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European Feed Manufacturers Guide (EFMC)

A community guide to good practice for the EU industrial compound feed and premixtures manufacturing sector for food producing animals

Version 1.1

November 2009

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0. INTRODUCTION

The industrial compound feed sector is a significant link in the production chain of food products from animal origin. Producing safe feed and food products is first and foremost a question of good management practices at each stage of the feed and food chain from primary production to final processing. It is therefore the responsibility of each operator in the feed and food chain to implement good practices to ensure the safety of the goods he produces.

In parallel with the development of the EU feed legislation which mainly focused on food safety objectives, the EU compound feed industry has developed feed safety assurance systems laying down a number of requirements to support the proper implementation of the feed and food safety standards and establishing its own standards where required. These feed safety assurance systems have been developed either individually or collectively at national level. Since 1998, FEFAC has established guidelines for the development of national guides to good practice for the manufacturing of compound feed and premixtures in order to foster the practical implementation of good hygiene practices and to achieve a common technical ground for the development of feed safety assurance systems.

Regulation (EC) No 183/2005 on feed hygiene acknowledges the positive contribution of good hygiene practices to achieve the objectives laid down in the EU feed safety legislation and encourages the development of national or Community guides to good practice by feed business sectors, in consultation with any interested party.

The FEFAC guidelines were adapted to meet the requirements of the Feed Hygiene Regulation and were renamed as the European Feed Manufacturers Guide (EFMC). The main objective of the EFMC is to help ensure the safety of feed for food producing animals and of food stemming from those animals and designed for human consumption through implementation of Good Manufacturing Practice during the purchase, handling, storage, processing and distribution of compound feed for food producing animals in accordance with the objectives of the CODEX Code of Practice on Good Animal Feeding and the requirements laid down in the EU General Food Law (Regulation (EC) No 178/2002), in particular Article 17. The guidance document[1] on the implementation of the General Food Law approved by the Standing Committee on the Food Chain and Animal Health at its meeting of 20 December 2004 must be regarded as an essential document that operators should refer to for compliance with the General Food Law Principles.

From 2002 on, FEFAC organised annual meetings with other partners of the chain listed in Annex V of the Guide. The purpose of these meetings was to involve our chain partners at an early stage of the development of the EFMC and also to discuss the development of guides to good practice in the feed chain at large. A formal consultation, extended to EU organisations of consumers, retailers and modern restaurants was launched in July 2004 with a view to prepare the adoption of the final draft EFMC by the FEFAC Council. The outcome of this formal consultation was considered at a stakeholders' workshop on 20 October 2004. The comments focused exclusively on provisions regarding the sourcing of feed materials, provisions that are no longer mentioned in the present guide. The final draft EFMC was notified to the EU Commission in accordance with Article 22 of Regulation (EC) No 183/2005 and then further amended to take into account the comments and requests of the Standing Committee on the Food Chain and Animal Health. It was once more assessed by the Standing Committee on the Food Chain and Animal Health at its meeting on 29 January 2007. The title "European Feed Manufacturers' Guide (EFMC): a Community

[1] The document is available at the following link: http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf

Guide to Good Practice for the Industrial EU Compound Feed and Premixture Manufacturing Sector for Food Producing Animals" and the references of the EFMC were published in the OJEC No C64 of 20 March 2007, page 17.

A special Committee, the so-called EFMC Committee, was established within FEFAC to review, on a regular basis and at least once a year, the European Feed Manufacturers' Guide against any new development in the technological, scientific, normative and legislative area and, if need be, to proceed to necessary adjustments, in consultation with other interested parties. The draft updated versions of the guide will be notified to the EU Commission for assessment.

With a view to ensuring that the coexistence of nationally developed guides to good practice does not result in undesirable barriers to trade within the EU, the present EFMC is also designed to provide practical information for the benchmarking of national guides to good practice for the production of safe compound feed and premixtures in order to facilitate the mutual recognition of these existing national guides to good practice by the public authorities, national guides owners and stakeholders in the feed and food chain. The EFMC may also be used as a reference document for the development of feed safety assurance systems. In this case, the development of certification rules is the responsibility of the national scheme owners and should be based on EN 45011.

