processed in the buildings. All equipment used for processing feed ingredients must be fit for the purpose for which it is used.

- 3.3.1** Equipment coming into contact with feed ingredients must be designed and constructed to ensure that, where necessary, it can be adequately cleaned, disinfected and maintained to avoid the contamination of the feed ingredients.
- 3.3.2** Risk assessment procedures must be used to identify and control any hazards that may be associated with particular equipment. Where appropriate, corrective action must be taken as a result of these findings. Records must be kept detailing the date and nature of any corrective actions undertaken.
- 3.3.3** All drains, gutters and down-pipes must be designed and maintained in a manner that ensures they do not present a hazard to any raw materials or feed ingredients processed or stored on the site.

3.4 Storage Facilities

Adequate facilities for storage of feed ingredients and *non-feed products* (e.g. cleaning materials, lubricants, fuels, etc) must be provided.

- 3.4.1** Raw materials and feed ingredients must be stored in such a way that they can be identified easily and that confusion with other products is prevented.

- 3.4.2** In the case of flat stores, facilities must be organised to ensure that mud, snow and other potential contaminants carried by vehicles cannot adversely affect stored raw materials or feed ingredients.
- 3.4.3** Where the participant utilises *facilities* for the storage of raw materials or feed ingredients at sites other than the original manufacturing / processing site (whether owned or subcontracted stores), these must also comply with the relevant sections of this standard and the safety of the raw materials and feed ingredients must be maintained.
- 3.4.4** Participants must include audits of any owned or subcontracted stores within their internal auditing programme. Unless they are already certificated under an assurance programme acceptable to *FEMAS*¹, stores must be audited at least annually by the participants own, suitably qualified personnel or designated third parties.
- 3.4.5** Stock control measures must be documented and adequate to ensure that neither raw materials nor feed ingredients deteriorate prior to use / despatch, or during storage. Wherever practical, raw materials must be used and feed ingredients must be supplied on a first in, first out basis.

3.5 Intake & Loading Facilities

The participant must ensure that all intake and loading facilities are designed and constructed in a manner that maintains the safety of feed ingredients.

- 3.5.1** Neither intake nor loading may be carried out in conditions such that inclement weather or risks of contamination will adversely affect the raw materials or feed ingredients being handled.
- 3.5.2** Intake and loading facilities must be designed to ensure that access by birds and other pests is kept to an absolute minimum.

3.6 Planned Maintenance

All equipment must be subject to a programme of planned maintenance that ensures it is kept in safe and hygienic working condition.

- 3.6.1** The participant must keep records of maintenance carried out on all equipment critical to the production of safe feed ingredients.

¹ Participants should confirm the acceptability of certification schemes by contacting *the authorised Certification Body* before contracting certified stores. In most circumstances, only store schemes accredited *under a feed or food safety programme* to EN45011 / ISO Guide 65 will be acceptable to FEMAS.

3.7 Driers / Drying

Where mechanical drying is undertaken, procedures must ensure that any adverse effect on the feed ingredients being dried is minimised.

3.7.1 Where drying operations result in combustion gases coming into contact with raw materials or feed ingredients, participants must be able to demonstrate that drying does not increase the levels of undesirable substances beyond the maximum levels prescribed for feed ingredients in the regulations of the country of production and the country of the purchaser receiving the feed ingredients.

3.7.2 *Any potential for adverse effects on the feed ingredients caused by the drying process (for example due to heat damage) must be understood and managed to minimise damage to the feed ingredients.*

3.8 Cross-Contamination

Participants must ensure that formal systems are in place that minimise the risk of cross-contamination of raw materials or feed ingredients with other products.

3.8.1 Equipment and procedures must be designed and operated to ensure that cross-contamination between different types of feed (or other) materials is minimised.

3.9 Packaging & Pallets

Feed ingredient packaging and pallets must be suitable for the means of delivery / transport used and the type of feed ingredients concerned. Packaging must be designed to protect the feed ingredients during normal storage, handling and delivery conditions.

3.9.1 Pallets and mini-bulk tanks must not be accepted back from any farms where livestock are kept unless the pallets and mini-bulk tanks are thoroughly and effectively cleaned and disinfected prior to re-use. Any cleaning of pallets and mini-bulk tanks must be done in areas where feed ingredients will not be adversely affected by this activity.

3.9.2 No bags may be accepted back from farms for re-use.

3.10 Pest Control

Participants must take active measures to control and limit pest activity throughout the supply chain for which they are responsible. Risk assessment methods must be used to identify potential problems with all classes of animals (e.g. birds, insects, reptiles and mammals) whether they are wild, feral or domestic. Under all circumstances, records must be available to show that risks from pests are adequately managed and consistently under control.

