Feed Ingredients and Additives Association of Australia Inc
Reg. no.: A0055138F ABN: 18 347 123 656
PO Box 187, Beecroft NSW 2119
Phone: +61 424 625 267
Email: info@fiaaa.com.au

Feed Ingredients & Additives Association of Australia Inc

Australian & New Zealand Code of Practice for Animal Feed Ingredient & Additive Suppliers

Version 5 AUSNZ September 2016

TABLE OF CONTENTS

1. Introduction

This Code of Practice for Animal Feed Ingredient & Additive Suppliers**('Code')** is to prescribe minimum standards for good practice in hygiene and the application of HACCP principles for the production and supply of feed ingredients and additives.

Implementation of the Code is to result in measures that ensure the safety and quality of feed ingredients and additives; the operation of businesses in accordance with feed hygiene requirements, improved traceability and compliance with all legislative and regulatory requirements e.g. Department of Agriculture Biosecurity (Dept Ag) requirements and Australian Pesticides and Veterinary Medicines Authority (APVMA) regulations. and for New Zealand Ministry For Primary Industries (MPI) requirements and Agricultural Compounds and Veterinary Medicines (ACVM).

Underlying principles include:

- protecting the health of livestock and to enable livestock producers to achieve expected levels of performance,
- protecting the health of consumers of food products derived from livestock fed ingredients and additives,
- Contributing to the delivery of livestock products of consistent and appropriate quality to enable livestock producers to market food commodities that meet national and international food standards.

The Code applies equally to feed additives domestically manufactured and imported from overseas.

Additionally, the Code may form the basis for certifying product for export market access. Importing country requirements set by overseas governments for access to their individual markets are not handled by this Standard but are dealt with under Commonwealth legislation dealing with export certification.

Various stakeholders have commented on aspects of this Code and their comments have been incorporated where appropriate including: APVMA , Dept Ag, Department of Primary Industries Victoria, Biosecurity Queensland, and Stockfeed Manufacturers Council of Australia.

The Code is intended to align with current animal feed legislation and various activities on national, and/or association levels and take into account the principles of feed and food safety as well as HACCP principles that are set out in various international documents such as, in particular:

- 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)
- Other Codes of Practice and Quality Assurance Schemes such as FeedSafe®, (http://www.sfmca.com.au/feedsafe/about_feedsafe) and the Australian Standard for the Manufacture and Marketing of Petfood (AS5812) and for New Zealand ***(http://nzfma.org.nz/about/about-feedsafenz and the New Zealand Standard for the Manufacture and Marketing of Petfood (http://www.petfoodnz.co.nz)***

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

The text of the Code is designed to set out requirements and to be used by suppliers as a tool to develop their own procedures. FIAAA has an audit and certification system for members to

® SFMCA October 2002

demonstrate member commitment to safe feed ingredients. This Code is seen as providing a minimum standard against which audits can be conducted.

2. Scope

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

2.1. minimising the risk of contaminated feed ingredients and additives entering the feed/food chain;

2.2. enabling suppliers to implement the objectives of feed hygiene & safety requirements of relevant Australian and New Zealand Standards and Codes of Practice;

2.3. providing measures to ensure that other applicable regulatory feed safety requirements are met efficiently & sustainably.

This Code shall apply to feed ingredients & additives suppliers at all stages of production and supply to the feed manufacturing industry. It also applies to the import of feed ingredients and additives from overseas.

Compliance with this Code does not exonerate the supplier from meeting the statutory or regulatory requirements of Australia and each state or territory in Australia or New Zealand. Particular attention is drawn to the need to comply with Occupational Health and Safety as well as Environmental Regulations with particular relevance to products covered by this Code.

The Code provides for certification of suppliers of feed ingredients and additives but is not a warranty for individual products.

3. Terms and Definitions

The following terms and definitions are used in this guide and associated annexes:

Adequate: The terminologies "adequate", "where appropriate", "where necessary", or "sufficient" mean that it is up to the business supplier in first instance to decide whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives of the Code. In determining whether a requirement is adequate, appropriate, necessary, or sufficient, account should be taken of the nature of the feed and of its intended use.

Batch: unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together. It consists of an identifiable quantity of feed ingredient or additive and is determined to have common characteristics, such as origin, variety, type of packing, packer, consignor or labeling.

Calibration: The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.