Medicated feed are a specific form of compound feed, which and are often produced in the same plant as conventional compound feed. Therefore, their manufacturing, storage and delivery have to comply with EU legal feed hygiene requirements as laid down in Regulation (EC) No 183/2005. This is why, any EFMC provision pertinent for conventional compound feed is also pertinent for medicated feed. In addition, medicated feed are subject to specific EU legislation, i.e. Directive 90/167/EEC, which provides for additional hygiene and safety practices. Considering the differences in terms of implementation of this Directive at national level, it was decided to include these additional requirements in a separate Annex II. However, any national good practices developed in accordance with article 4(d) of Directive 90/167/EEC may take precedent over the present good practices laid down hereafter.

The EFMC only covers safety related issues, i.e. the safety of feed for animals to ensure human as well as animal health. The following essential feed safety related criteria have to be covered in any code of practice applied by compound feed, and premixtures manufacturers:

- the type of products: premixtures, compound feedingstuffs;
- the operations covered:
    - the sourcing of feed materials, premixtures and feed additives
    - the production, storage, transport and distribution of premixtures and compound feed
- an "HACCP"- based risk analysis addressing the risks linked to chemical, physical and microbiological hazards
- a full traceability system including a detailed record keeping procedure
- a detailed sampling plan, including uniform sampling methods and sample storage
- a complaint and recall procedure
- written procedures are laid down and their implementation is subject to internal and independent checks.

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EUROPEAN FEED MANUFACTURERS' GUIDE (EFMC)

A COMMUNITY GUIDE TO GOOD PRACTICE FOR THE EU INDUSTRIAL COMPOUND FEED AND PREMIXTURES MANUFACTURING SECTOR FOR FOOD PRODUCING ANIMALS

Version 1.1 November 2009

1. SCOPE AND DEFINITIONS

1.1. Scope

The present European Feed Manufacturers' Guide (hereafter referred to as the Guide) covers premixtures and compound feedingstuffs for food producing animals. To facilitate the reading and use of the present Guide, any provision applying to compound feed applies also to medicated feed unless otherwise specified in Annex II of this Guide. It covers all operations referred to in Article 5 par. 2 of Regulation (EC) No 183/2005 under the responsibility of the compound feed and/or premixture manufacturer, from purchase, handling and storage to processing and delivery of compound feed and premixtures. The Guide does not cover the production of premixes for medicated feedingstuffs. The Guide, although primarily designed for the industrial manufacturing of feed, may also be applied by on- farm compound feed producers using premixtures and/or feed additives and covered by Article 5, par. 2 of Regulation (EC) No 183/2005.

1.2. Legal Definitions

Batch: Unit of production produced in a single plant using uniform production parameters, or a number of such units [produced consecutively], when stored together, and that can be identified for the purposes of recall and re-treatment or disposal should tests show that to be necessary (Regulation (EC) No 1774/2002).

Compound feed: Mixtures of at least two feed materials, whether or not containing additives, for oral animal-feeding in the form of complete or complementary feed (Regulation (EC) No 767/2009).

Complete feed: Compound feed which, by reason of their composition, is sufficient for a daily ration (Regulation (EC) No 767/2009).

Complementary feed: Compound feed which has a high content of certain substances but which, by reason of their composition, is sufficient for a daily ration only if used in combination with other feed (Regulation (EC) No 767/2009).

Feed (or feedingstuff): Means 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: Substances, micro- organisms or preparations, other than feed materials and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions (Regulation (EC) No 1831/2003):

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

Feed hygiene: Means the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use (Regulation (EC) No 183/2005).

Feed material: Various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures (Directive 96/25/EC).

Food: Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans (Regulation (EC) No 178/2002).

Hazard: Biological, chemical or physical agent in, or condition of, feed with the potential to cause an adverse health effect (Regulation (EC) No 178/2002).

Medicated feed(ingstuffs): Any mixture of a veterinary medicinal product or products and feed or feeds which is ready prepared for marketing and intended to be fed to animals without further processing, because of its curative or preventive properties or other properties as a medicinal product (Directive 2001/82/EC).