- 3.10.1** Animals must, wherever possible, be excluded from the grounds of factories, and the area surrounding stores and processing plants. Where the presence of pigeons, seagulls and other pests is unavoidable, procedures must be implemented to protect raw materials and feed ingredients from potential contamination. Wherever there is a significant risk from pests, access points must be proofed against their entry. Doors must be kept closed whenever possible and must be close-fitting and proofed against pests when closed.
- 3.10.2** Buildings must be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access must be kept sealed wherever possible. Where sealing is not possible measures such as wire mesh screens must be in place to reduce the possibility of pest entry.
- 3.10.3** Pest infestations must be dealt with promptly and any actions taken must be compatible with feed products.
- 3.10.4** Appropriately qualified / trained personnel must carry out any control treatment required.
- 3.10.5** In cases where shooting is undertaken as part of the pest control programme, lead, or other toxic ammunition, must not be used.
- 3.10.6** All bait containers must be fixed in their intended position unless there is a specific reason why this is not appropriate.
- 3.10.7** Open bait containers and loose baits must not be positioned in areas where their use may result in a hazard to raw materials or feed ingredients.
- 3.10.8** Pest control procedures must be documented and must ensure that no materials designed to kill or deter pests can contaminate raw materials or feed ingredients. Pest control records must include:
- i) Details of any poisons used, including safety data sheets;
 - ii) Qualifications of personnel involved in pest control activities;
 - iii) Map(s) indicating the location of any bait stations and the baits with which they are baited;
 - iv) Records of any pests found;
 - v) Details of corrective actions implemented.

3.11 Cleaning

Cleaning must remove residues and dirt that may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the business and may include disinfection / sanitising, but must be compatible with feed ingredients. Participants must ensure that at all stages of the production, storage or handling of raw materials and feed ingredients sufficient standards of cleanliness are operated such that exposure to pests and pathogens is minimised.

3.11.1 Cleaning programmes must be documented and ensure that feed ingredient production, storage and transport facilities are cleaned in a manner that is sufficient to maintain feed ingredient safety at all times.

3.11.2 Cleaning and disinfection programmes must be monitored for their suitability and effectiveness. An authorised person must carry out inspections of cleaning and a record of all inspections must be kept.

3.11.3 Only food compatible cleaning and disinfectant / sanitising agents may be allowed to come into contact with feed ingredients and must be used in accordance with manufacturers' recommendations and safety data sheet requirements. Where cleaning agents and disinfectants / sanitizers come into contact with feed ingredients, the participant must ensure that control systems provide the correct and effective dilution levels at all times.

3.11.4 Cleaning and disinfection / sanitising chemicals must be stored, where necessary, separately in clearly identified containers to avoid the risk of (malicious or accidental) contamination.

3.12 Waste Management

Any materials considered to be waste must be visually identified as such and promptly segregated in a manner that will eliminate the likelihood of accidental or inadvertent use.

3.12.1 Waste must not be collected or stored in any container that may be used for raw materials or feed ingredients.

3.12.2 Containers used to store waste that is attractive to pests and vermin must be covered. Such waste containers must also be stored away from raw material and feed ingredient storage or production areas and removed from site as frequently as practical.

3.12.3 All waste must be disposed of legally.

3.12.4 The participant must provide hygienic means for disposal of litter.

3.13 Dust Control

Participants must take reasonable precautions to limit the accumulation of dust and other residual materials in areas where raw materials and feed ingredients are either processed or stored.

3.14 Air Movement

In cases where air is used for conveying or cooling, the participant must evaluate the risk of this becoming a vehicle for pathogens and take any necessary precautions.

3.15 Process Water & Water Used For Cleaning Purposes

Risk assessment of any water that comes into contact with the feed ingredients, or any process / handling equipment, must be included in the HACCP study.

3.15.1 Participants must either carry out water quality tests or receive test results from their water provider at a frequency dictated by risk assessment, to ensure that standards required by the risk assessment study are being achieved.

3.15.2 Records of water quality tests must be maintained.

3.15.3 Where additives (such as water softeners, anti-corrosion agents, etc.) are included in water that will come into contact with feed ingredients, either as water or steam:

- i) These additives must be considered in the HACCP study;
- ii) Any dosing systems must be calibrated and controlled to ensure the correct level of addition;
- iii) Records of additive dosing must be maintained.

3.15.4 No material recovered from waste water systems may be incorporated into feed ingredients.

3.15.5 *No waste water may be incorporated into feed ingredients unless risk assessment shows this to be safe and any necessary treatment is undertaken prior to use.*

3.15.6 Material recovered from interceptors and fat traps may only be incorporated into feed ingredients where risk assessment studies confirm it will not adversely affect the feed ingredients.

3.15.7 Separate water systems (e.g. fire control) must be identified and must not connect with, or allow reflux into, water used for processing or cleaning.

3.16 Control of Contaminants

Controls must be in place to protect raw materials and feed ingredients from contamination.

3.16.1 Intake points and processing equipment must be designed and operated to minimise the possibility of contaminant ingress.

3.16.2 All personnel and visitors must be *provided with adequate information* to ensure that the risk of contaminant ingress is kept to an absolute minimum.

3.16.3 Wherever possible, conveying systems and storage facilities must be enclosed to avoid contact with potential contaminants. Where this is not possible, appropriate controls must be in place to ensure minimal risk to feed ingredient safety.

3.16.4 The contamination of feed ingredients with non-food grade hydraulic oils or lubricants must be avoided and the risk of contamination with food grade hydraulic oils and lubricants must be minimised.