Carrier: Substance used to dissolve, dilute, disperse or otherwise physically modify a feed additive in order to facilitate its handling, application or use without altering its technological function and without exerting any technological effect themselves.

Code of Practice: Document identifying the principles of feed hygiene (to ensure the safety of feed for animals and in turn the safety of animal products intended for human consumption), . protecting the health of livestock and to enable livestock producers to achieve expected levels of performance, protecting the health of consumers of food products derived from livestock fed ingredients and additives and contributing to the delivery of livestock products of consistent and appropriate quality to enable livestock producers to market food commodities that meet national food standards.

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.

Corrective Action: Action to eliminate the cause of a detected non~conformity or other undesirable situation. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. *(ISO 9000:2005)*

Crisis: An event that represents an immediate and significant threat to animal and/or human health resulting from the production or supply of unsafe or illegal product; where the product has left the immediate control of the feed business supplier.

Feed additive: Any intentionally added component of feed not normally consumed as a feed ingredient, which affects the characteristics of feed or animals fed with it. It includes a pre-mix which consists only of feed additive components, micro-organisms, enzymes, acidity regulators, trace elements, vitamins, preservatives, colouring agents, binders, dust suppressants, carriers, flavours and other products.

Feed ingredient*:* A nutritive component part or constituent of any combination or mixture making up a feed. Ingredients may be of plant or animal (including aquatic) origin or other organic or inorganic substances.

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'.

HACCP (Hazard Analysis and Critical Control Point): A system which identifies, evaluates, and controls hazards to feed safety. *(CodexAlimentarius 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.

Homogeneity: The degree to which a property or a constituent is uniformly distributed throughout a quantity of material.

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).

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

Preventive Action: Action to eliminate the cause of a potential non-conformity or other undesirable potential situation. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence. *(ISO 9000:2005)*

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

Provider- an entity responsible for the supply of materials.

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

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

Recall: Any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the supplier. *(Reference EU Regulation No 2001/95/EC)*

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

Record: Written documents containing actual data.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

Shall: Indicates a statement is mandatory

Shelf life: A defined time period for which a product fully complies with its specification if stored appropriately.

Should: - Indicates a recommendation

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".

Supplier- Where used in this code supplier means manufacturer, importer, wholesaler, distributor, reseller, premixer, trader, agent, etc who wish to be certified under this code.

Traceability: The ability to trace and follow a food, feed, food producing animal or substance intended to be, or expected to be incorporated into a food or feed through all stages of production, processing and distribution.

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

4. Management System (MS)

4.1 General requirements

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

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

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

The MS shall ensure that all activities carried out by the supplier 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 specification of the product. (see 7.1)

4.2 Management principles

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

Each supplier shall perform and record the evaluation of risks associated with processes within their operations and subsequently define controls to be applied to these based on HACCP principles. The hazard risk assessment plan shall be regularly reviewed.

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

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

4.3 General documentation requirements

The supplier 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. Records shall contain all relevant data that will permit investigation of any non~conformance or deviation(s) from planned procedure(s).

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

4.3.1 MS documentation shall include:

4.3.1.1 a written quality and safety policy; a Quality Manual;

4.3.1.2 documented procedures and records; and

4.3.1.3 information needed by the supplier to ensure the effective planning, operation, and control of its processes.

The manual shall include:

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

4.3.1.5 procedures established as part of the MS, or reference to them;

4.3.1.6 procedures in support of the quality program;

4.3.1.7 procedures to ensure feed safety.

Minimum documents required shall include:

4.3.1.8 specifications and testing procedures for incoming materials and finished product;

4.3.1.9 master formulae and operating instructions for each product or group of products (where applicable);

4.3.1.10 batch processing records for each product (where applicable); and

4.3.1.11 procedures such as standard operating procedures (SOPs).

Documents shall:

4.3.1.12 have the title, nature and purpose clearly stated;

4.3.1.13 be approved, signed, dated or changed by appropriate authorised persons.; and

4.3.1.14 be kept up to date.

5. Management Responsibility

5.1. Management commitment

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

5.2. Quality and safety policy

Management shall:

Establish and put in place a quality and safety policy and ensure that objectives are established clearly stating the

5.2.1. obligation to produce safe, legal feed additives and to respect their customers' requirements.

5.2.2. This policy shall be communicated throughout the organisation and understood by all staff involved in the supply of feed additives.