Premixtures: Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended to direct feeding to animals (Regulation (EC) No 1831/2003).

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).

Risk analysis: A process consisting of three interconnected components: risk assessment, risk management and risk communication (Regulation (EC) No 178/2002).

Risk assessment: A scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation (Regulation (EC) No 178/2002).

Risk management: The process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options (Regulation (EC) No 178/2002).

Traceability: Ability to trace and follow a feed or substance intended to be, or expected to be incorporated into a 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).

Withdrawal period: Period necessary between the last administration of the veterinary medicinal product to animals under normal conditions of use and the production of foodstuffs from such animals, in order to ensure that such foodstuffs do not contain residues in quantities in excess of the maximum limits laid down in application of Regulation (EC) No 470/2009 (Directive 2001/82/EC).

1.3. Other Definitions

Carry-over: Means the level of transfer of any substance or product from one production batches to the immediate subsequent batch in a particular section of the plant, for example, a mixer or a hand tip point.

Control: Monitor and measure processes and product against policies, objectives and requirements for the product and report results.

Contamination/Cross-contamination: The undesired introduction of impurities of a chemical or microbiological nature or foreign matter into or onto an incoming or a finished feed during production, sampling, packaging or repackaging, storage or transport.

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

Corrective action: Action to eliminate the cause of a detected nonconformity or other undesirable situation.

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.

Critical limit: A criterion that separates acceptability from unacceptability.

Feed safety assurance: Part of feed safety management focused on providing confidence that feed safety requirements will be fulfilled.

Feed safety management: Coordinated activities to direct and control an organization with regard to feed safety.

Finished feed: A general term used to denote products obtained at the end of the processing chain of the company, i.e. compound feedingstuffs or premixtures, and ready for delivery to customers. By extension, it also applies to premixtures manufactured by the compound feed manufacturer for own use.

Flushing: Involves taking a known feed or feed material, for example ground grain, and moving a quantity through the system to purge feed from a previous batch that remains.

"HACCP" (Hazard Analysis and Critical Control Point): A system which identifies, evaluates, and controls hazards which are significant for feed safety.

Hazard analysis: The process of collecting and evaluating information on hazards, and conditions leading to their presence, to decide which are significant for feed safety and therefore must be addressed in the HACCP plan.

Hazard identification: The identification of biological, chemical, and physical agents, including in the production process, capable of causing adverse health effects and which may be present in a particular feed.

Incoming feed: A general term used to denote raw materials delivered at the beginning of the production chain, i.e. feed materials, feed additives, processing aids, premixtures.

Manufacture/Production: All operations of receipt of materials, production, packaging, repackaging, labelling, re-labelling, control, release, storage, and distribution of premixtures and compound feed and the related controls.

Record: Document stating results achieved or providing evidence of activities performed.

Returns: Compound feedingstuffs or premixtures generated either during the production process, or subsequently that are suitable for reworking. Returns originate from a variety of sources, each with its special characteristics. They include:

(a) Out- of- date stock

(b) Non-conforming feed - e.g. starting up problems, poor texture, deterioration in plant and on farm, errors in ordering or dissatisfaction.

(c) Sievings on plant processing, where applicable, or at bulk loading of textured feedingstuffs

(d) Flushings and cleanings - resulting from plant scouring and change-overs

(e) Broken bags and spillage.

A distinction must be made between internal returns (i.e. products which have not left the site) from external returns.

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

Supplier: Organisation or person that provides a product.

Validation: Confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.

Waste: Any substance or object in the categories set out in Annex 1 of the Waste Framework Directive, which the holder discards or intends, or is required to discard. Feed materials resulting from food or drink manufacturing and safe returns complying with the EU feed safety legislation shall not be regarded as waste.

Withdrawal feed: Feed distributed to animals during the withdrawal period for veterinary medicinal products. By extension, the term withdrawal feed also applies to feed distributed during the period when the use of coccidiostats and histomonostats is prohibited.