3.16.5 *Any material added to feed ingredients by the participant, and that is not included as an inherent part of the production process, must be confirmed as suitable for feed use and inclusions must be advised in all relevant feed ingredient specifications.*

3.17 Sieves, Screens, Filters & Separators, Magnets & Metal Detectors

3.17.1 Magnets and / or metal detectors must be included in processing systems where indicated as necessary by the risk assessment study.

3.17.2 Critical sieves, screens, filters, separators, magnets and metal detectors must be regularly checked to ensure that they are not damaged and that they continue to operate effectively.

3.17.3 Records of checks of all magnets and metal detectors must be kept.

3.17.4 Where screenings (materials separated from the primary production stream by sieves, screens, filters, separators, etc) are reclaimed or reprocessed for inclusion in feed ingredients, the risk assessment study must consider the potential hazards resulting from such practices (for example, where undesirable or unwanted materials are removed from a primary product and concentrated into a by-product supplied as a feed ingredient). Any necessary precautions must be implemented.

3.18 Glass & Brittle Materials Procedures

Participants must ensure that glass and brittle materials are not a hazard to feed ingredients. Where total exclusion *of glass and brittle materials from processing and storage areas* is not practical, formal procedures must be implemented to minimise

the risk of any breakages and to ensure that should breakages occur there would be no contamination of feed ingredients.

- 3.18.1** Light fixtures must be protected in process and storage areas to minimise the chance of feed ingredients being contaminated in the event of breakage.
- 3.18.2** Bottles and other glassware must be excluded from production, processing and storage areas unless specifically required under sampling procedures.
- 3.18.3** All breakages of glass and brittle materials in process and storage areas must be reported and records must show how risks to feed ingredient safety have been managed.
- 3.18.4** Following any breakage, cleaning equipment such as brushes, that may become contaminated with broken glass or brittle materials, must be disposed of after use unless effective controls are in place to ensure that any subsequent use will not adversely affect feed ingredients or raw materials.

SECTION 4 TRANSPORT REQUIREMENTS

4.1 General Requirements

All means of transport (whether by ship, barge, road vehicle, rail, container or other transport system) whether owned or contracted by participants to carry either raw materials or feed ingredients, whether in bulk or packed, must be appropriate and adequately controlled with specific regard to hygiene and potential contamination.

- 4.1.1 In the case of transporting raw materials or feed ingredients in sealed containers or packaging, risk assessments must consider any potential hazards and ensure that controls effectively preclude any serious risk of contamination.
- 4.1.2 When the participant is responsible for arranging transport of feed ingredients to purchasers operating under a certificated assurance programme, he must ensure that the specific transport requirements of that programme are met. *In such circumstances, the subcontracting of transport is not permitted except where the subcontractor also meets the requirements of the assurance programme concerned.*
- 4.1.3 Cargoes being carried concurrently with raw materials and feed ingredients must not adversely affect the safety of the raw materials and feed ingredients.
- 4.1.4 To facilitate traceability where transport is used to carry raw materials and feed ingredients, the individual load compartments used must be recorded. For road / rail vehicles this may be the trailer / car number or, where load compartments are split into sections, the individual section must be recorded. For water transport, where load compartments are split into holds, the individual hold numbers must be recorded.

4.2 Owned & Contracted Land Transport

Participants must adopt procedures that reflect the different risks associated with the carriage of packaged and bulk goods.

4.2.1 Transport Of Bulk Goods

Where participants own or contract land transport to carry raw materials or feed ingredients in bulk, internal procedures and contractual agreements must include provisions that preclude the use of transport whose construction or previous use may adversely affect the safety of any feed ingredients.

- 4.2.1.1 Unless risk assessment specifically establishes that no potential hazards exist from the carriage of previous loads, records must be available showing the previous three loads carried by bulk transport and any cleaning subsequently undertaken as a consequence. In such cases, participants' procedures must confirm that previous loads and cleaning

methods are compatible with the raw materials or feed ingredients to be carried subsequently.

- 4.2.1.2 Any terms for hiring bulk transport must clearly specify the controls required and include a similar obligation for any subcontractors used.

4.2.2 Land Transport Contracted By Third Parties

Where the means of land transport is contracted by a third party, participants must take reasonable precautions to avoid potential hazards.

- 4.2.2.1 Where feed ingredients are to be loaded into transport contracted by the purchaser of the feed ingredients, participants must ensure that any transport offered is suitable to receive the feed ingredients supplied.
- 4.2.2.2 For bulk loads, the three previous loads carried must be recorded and assessed for compatibility by a competent person prior to loading.
- 4.2.2.3 Should participants be instructed by a purchaser to load transport that is considered unsuitable by the participant, participants must advise the purchaser of any concerns in writing and obtain written confirmation of such instructions from the purchaser, prior to loading. Copies of associated correspondence must be retained.
- 4.2.2.4 Where suppliers of raw materials provide the means of transport, participants must ensure that such transport complies with the requirements of this standard.

4.2.3 Inspections Of Land Transport Prior To Loading

For all means of land transport loaded by the participant (whether contracted by the participant or a third party), physical checks must be undertaken by an authorised person to confirm cleanliness prior to loading.