5.2.3. Provide the necessary resources for the fulfilment of the quality and safety policy.

5.2.4. Ensure all key aspects of the Management and Quality systems are documented, reviewed, updated and communicated to key staff as frequently as necessary.

5.3. Responsibility, authority and communication

Management shall:

5.3.1. appoint a quality team and team leader;

5.3.2. define the scope of the quality system, by identifying the products and supplier sites which are covered by the system and ensuring that safety objectives are established as part of the system;

5.3.3. ensure job descriptions are available that clearly define the responsibilities of all staff (employed and contracted) involved in the supply of feed ingredients & additives;

5.3.4. identify and record any problems and remedial actions with regard to products quality, safety and the supplier's management system;

5.3.5. initiate action(s) to prevent the occurrence of non-conformities relating to product quality and safety; and the supplier shall provide adequate resources for the implementation, management and control of the quality systems;

5.3.6. assign the responsibility and authority for ensuring compliance with regulatory requirements and industry codes of practice to clearly identified persons;

5.3.7. issue, maintain and make available to the operation's staff and relevant external bodies an organisational chart of the operation.

5.4. Management representative

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

5.4.1. ensuring that processes needed for the management and quality systems are established, implemented and maintained;

5.4.2. reporting to top management on the performance of the management systems and any need for improvement; and

5.4.3. ensuring the promotion of awareness of customer requirements throughout the organisation.

5.5. Management review

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

5.5.1. records of this review shall be maintained;

5.5.2. the need to update or change the Management Systems shall be evaluated at these reviews;

5.5.3. results from external and internal audits shall be reviewed, including resolutions;

5.5.4. customer complaints and requests shall be reviewed, including resolutions;

5.5.5. internal problems and changes to the operation processes shall be reviewed;

5.5.6. decisions made to change any aspect of the Management Systems shall be communicated to key staff;

5.5.7. management shall ensure a system is in place to audit the Management Systems.

6. Resource management

6.1. Provision of resources

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

6.1.1. Suppliers shall have sufficient staff possessing the skills and qualifications necessary for the manufacture and/or storage and supply of the products concerned.

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

6.2. Human resources

6.2.1. Competence, awareness and training

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

Education and training of personnel shall be documented and maintained.

Staff shall be trained in appropriate standards of hygienic behaviour in order to contribute to the overall feed safety part of the food chain. (for training guidelines see for Australia APVMA GMP 212-231or New Zealand ***ACVM GMP 212-231***). Also refer to http://www.foodsafety.govt.nz/industry/acvm/petfood-stock-feed-supplements/

6.2.2. Personal Hygiene

Ensure that personnel hygiene facilities are clearly and suitably designated, located and maintained.

Provide appropriate work wear such as protective clothing and safety footwear, and maintain them in hygienic conditions.

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

6.3. Infrastructure

6.3.1. Basic requirements

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

6.3.2. Requirements for facilities, production areas and equipment

The layout, design, construction and size of the facilities and equipment shall:

6.3.2.1. permit adequate cleaning and/or sanitation;

6.3.2.2. be such as to minimise the risk of error and to avoid contamination, cross~transference and any generally adverse effects on the safety and quality of the products.

6.3.3 **Facilities & production and storage areas**

Where necessary, facilities shall be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable microorganisms and the shedding of particles that can affect the safety and quality of products.

6.3.4 **Equipment**

Equipment should be located, designed, constructed and maintained to suit the manufacture and/or supply of the products. Aspects to consider include such as ventilation, hygienic maintenance, lighting, water, drainage, CIP and pest management.

6.4. Maintenance and control of monitoring and measuring devices

A documented maintenance program for manufacturing operations shall be implemented. Records shall be kept of work carried out.

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

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

Where necessary to ensure valid results, measuring equipment shall:

6.4.1. 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;

6.4.2. be adjusted or re-adjusted as necessary;

6.4.3. be identified to enable the calibration status to be determined;

6.4.4. be safeguarded from adjustments that would invalidate the measurement result; and

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

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

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

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application should be verified. This verification should be undertaken prior to initial use and reconfirmed as necessary. For reference: Australia APVMA GMP includes chapter 6 Computers or New Zealand *ACVM GMP includes chapter 6 Computers* (http://www.foodsafety.govt.nz/industry/acvm/petfood-stock-feed-supplements/)

6.5. Cleaning

A cleaning and inspection program shall be documented. Effectiveness of the program shall be demonstrated.

Ensure that all inside and outside areas, buildings, facilities and equipment are kept clean and in good state to function as intended and to prevent contamination.