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

2. FEED SAFETY MANAGEMENT SYSTEM

2.1. General Requirements

- The purpose of the EFMC is to ensure the achievement of feed safety standards that reflect the importance of compound feed and premixtures within the human food chain and to meet contractual and legal obligations.
- A Feed Safety Management System must be established, documented, implemented and maintained. The system must be adapted to regulatory and other feed safety developments.
- The structure of the Feed Safety Management System must include policies, requirements and documented procedures that reflect best practices.
- A formal risk assessment must be carried out with the aim of identifying and controlling hazards that might adversely affect the safety of any supplied feed. Risk assessments must be carried out in accordance with HACCP principles.
- The Feed Safety Management System must ensure that all activities with impact on the safety are consistently defined, implemented and maintained. ISO standards or other comparable standards may be used to define the Feed Safety Management System.

2.1.1. Risk Analysis and HACCP (see Annex I on the application of the HACCP principles)

2.1.2. Management Responsibilities

- The Management (from CEO to the operational management) must be committed to the implementation of a Feed Safety Management System, which has to be documented.
- The Management must:
  - Define the scope of the Feed Safety Management System by identifying products/product categories and production sites covered by the system and by ensuring the establishment of safety objectives.
  - Ensure that feed safety requirements are part of the business goals of the company.
  - Review the Feed Safety Management System at defined intervals of not more than 12 months, and when major or significant changes to plant or products occur, to ensure its suitability and effectiveness of (changes and improvements).

2.1.3. Feed Safety Management Structure

- An organisation chart must be established and kept permanently updated. The chart should specify the respective staff responsibilities in relation to feed safety.
- The authority of the staff performing feed safety related tasks has to be documented. One nominated Feed Safety Manager must have the appropriate authority to carry out his mission.
  - All staff involved must be suitably experienced, trained and qualified.
  - The scale of resource dedicated to the feed safety management must be appropriate to the type or quantity of compound feed and premixtures being supplied and the hazards involved.
  - Regarding internal communication, all staff must be regularly informed about issues with an impact on feed safety.

2.1.4. Training

- The Management must ensure that all staff members are adequately trained in the practice of the tasks they may be required to perform and should be informed about issues which have an impact on feed safety. The required levels of knowledge and skills must be maintained by on-going training.
- Training must cover not only specific tasks but also good manufacturing and/or delivery practice in general and the importance of personal hygiene. It may include where appropriate:
  - An understanding of the present Guide to Practice, of its Annexes and of company procedures
  - An understanding of the plant
  - The accuracy and use of equipment
  - The maintenance of accurate records and documentation
  - Implementation of the HACCP Plan relating to CCPs including monitoring, recording, reporting and taking appropriate action as detailed within the Plan and company procedures
  - The significance of incoming feed that are handled and particular precautions to be observed in use and dangers of misuse.

- Safety precautions to be taken in handling additives as indicated by their manufacturer
- The significance of potentially hazardous substances and the special requirements of manufacturing feedingstuffs from feed materials containing these and
- The importance of correct loading.

- The training must be documented.

2.1.5. External Communication

- External communication among the different members of the feed and food chain is an essential tool to ensure in the best possible way the safety of feed and food products.
- Therefore, the users of this Guide must also make sure that their needs to ensure the safety of the compound feeds and premixtures they produce are passed on and recognised by their suppliers and customers.
- Manufacturers of compound feeds and premixtures must ensure that all feed safety hazards are not only identified, evaluated and controlled but also communicated throughout the food chain so that any harm of animal or human health can be prevented.

2.2. Traceability, Record Keeping and Product Recall

2.2.1. General Requirements

- A system of documentation must be established to ensure traceability, which identifies i) suppliers and intermediaries of incoming feed to feed plant, and ii) to whom these incoming feed have been supplied once processed into finished feed.
- The traceability system should also allow tracing-back from the final product through quality control data and batch records to the feed ingredients used and the suppliers.
- There must be trace-back or trace-forward of finished feed if actual or potential health risks have been identified.

2.2.2. Product Traceability Records

The manufacturer must record:

- The name and address of all suppliers/intermediaries and the sources of incoming feed, including the batch numbers for purchased feed additives
- The approval or registration number of suppliers according to EU legislation
- For compound feed manufacturers, the name and address of premixture manufacturers or intermediaries, including batch numbers
- The nature and quantity of finished feed and their manufacturing date. Records must show that each batch was manufactured in accordance with the actual formula and that special procedures to observe safety requirements and for the avoidance of carry-over were followed
- The name and address of the customer to whom each batch is delivered, where applicable.