- 4.2.3.1 Checks must ensure that load compartments are free of contaminants.
- 4.2.3.2 Any covers (e.g. sheets or tarpaulins) must be checked as clean and in good condition.
- 4.2.3.3 Records of inspections must be maintained.

4.3 Water-borne Transport

Where participants are responsible for loading raw materials or feed ingredients into vessels and discharging raw materials or feed ingredients from vessels, they must designate a competent person (designated inspector) to ensure that the safety of any raw materials or feed ingredients is maintained. Such controls must apply whether the participant or a third party contracted the vessel.

4.3.1 Designated Inspectors

The designated inspector must be either:

- i) A member of a recognised inspection firm, performing under internationally recognised standards, or
- ii) An inspector assigned by the participant, who is recognised as a qualified loading inspector.

4.3.2 Control Of Raw Materials At Discharge From Water-borne Transport

Where participants receive raw materials by water, the participant must designate an inspector to supervise the discharge of raw materials from vessels.

- i) The inspector's duties must include confirmation that the safety of raw materials has not been adversely affected during transit;
- ii) Unless risk assessment specifically establishes that no potential hazards exist from the carriage of previous cargoes, participants' must confirm from ship's records the previous three cargoes carried in each hold used (and any cleaning subsequently undertaken) and their compatibility with raw materials for use in feed as the subsequent cargo;
- iii) Unless risk assessment specifically establishes that no potential hazards exist from the handling of previous cargoes, recorded inspections of handling equipment (grabs, conveyors, hoppers, dock transport, etc.) must be undertaken to confirm their cleanliness and suitability, prior to discharge.

4.3.3 Control Of Feed Ingredients On Loading Into Water-borne Transport

It is essential for the safety of feed ingredients that a Loading Compartment Inspection (LCI) of the cargo-hold is done before loading commences and security be constantly maintained during the loading process. LCI and security measures must be controlled by a designated inspector. Designated inspectors must ensure that:

- i) Before loading commences, the cargo-hold is suitable, clean, dry (unless liquids are to be transported), free of any odours and in every way ready for loading feed ingredients. This must be recorded and, where the participant has chartered the vessel, the LCI Report must form part of the shipping documents provided with the cargo;
- ii) The vessel's records confirm the previous three cargoes carried in each hold used (and any cleaning subsequently undertaken) and their compatibility with feed ingredients as the subsequent cargo. This must be recorded in the inspector's LCI Report;
- iii) Handling equipment (grabs, conveyors, hoppers, dock transport, etc.) is clean and suitable prior to loading. This must be recorded in the inspector's LCI Report.

4.3.4 Control Of Feed Ingredients At Discharge From Water-borne Transport

Where sales contracts or company practices require participants to transport feed ingredients by water prior to receipt by the customer, the participant must

designate an inspector to supervise the discharge of feed ingredients from vessels. The inspector's duties must include:

- i) Confirmation that the safety of feed ingredients has not been adversely affected during transit;
- ii) Recorded inspections of handling equipment (grabs, conveyors, hoppers, dock transport, etc.) to confirm their cleanliness and suitability, prior to discharge.

SECTION 5 PRODUCT SAFETY MANAGEMENT

5.1 HACCP

A formal risk assessment must be carried out with the aim of identifying and controlling hazards that might adversely affect the safety of any feed ingredients supplied. Risk assessments must be carried out in accordance with recognised HACCP principles such as those outlined by the Codex Alimentarius Commission of the World Health Organisation in 'Recommended International Code of Practice General Principles of Food Hygiene – CAC/RCP 1- 1969, Rev. 4 – 2003'.

5.1.1 Prerequisites

For practical purposes, participants may wish to recognise 'prerequisites' for the HACCP system they implement (i.e. specified, formal procedures that control potential hazards on a site-wide basis, such as: pest control, glass policies, training, raw material and feed ingredient specifications, etc.).

5.1.1.1 Where prerequisite methodology is used, the prerequisites identified must be defined as part of the HACCP Plan and included in any auditing schedule established as a result of the HACCP Plan.

5.1.2 HACCP Team

In order to establish a risk assessment system, the participant must appoint a HACCP Team to produce an effective HACCP Plan.

5.1.2.1 The HACCP Team must include personnel from all of the relevant operations and functions within the company and at least one member with demonstrably effective HACCP training. *Where participants delegate key activities to third parties, it is desirable for representatives of the third party organization to be included in the HACCP Team.*

5.1.2.2 The members of the HACCP team must be recorded within the HACCP Plan.

5.1.2.3 It is acceptable for individual personnel to fulfil multiple roles in the HACCP Team or to utilise resources from outside of the company, provided that the role of the Team remains effective.

5.1.3 Feed Ingredient Specifications

Each feed ingredient must have a written specification that is made available to purchasers and potential purchasers of the feed ingredients offered by the participant.

5.1.3.1 Specifications must be amended when any relevant changes take place. The written specification must include:

- i) Nutritional and analytical characteristics;
- ii) Precise identification of the feed ingredient supplied (by name);

- iii) Origin/source (factory);
- iv) Any processing of the feed ingredient;
- v) Any special characteristics that may affect or restrict the potential use of the feed ingredient;
- vi) Hazards or limitations for intended use, where these apply.