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

A schedule shall be documented with method and frequency of cleaning including responsibilities for the tasks.

Cleaning agents where used shall be used and stored according to the manufacturer's instruction(s), clearly labeled, separately stored from raw materials and finished products and applied properly to avoid contamination of raw materials and finished products.

6.6. Pest control

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

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

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

The positions of traps and bait stations shall be mapped.

The Quality plan shall consider the risk of contamination due to infestation or use of pesticides. Spoilage and dust shall be controlled to prevent pest invasion.

The results of the pest control are part of the management review.

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

6.7. Waste control

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

6.7.1. Identify waste clearly and dispose in a manner which avoids contamination of raw materials and finished products;

6.7.2. Waste containers should be clearly marked and designated for that purpose only;

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

7. Product Supply

7.1. Product requirements

7.1.1. Determination of requirements related to the product

The supplier shall determine:

7.1.1.1. statutory and regulatory requirements related to the product;

7.1.1.2. requirements specified by the customer, including requirements related to delivery and post activities and

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

7.1.1.4. specifications

7.1.2. Compliance of the product to the requirements

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

7.1.2.1 the provider has the ability to meet the defined requirements

7.1.2.2 should product requirements change, that relevant documents are amended and that relevant personnel are made aware of the changed requirements

7.1.3. Customer communication

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

7.1.3.1. product information;

7.1.3.2. enquiries, contracts or order handling, including amendments; and

7.1.3.3. customer feedback, including complaints.

7.2. Feed Safety Program

Outcome- Feed (product) safety is managed in a controlled manner based on a systematic procedures.

The program comprises all activities and process steps ranging from purchase of raw materials to transport of the finished products.

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

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

It is recommended that suppliers follow the guidance for application of HACCP provided in the Codex Alimentarius Guidelines.

7.3. Design and development

7.3.1. Development of new products and processes

The supplier shall plan and control the design and development of new products or processes: ensuring product safety during the developmental stages of a new product. Hazard analysis shall be applied (see 7.2)

7.3.2. Change control

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

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

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

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

7.4. Handling of incoming materials

7.4.1. Sourcing of incoming materials

All suppliers shall place special emphasis on ensuring their suppliers and products are of the required quality and standard and comply with all regulatory requirements.

Management requirements

7.4.1.1. Purchasing information shall describe the product to be purchased.

7.4.1.2. Selection and approval of all products shall include their origin, transport, storage, and handling.

7.4.1.3. Any potential hazard associated with a product shall be documented.

7.4.1.4. Each product shall have a written specification.

7.4.1.5. In addition to the analytical characteristics of the product, the specification should include, reference to any specific regulatory requirements.

7.4.1.6. Where appropriate, requirements for analytical monitoring shall be defined.

7.4.1.7. There shall be a list of internally approved suppliers. Each supplier shall be subject to periodical review. There shall be a system of regular review of the supplier listing.

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

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

Supply requirements

7.4.1.10. Every product shall be evaluated to assess any potential hazard identified in 7.4.1.3

7.4.1.11. There shall be a check that these products are being produced in compliance with the requirements of this Code.

7.4.2. Verification of incoming materials

Incoming materials shall be checked and formally approved prior to use according to written procedures.

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

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

Materials such as packaging and labels not incorporated into the finished product shall also be assessed as to conformance to specification.

Handling of incoming materials should be in accordance with its status, for example, a received product which is deemed unfit for use shall be identified as such and segregated from those products released for use. In the same light, perishable materials should be treated appropriately. If incoming materials are rejected and thus not incorporated for any reason related to product quality and safety, their disposal, destination, or return to supplier shall be recorded.

7.4.3. Certificates of Analysis and Conformance

All incoming raw materials to be incorporated into products shall be tested (locally or overseas by a lab complying with section 7.4.4) and verified with a certificate of analysis.

Certificates of analyses shall apply to all feed ingredients and feed additives except where a certificate of conformance applies.Certificates of conformance shall apply to proprietary blends, pre-mixes and multi-ingredient products.

Certificates of Analysis shall contain an analysis or Certificates of Conformance a conformace statement, relating to the specification and claimed composition made relating to the product.

Certificates of analysis shall include the relevant test method, conducted by a laboratory as per 7.4.4 and be signed by a qualified officer.