5.1.4 Definition Of Process Steps

The HACCP Team must identify and record all of the steps involved in their operations from raw material procurement and supplier approval, through to the point at which any feed ingredients produced are transferred to a purchaser (process analysis).

- 5.1.4.1 The process analysis must be illustrated using a flow diagram that shows each step of the process / operation. Flow diagrams must include:
 - i) Clear identification of each step.
 - ii) The use of any processing aids and technological additives.
- 5.1.4.2 Design and development changes in processes / operations must be identified and records maintained.
- 5.1.4.3 Changes in processes / operations must be reviewed, verified and validated, as appropriate, and approved under the HACCP Plan before implementation. The review of design and development changes must include evaluation of the effect of the changes on feed ingredient safety.

5.1.5 Hazard Analysis / Identification (CODEX Principle 1)

The HACCP Team must identify and record any possible chemical, physical or microbiological hazards that could adversely affect the feed ingredients supplied, giving consideration to the characteristics and intended use of the feed ingredients involved and in accordance with recognised HACCP principles.

- 5.1.5.1 Participants must carry out a separate Hazard Analysis for each raw material and feed ingredient.

5.1.6 Determination Of Control Measures

For each process step, the participant must either specify or reference the system / procedure in place to control potential hazards at that step in the operation (control measures). These must be recorded in the HACCP Plan.

- 5.1.6.1 Control measures must be sufficiently robust to either prevent the occurrence of new hazards or detect / eliminate the presence of existing hazards.

5.1.7 Determination Of Critical Control Points (CODEX Principle 2)

Control measures that are essential in detecting and eliminating hazards (i.e. the hazard would not be detected or removed at any later stage in the operation) must be regarded as Critical Control Points (CCPs) and must be identified as such within the study.

5.1.7.1 CCPs must be recorded in the HACCP Plan.

5.1.7.2 Where practical, processing and control equipment that has been identified as a CCP must be clearly identified at its location within the processing plant.

5.1.8 Establishing Critical Limits (CODEX Principle 3)

The HACCP Team must identify the critical limits for all of the hazards that have been identified and be able to show the basis on which the suitability of these limits is based.

5.1.8.1 Critical limits must be set at levels such that the safety of the feed ingredients is assured.

5.1.9 Monitoring (CODEX Principle 4)

The CCPs in the operation and the feed ingredients themselves must be inspected and sampled (monitored) to ensure identified hazards remain under control.

5.1.9.1 Monitoring must be implemented in accordance with a documented schedule. All results of inspections and sampling must be recorded.

NOTE: It is acceptable for monitoring of some hazards to be organised and / or compiled on an industry or sector-level in order to establish background data and spread the efforts and cost of monitoring.

5.1.10 Preventive / Corrective Actions (CODEX Principle 5)

Participants must take suitable, prompt and effective remedial action when information shows that hazards are not within critical limits.

5.1.10.1 Participants must record action taken when critical limits are breached and ensure that actions deal with *both the cause of the problem and the consequences of the problem*.

5.1.11 HACCP System Reviews (CODEX Principle 6)

The HACCP Team must carry out regular reviews to verify the requirements of the HACCP plan are being met in practice and that the plan effectively and consistently ensures that the participant produces safe feed ingredients.

5.1.11.1 At least one complete HACCP review must be carried out each year and must include any prerequisites established as part of the HACCP Plan. A record must be kept of HACCP reviews showing the HACCP Team findings and any actions implemented.

5.2 Raw Materials

Participants must demonstrate the following for each raw material (including additives and technological additives) utilised to produce feed ingredients:

- i) The name and address of the supplier of the raw material;
- ii) Information of the production or process from which the raw material is derived;
- iii) A risk assessment for each raw material, identifying potential hazards and the means by which these hazards are controlled by the supplier, the participant or both parties;
- iv) Participants are reminded of the [FEMAS Non-GM Module](#) relating to products that are potentially of genetically modified origin – see 1.3 above.

5.2.1 Where risk assessments identify the need for specific controls or limits to ensure the appropriate management of potential hazards, these must be included in the specifications agreed with suppliers of the affected raw materials.

5.3 Buying-in and Trading of Feed Ingredients

Where participants buy-in feed ingredients in order to meet contractual agreements, whether due to mechanical breakdowns or as part of normal trading activity, feed ingredients may only be sourced from companies currently certificated against FEMAS (or another assurance scheme acceptable to [FEMAS](#)² and the purchaser) and to a scope compatible with the FEMAS scope of certification held by the participant.

5.4 Assessment of Suppliers

5.4.1 Raw Materials Suppliers

Participants must develop and document procedures for ensuring that their suppliers of raw materials are controlled, such that:

- i) Suppliers are evaluated for their ability to meet contractual requirements and that the results of the evaluation are recorded;
- ii) Written details are recorded of the technical requirements that suppliers are expected to fulfil with their raw material;
- iii) The specification of any raw materials provided is agreed and recorded in writing;
- iv) Records of the performance of suppliers are available and reviewed at least annually to determine their continued suitability.

² Participants should confirm the acceptability of other certification schemes by contacting [the authorised Certification Body](#) before purchasing any goods. In most circumstances, only schemes accredited [for feed safety](#) to EN45011 / ISO Guide 65 will be acceptable to FEMAS.

5.4.2 Service Providers

Participants must develop and document procedures for ensuring that any providers of services (including transport, storage & handling and packaging) that may directly affect the feed ingredient are controlled, such that:

- i) Service providers are evaluated for their ability to meet contractual requirements and that the results of the evaluation are recorded;
- ii) Written details are recorded of the technical requirements that service providers are expected to fulfil with their service;
- iii) Records of the performance of service providers are available and reviewed at least annually to determine their continued suitability.

5.5 Sales Contracts

Feed ingredients must be sold in accordance with specifications and defined contractual terms that are made available to any potential purchaser. Terms may be in accordance with a recognised industry contract or be included in a contract developed by the participant or the purchaser of the feed ingredients.

5.5.1 The participant must inform the purchaser in the contract and / or specification of any specific transport, storage or usage requirements / conditions necessary to maintain the feed ingredients' characteristics.

5.5.2 Feed ingredient specifications must be agreed between the participant and the purchaser and confirmed in the contract.

5.5.3 Participants must be able to demonstrate appropriate methods for confirming and recording the type, quantity and specification of orders received.

5.5.4 Participants must ensure that all feed ingredients supplied meet the agreed specifications. In all cases, the feed ingredients provided must be demonstrably equivalent to those contracted for supply.

5.5.5 All contracts must clearly state the following with regard to any feed ingredients supplied:

- i) Feed ingredient name;
- ii) Feed ingredient specification;
- iii) Quantity;
- iv) Collection / delivery period.

5.5.6 All contract terms must be precise and unambiguous.

5.6 Process Control

Processing must be planned, scheduled and controlled by a designated and competent person, to ensure compliance with documented feed ingredient specifications and documented parameters for critical processes.

- 5.6.1** All process controls relevant to the safety of the feed ingredients being produced must be demonstrably effective and managed in accordance with formal HACCP principles.
- 5.6.2** Procedures must include corrective actions to be taken in the event of critical process parameters being breached.
- 5.6.3** Where mixing or dispersion forms an essential part of the process, tests must be undertaken to establish initial effectiveness of equipment and, on a subsequent frequency determined by risk analysis, to ensure that no loss of efficiency occurs through the effects of wear and tear. Records must be kept of such tests.
- 5.6.4** In situations where breakdown or other unforeseen circumstances result in the production of feed ingredients that do not meet specification, the resulting products must be treated in accordance with Non-Conforming Product procedures.

5.7 Control of Monitoring & Measuring Devices

All inspection, measuring and test equipment used to confirm that feed ingredients meet specified feed safety requirements must be calibrated at intervals not exceeding 12 months.

5.7.1 The participant must ensure that:

- i) Calibration acceptance criteria are defined;
- ii) Calibrated equipment is traceable to national standards or when this is not possible that the basis of the calibration is defined;
- iii) All relevant equipment is uniquely identified and traceable to calibration records;
- iv) The calibration frequency is defined.

5.7.2 If equipment is found to be performing outside acceptable calibration limits the participant must investigate the effect this will have on the conformity of any feed ingredients and take appropriate corrective action to recalibrate the equipment. Depending on the severity of the discrepancy and the nature of the test, the participant must be able to demonstrate that appropriate action has been taken (for example feed ingredient recall).

5.7.3 Records of the results of calibration and verification must be maintained.

5.8 Preservation of Microbiological Status

Where production processes contain an effective 'kill step' that is critical in maintaining the acceptable micro-organism count in feed ingredients, the participant must ensure that adequate controls are in place to prevent feed ingredients becoming re-contaminated with pathogens at subsequent process stages.

5.8.1 Good plant design will play a large part in preventing re-contamination by pathogens, but where design faults exist appropriate controls must be in place.

5.8.2 The participant must pay particular attention to areas where condensation may occur or where material is allowed to bypass the kill step and rejoin the finished goods stream.

5.9 Technological Additives *and Process Aids*

Where technological additives *and / or process aids* are used during production / processing, these must be feed compatible.

5.9.1 Participants must ensure that control systems provide the correct and effective dosing levels for technological additives *and process aids* at all times.

5.9.2 Dosing systems for technological additives *and process aids* must be calibrated by a competent person and calibration records maintained.

5.10 Feed Ingredient Delivery Documents & Labels

Delivery documents must be clear and unambiguous. All relevant contractual and legal information must be included on delivery documents or on labels attached to the product packaging.

5.10.1 For feed ingredients sold in bulk, as well as in bags, delivery documents / labels must include any details (such as Statutory Statements) required under Labelling Regulations in the country of production and / or receipt.

5.10.2 Any information provided on delivery documents / labels must be valid for the feed ingredients associated with them.

5.11 Identification of Products Not Intended For Feed Use

Any raw materials, intermediate or finished products produced or stored in the same premises by the participant but not intended for feed use must be clearly segregated from feed ingredients and identified as such during all stages of production / processing, packing, storage, despatch and supply.

5.12 Certificates of Conformity

Where feed ingredients are supplied with a certificate of conformity or a certificate of analysis, the participant must ensure that appropriate documented records are available to support the validity and accuracy of these certificates.