7.4.4. Testing

Testing shall be conducted by registered laboratories (National Association of Testing Authorities (NATA), International Laboratory Accreditation Co-operation (ILAC) or equivalent). Test methods shall be verified.

Testing conducted in-house is also acceptable providing tests are verified against an external laboratory (NATA or equivalent) or an equivalent verification procedure.

Frequency of verifications shall be defined in the risk assessment plan.(see 4.2).

7.4.5. Contaminants

All incoming materials shall comply with Australian regulations with respect to contaminants. (Including APVMA Maximum Residue Limits (see http://apvma.gov.au/node/10806) and National Feed Standard when published). For New Zealand regulations are (http://www.foodsafety.govt.nz/industry/acvm/petfood-stock-feed-supplements/***ACVM Maximum Residue Limits see http://ACVM.gov.au/node/10806***). If not regulated then the following shall be used- COMMISSION REGULATION (EU) No 1275/2013 Ref- http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002L0032-20131227&from=EN

7.4.6. Fit for Purpose

All incoming materials shall comply with legal and regulatory requirements and be fit for the purpose intended.

7.4.7. Retention Samples

Samples of all incoming material batches shall be retained (locally or at site of manufacture/supply) and stored appropriately for a minimum of the shelf life of the product or a minumum of 12 months from date of receipt.

7.5. Production of finished goods

This applies to both manufacturers in Australia and overseas. Overseas manufactured products are required to provide evidence that the finished products have met these requirements.

7.5.1. Quality Control and Production

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

7.5.1.1. Specifications:

- Each product shall have a written specification, which is amended when any change takes place.
- The availability of information that describes the characteristics of the finished product.
- Each product shall have a unique name or code.

7.5.1.2. Procedures and work instructions:

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

7.5.1.3 Quality requirements:

- Details of packaging and labeling shall be available. Product labeling shall be in accordance with the relevant Australian or NZ legislation. (see 7.7.2.3 and http://www.comlaw.gov.au/Details/F2015C00220) or New Zealand regulations (see http://www.foodsafety.govt.nz/industry/acvm/petfood-stock-feed-supplements/***ACVM Maximum Residue Limits see http://ACVM.gov.au/node/10806***).
- Each package shall be labeled by a unique identifier (which can be a combination of codes) in order that the batch to which it belongs can subsequently be identified and traced.
- All finished product shall be inspected prior to dispatch, in accordance with written procedures, to ensure it meets specification. (see 7.6 for verification)
- A retention sample of adequate size shall be taken of each batch and held, either at the source or supplier, as a minimum, for a time equivalent to the defined shelf life of the product. The samples shall be sealed and labeled, stored in a manner that should prevent abnormal change, and kept at the disposal of the authorities for a period appropriate to the use.
- If products are rejected and thus not put into circulation for any reason related to product quality and safety, their disposal, destination, or return to supplier shall be recorded.

7.5.1.4 Rules governing packaging:

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

use.

7.5.1.5 Rules controlling storage:

- Finished products 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 designed places, adapted and maintained, in order to ensure appropriate storage conditions which manage the risks of contamination and possible infestation by harmful organisms.
- Materials should be stored in a manner which enables easy identification, avoids cross~ transference and prevents deterioration. A stock rotation system shall 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.

7.5.1.6 Rules concerning loading and delivery:

- Products shall be delivered with, in mind, the protection of animal and human health and the environment as prime considerations.
- Containers and equipment used for internal transport, storage, conveying handling and weighing shall be kept clean.
- A final inspection shall take place to ensure delivery of correct product

7.5.2 Verification of processes for production

The different stages of production shall be carried out according to written procedures which define, check and control the critical points in the production process. Records shall be kept which confirm that procedures are followed and/or identify any departure from them.

Each product batch shall be mixed to achieve a homogeneous product. Written protocols for testing mixer efficiency (homogenous mixing), shall be established and test records shall be kept.

The supplier 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 expected results. Frequency of verifications shall be considered under the supplier's Quality system. Particular attention should be given to cross-transference and homogeneity.

The supplier shall establish arrangements for these processes including:

7.5.2.1 defined criteria for review and approval of the manufacturing processes;

7.5.2.2 approval of equipment;

7.5.2.3 qualification of personnel;

7.5.2.4 use of specific methods and procedures; and

7.5.2.5 requirements for records.