5.13 Inspection, Sampling and Analysis

5.13.1 Inspection

Participants must have inspection regimes in place that ensure the safety of all raw materials on arrival and feed ingredients on despatch. Inspections must include, as appropriate, assessment of:

- i) Colour;

- ii) Physical form;
- iii) Odour;
- iv) Contamination by insect pests, droppings and other extraneous matter;
- v) Mould;
- vi) Excessive damage;
- vii) Compliance with specification.

5.13.2 Sampling

Sampling schedules must be the responsibility of the designated Quality Manager. Details of the location, method and frequencies for sampling must be documented and appropriate for the raw materials and feed ingredients concerned.

5.13.2.1 All raw materials and feed ingredients must be subject to a sampling regime. Sampling techniques and frequencies must be adequate to ensure the true representation of any feed ingredients supplied.

5.13.2.2 The sampling regime must be appropriate to both the volume and nature of the raw materials and feed ingredients concerned.

5.13.2.3 Samples of both raw materials and feed ingredients must be retained for a minimum period of six months, unless risk assessment studies show that shorter periods are sufficient or longer periods required.

5.13.2.4 Samples must be kept in appropriate, air-tight containers and labelled in such a way as to assist traceability.

5.13.2.5 Storage conditions for samples must be such that deterioration is minimised.

5.13.2.6 Disposal of samples must be controlled under formal procedures and where they are incorporated back into feed ingredients, this must not create any potential hazard.

5.13.3 Personnel Taking Samples & Undertaking Tests

Personnel involved in either taking samples or testing must be allocated on the basis of their competence. Records of personnel training, experience and qualifications must be available and support the allocation.

5.13.4 Analysis

Where analysis is carried out, participants must be able to demonstrate that adequate tests are being undertaken using methodology that is appropriate to the raw materials and feed ingredients concerned.

5.13.4.1 Testing schedules for analysis must be the responsibility of the designated Quality Manager and must include both chemical and microbiological testing, as identified by the HACCP plan.

5.13.4.2 Testing methodology must be robust enough to ensure both the safety of the raw materials used and feed ingredients supplied. The nature and

frequency of tests carried out must show consideration of the volume and potential risks associated with the raw materials and feed ingredients concerned.

5.13.5 Undesirable Substances

In addition to sampling and testing required to establish other analyses, evidence must be available to show that feed ingredients meet acceptable, and if applicable, statutory standards for levels of undesirable substances such as mycotoxins, dioxins, heavy metals and pesticide residues.

5.13.6 Microbiological Analysis

Sampling and testing schedules for microbiological analysis must be the responsibility of the designated Quality Manager.

5.13.6.1 Participants must be able to demonstrate that the level of microbiological sampling and testing carried out will ensure the safety of any feed ingredients supplied.

5.13.6.2 Under some circumstances it is appropriate for microbiological testing to be carried out on buildings and equipment. When this is the case, appropriate records must exist to show that correct methods are being used and, where necessary, corrective action implemented.

5.13.7 Testing Laboratories

The methods of analysis employed in laboratories must be appropriate for the raw materials and feed ingredients being tested.

5.13.7.1 The effectiveness of testing laboratories must be regularly reviewed and approved by one or more of the following methods:

- i) Accreditation by a nationally recognised accreditation authority according to EN/ISO-17025 for the test under consideration;
- ii) Validation by participating in relevant ring tests;
- iii) Validation by other recognised means or comparison with results of a recognised laboratory with verified quality control procedures.

NOTE: Formal validation of laboratory results is not required for testing facilities used solely for process checks, unless such checks are identified as critical in the HACCP study.

5.13.8 Test Records

The parameters for acceptance or rejection of both raw materials and feed ingredients must be clearly defined.

5.13.8.1 Test results for all raw materials and feed ingredients must be recorded and include clear evidence of action in the event of results falling outside of acceptable parameters.

- 5.13.8.2 Test results must be reviewed by an authorised and competent person(s) with responsibility for ensuring that both raw materials and feed ingredients meet specified parameters.

5.14 Traceability

5.14.1 Traceability of Raw Materials

Participants must be able to demonstrate traceability for the raw materials utilised to produce feed ingredients. This will require the ability to produce a traceability trail for each raw material back to the point in the supply chain necessary to control any hazards identified in the risk assessment for each raw material.

- 5.14.1.1 Although the participant need not hold all relevant traceability records for raw materials, they must be capable of accessing such records if required to do so.
- 5.14.1.2 To ensure traceability of raw materials, the participant must:
- i) Record the names and addresses of suppliers of incoming raw materials, technological additives and process aids;
 - ii) Record the type and quantity of incoming raw materials and, where appropriate, the respective dates of manufacture and the number of the batch or lot received;
 - iii) Identify the transport means and unique identification reference of the transport for all incoming raw materials.

5.14.2 Traceability of Feed Ingredients

Participants must be able to demonstrate traceability for all feed ingredients supplied. This will require the ability to produce a traceability trail for each consignment of feed ingredients showing the period in which they were produced and the consignment(s) of raw materials from which they were produced.