7.5.3 Identification and traceability

To ensure traceability, the supplier shall:

7.5.3.1 identify and record the product by suitable means; and

7.5.3.2 maintain a register, that contains:

7.5.3.3 the names and addresses of manufacturers of incoming materials, additives or of intermediaries. Incoming materials shall be verified according to section 7.4.2.

7.5.3.4 the nature and quantity of the products, 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.

7.5.4 Preservation of product

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

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

7.6 Finished Product Verification

This applies to both manufacturers in Australia and overseas. Overseas manufactured products are required to provide evidence that the finished products have met these requirements.

7.6.1 Certificates of Analysis and Conformance

All products shall be tested or verified with either a certificate of analysis or certificate of conformance. Certificates of analyses shall apply to all feed ingredients and feed additives except where a certificate of conformance applies. Certificates of conformance shall apply to proprietary blends, pre-mixes and multi-ingredient products.

Certificates of Analysis shall contain an analysis or Certificates of Conformance a conformace statement, relating to the specification and claimed composition made relating to the product.

All product batches shall be tested and/or verified against specification and certificates be available for customers.

Certificates of analysis shall include the relevant test method, conducted by a laboratory as per 7.6.2 and be signed by a qualified officer.

7.6.2 Testing

Product testing shall be conducted by registered laboratories (National Association of Testing Authorities (NATA) or equivalent). Testing conducted in-house is also acceptable providing tests are verified against an external laboratory (NATA or equivalent) or an equivalent verification procedure.

Frequency of verifications shall be defined in the risk assessment plan.(see 4.2).

7.6.3 Contaminants

All products shall comply with Australian regulations with respect to contaminants. (Including APVMA Maximum Residue Limits (see http://apvma.gov.au/node/10806) and National Feed Standard when published). For New Zealand regulations are (http://www.foodsafety.govt.nz/industry/acvm/petfood-stock-feed-supplements/***ACVM Maximum Residue Limits see http://ACVM.gov.au/node/10806***). If not regulated then the following shall be used- COMMISSION REGULATION (EU) No 1275/2013 Ref- http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002L0032-20131227&from=EN

7.6.4 Fit for Purpose

All products shall comply with legal and regulatory requirements and be fit for the purpose intended.

7.6.5 Retention Samples

Samples of all product batches despatched including records shall be retained and stored appropriately for a minimum of the shelf life of the product or a minumum of 12 months from date of despatch.

7.6.6 Release for supply

Procedures must be in place to ensure that all finished product has been made correctly and meets all the quality tests before it is released for supply or sale. (see 7.5.1 and 7.5.2)

7.7 Product registration

The supplier of the feed ingredient or additive shall assess whether the product is required to be registered by the APVMA or ACVM prior to sale. Registration may apply to either specific active ingredients or claims made relating to products.

Some feed additives have been deregulated such that they may be sold providing certain conditions are met. These are able to be self-assessed.

Where dietary and therapeutic claims (nutrients in a product intended for the alleviating, preventing or curing of a disease or condition) are made they shall comply with Australian Agricultural and Veterinary Chemicals Legislation (see http://www.comlaw.gov.au/Details/F2015C00220) or for New Zealand Agriculatural and Veterinary Medicines Legislation see http://www.foodsafety.govt.nz/industry/acvm/petfood-stock-feed-supplements)

Regulations permit use of products under a self assessment model providing certain conditions are met.

A substance or mixture of substances is an excluded nutritional or digestive product if:

7.7.1 the substance or mixture is intended for consumption by an animal; and

7.7.2 the following requirements are met in relation to the substance or mixture:

7.7.2.1 that the product is only for oral consumption by animals;

7.7.2.2 satisfies requirements about claims (the described intended purpose for the product);

7.7.2.3 satisfies requirements about product labelling;

7.7.2.4 satisfies requirements about quality and standards of manufacture; and

7.7.2.5 satisfies requirements about ingredients.

Details of each requirement are referenced in the above Regulations. A summary of each of the requirements above are published at http://www.comlaw.gov.au/Details/F2015C00220. For New Zealand refer to http://www.foodsafety.govt.nz/industry/acvm/petfood-stock-feed-supplements/

Products not meeting all these requirements will continue to be deemed Veterinary Chemical Products requiring registration by APVMA or ACVM.

7.8 Transport

7.8.1 General requirements

Measures shall be taken to ensure that the transportation of raw material and finished products is adequate in order to minimize the risk of contamination and is in accordance with regulations.

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

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

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

The supplier shall communicate its requirements on transportation to the transport operator; these requirements shall be documented and verified regularly.