- 5.14.2.1 Traceability must continue through any storage location (by bay, silo or tank), ships (by hold or tank), vehicles (by trailer reference), port(s), bulk handling equipment, to the point at which responsibility for the feed ingredients is passed to the purchaser.
- 5.14.2.2 Although the participant need not hold all relevant traceability records for feed ingredients, they must be capable of accessing such records if required to do so.
- 5.14.2.3 To ensure traceability of feed ingredients, the *participant* must:
- i) Record the type and quantity of the feed ingredients supplied and, where appropriate, the number of the batch or lot supplied;
 - ii) *Record details of the recipient;*
 - iii) Identify the transport means and unique identification reference of the transport for all feed ingredients despatched.

5.15 Non Conforming Products

Participants must establish a documented procedure for dealing with *any* raw materials *or* feed ingredients that do not comply with specifications. This procedure must include:

- i) Identification of batches / lots affected;
- ii) Documentation for managing and recording non-conforming products;
- iii) Evaluation of the cause of the non-conformance;
- iv) Segregation of batches / lots affected;
- v) Communication with relevant parties;
- vi) Preventive or corrective action to avoid repetition of the non-conformance.

5.15.1 Responsibility for review and disposal of non-conforming products must be defined. All incidences of non-conforming raw materials or feed ingredients must be recorded and decisions regarding actions to be taken must only be made by authorised personnel.

5.15.2 Non-conforming feed ingredients must be dealt with in one of the following ways:

- i) Sent to waste
- ii) Reworked
- iii) Accepted by concession (if agreed in writing by the client)
- iv) Downgraded (if meeting the specification of another feed ingredient)

5.15.3 Requirements for reprocessing non-conforming feed ingredients must be documented and any affected feed ingredients be re-evaluated on completion to ensure that the batch / lot concerned subsequently meets specified requirements.

5.15.4 The approval and use of reworks (e.g. from quality rejects, customer returns or spillage) must be considered within the HACCP plan. Those that are not approved must become waste and be disposed of accordingly.

5.15.5 Feed ingredients that do not fully meet a customer specification must only be supplied if the customer is notified of the problem in writing and confirms in writing that he is prepared to accept them.

5.16 Complaints Procedure

Participants must document the procedure for handling customer complaints. This procedure must include systems for:

- i) Recording the characteristics of complaints;
- ii) Allocating responsibility for managing complaints;
- iii) Recording the name of complaining customers;
- iv) Recording the feed ingredients under complaint;
- v) Investigating the causes of complaints;
- vi) Recording any actions taken to address complaints;
- vii) Recording correspondence with customers with regard to complaints.

5.16.1 With due regard to the seriousness and frequency of complaints, corrective actions must be carried out in a timely and effective manner.

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

5.16.3 Wherever possible, complaints must be resolved to the customer's satisfaction.

5.17 Recall Procedure

Participants must develop a documented recall procedure that ensures customers can be informed promptly in the event of any irregularity that may adversely affect feed ingredient safety.

5.17.1 The recall procedure must detail responsibilities and include actions to be implemented in the event of a recall. Feed ingredients must specifically be included in the applicant's recall procedures, whether or not supply of feed ingredients is the main activity of the applicant's business.

5.17.2 As part of the recall procedure, all relevant contacts must be listed and kept up-to-date. Contacts listed must include the Competent Authorities to be notified in the following circumstances:

- i) In the event of a serious safety risk;
- ii) When legal limits are exceeded and national legislation requires notification.

5.17.3 Recall procedures must include systems for:

- i) Identifying the non-conforming feed ingredient batch(es) / lot(s), *including other feed ingredients and batches / lots or raw materials that may be affected*;
- ii) Ensuring that where recall of a non-feed product is required, recall of feed ingredients is also considered and, if necessary, implemented;
- iii) Identifying the location of affected batches / lots;
- iv) Management of returned feed ingredients, including segregation from other products;
- v) Recording the destination of any recalled products.

5.17.4 Products that have been recalled may only be reprocessed or otherwise put back into circulation following formal assessment that it is both legal and safe to do so. Records must be kept of any such assessment.

5.17.5 The recall procedure must be tested at least annually to ensure its effectiveness. Such tests must be documented and evaluated for improvements.

5.18 Internal Audits

Participants must have a documented procedure for internal auditing.

5.18.1 Internal auditing procedures must require the participant to carry out a programme of planned internal audits to check that internal systems are operating as intended and are also effective. Such internal audits must encompass:

- i) Compliance with the requirements of this standard;
- ii) Compliance with the requirements of the participant's HACCP Plan;
- iii) Compliance with the participant's formal procedures;
- iv) Compliance with legislation pertaining to feed ingredient safety and quality;
- v) Satisfaction of specified customer requirements.

5.18.2 The programme of internal audits must ensure that all relevant activities are audited at least once a year.

5.18.3 All personnel carrying out internal audits must be trained to carry out such audits and be able to demonstrate their effectiveness in the role.

5.18.4 Internal audits must be formally reported to those with responsibility for the area audited and record any aspects where the operations are not in compliance with operational requirements. Such areas of non-compliance must be corrected and audit report records signed off by an authorised person to indicate that problems have been corrected satisfactorily.