The supplier's evaluation of the performance of the transport operator shall confirm the effectiveness of the transport operator's actions to meet the requirements.

When transport of finished products is arranged with delivery terms and where the buyer takes responsibility for the transport, it is the supplier's responsibility to communicate, to the buyer, that the requirements in this standard will be applied on the transport prior to and on loading and transportation/delivery.

7.8.2 Transport of packaged goods

Products should not be transported, even if sealed, with goods that compromise the safety of the raw material or the finished product.

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

7.8.3 Transport of bulk products

A system shall be in place to safeguard against contaminants which may compromise the integrity of products according to applicable Regulations.

The supplier shall ensure that the transport operator of bulk products has sufficient knowledge about handling products. In the best case, this should be proven by certification to a recognized standard.

Valid information about the product to be loaded shall be given by the supplier to the transport operator. The transport operator can then define the suitable container to provide the best protection.

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

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

- information that enables container traceability;
- previous load(s);method of cleaning;
- cleaning company;
- if applicable, the cleaned discharge equipment.
- after cleaning, the efficiency of the cleaning operation shall be checked and recorded.
- exceptions from the requirement on cleanliness may be done if the previous load does not compromise the safety of the one to be loaded.

8. System Review

8.1. General requirements

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

8.2. Internal audits

The supplier shall ensure that internal audits are performed to verify that the management systems is:

8.2.1. effectively implemented and maintained;

8.2.2. in compliance with regulatory and other defined requirements;

8.2.3. the scope of the audits shall be defined and their frequency scheduled in relation to the risk associated with the activity to be audited; and

8.2.4. auditors shall be trained, competent and independent.

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

Corrective actions shall be scheduled and verified when completed.

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

8.2.5. preparation and issue of audit plans;

8.2.6. methods used to conduct the audits;

8.2.7. reporting of findings;

8.2.8. distribution of reports.

9. Control of non~conforming products

9.1. General requirements

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

The procedure shall include:

9.1.1. identification of product and batch code;

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

9.1.3. evaluation of the cause of the non-conformance;

9.1.4. segregation of affected batch or batches;

9.1.5. provision for disposal of products where appropriate;

9.1.6. recording of internal information of relevant parties.

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

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

9.1.7. rework;

9.1.8. reclassification or dispensation; or

9.1.9. rejection and subsequent destruction or disposal.

Records of all non-conformances shall 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 hazard risk assessment plan (see 4.2). Potential reworks which are not approved become waste material and should be dealt with according to waste disposal procedures.

9.2. Complaint handling system

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

9.2.1. allocate responsibility for controlling complaints;

9.2.2. record name of complaining customer;

9.2.3. record product name and identification code;

9.2.4. identify and record each complaint; and

9.2.5. 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.

9.3. Recall

A formal recall procedure shall be documented so that customers can be informed immediately of any irregularities that may compromise feed safety.

The recall procedure shall be regularly reviewed to ensure conformance with the quality manual and regulatory requirements and the supplier's organization.

The recall procedure shall include requirements to:

9.3.1. define and allocate responsibility for the recall process;

9.3.2. identify each batch of non~conforming product including consequences to other product batches or raw materials throughout the entire process.

9.3.3. identify the destination of affected batches;

9.3.4. notify customers of affected batches and coordinate product return;

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

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

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

9.3.7. ensuring immediate corrective and preventive actions are undertaken;

9.3.8. verifying that corrective and preventative actions are effective.

Feed additive and premixture businesses may also remove products from the market for reasons other than food safety; these cases should be handled in the same manner described here.

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

9.4. Crisis Management

If a feed business supplier considers or has reason to believe that a feed which it has been imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements it shall immediately initiate procedures to recall the feed in question from the market and inform the competent authorities thereof.

9.4.1. The crisis management procedure shall be documented

9.4.2. Responsibility shall be defined for notifying customers and regulatory authorities

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

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

10. Statistical techniques

The supplier shall, where appropriate, evaluate and identify the need for the use of statistical techniques. Where statistical techniques are applied, the need for these techniques shall be demonstrated. The adequacy of these techniques shall be demonstrated:

10.1. standard error shall be calculated and documented;

10.2. standard error shall be of an appropriate level to sufficiently ensure feed safety;

10.3. data exceeding standard error and trends shall be monitored;

10.4. corrective actions shall be specified in the event of a breach of error limits.