2.2.3. Documentation Requirements

- The user of this Guide must produce and implement an own set of operating procedures incorporating the requirements of this Guide.
- The procedures can be part of a Feed Safety Management System as part of a national, industry or company scheme.
- The required procedures in this Guide have to be:
  - Documented
  - Reviewed and approved
  - Readily available and understood
  - Revised to reflect significant changes
  - Dated, and signed by an authorised person.
- The Feed Safety Management System documentation must include the documented procedures and records required by the EFMC.

2.2.4. Incoming Feed Sourcing

2.2.4.1. Purpose

Incoming feed must be:

- Traceable
- Conform to the required standard specifications for incoming feed (see 3.5.2) and
- Controlled for undesirable substances and other known hazards according to a control plan established based on an “HACCP”-study.

2.2.4.2. Supplier Assessment

Incoming feed must be:

- Delivered by suppliers approved or registered according to the relevant legislation (Feed Hygiene Regulation, Animal By-Products Regulation) and
- Delivered by suppliers having undergone an evaluation by the purchaser prior to delivering the incoming feed or participating in a feed safety assurance system, subject to certification by a third party in accordance with EN 45011, and recognised by the purchaser. These safety assurance systems must be based on relevant sector-based guides to good practice where they exist, developed in accordance with Article 22 of Regulation (EC) No 183/2005.

2.2.5. End Product Specifications

- There must be internal product specifications in full detail prior to manufacture, independently from the written specifications routinely available to purchasers for each finished feed. The written specifications for purchasers must at least include:
  - The precise identification of the finished feed (name) and
  - Any hazards or limitations for their use.

2.2.6. Record Keeping

- All records required by the EFMC must be kept for the required minimum period according to the relevant legislation and/or national provisions.
- The storage conditions must prevent any deterioration or damage to the records.
- The records must be sorted and filed for complete and easy information and be legible.

2.2.7. Control Plan

- A control plan must be drawn up and implemented for incoming feed, finished feed and intermediates.
- The control plan, which has to be based on Critical Control Points, must:
  - Ensure that finished feed comply with the specifications defined by the manufacturer and the relevant legislation
  - Address the nature, content and homogeneous dispersion of the additives concerned in the finished feed. Frequent homogeneity tests shall be conducted at the most relevant stages of the process (see Annex III C)
  - Ensure that the levels of incidental presence of substances and products subject to restriction of use are as low as reasonably achievable (ALARA principle)
  - Ensure that the bacteriological status, the analytical constituents of finished feed and the undesirable substances they contain are recorded.
- The feed safety control plan must:
  - Define checks on Critical Control Points and sampling procedures as well as the frequency of checks in the acquisition of incoming feed and the manufacturing process
  - Specify which methods of analysis must be used and how frequently they must be used
  - Determine what action must be taken in case of non-compliance
  - Define the responsibilities of the staff involved in the production and feed safety control.
- The control plan must:
  - Be effectively implemented
  - Record the results of relevant controls (including samples), which must be kept by the manufacturer, and which must be retained to be able to trace incoming and finished feed
  - Record the manufacturing history of each batch produced
  - Identify areas of responsibility in the event of a complaint.

2.2.8. Internal Audits

- There must be a documented procedure requiring the carry out of an audit programme to check that internal systems are operating as intended and that they are effective.

- Internal audits must show the compliance with the requirements of this Guide, the "HACCP" system, the applicants' formal procedures and the legislation pertaining to compound feed and premixtures' safety.
- All relevant activities must be audited at least once a year.
- Internal audits must be carried out by qualified personnel, be formally reported and record any aspects where operations are not in compliance with operational requirements. Any non-compliance must be corrected and the audit report then be updated accordingly.
- All personnel carrying out internal audits must be trained to carry out such audits and be able to demonstrate their effectiveness in this role.

2.2.9. Non-conforming Feed and Product Recall

- There shall be a procedure for product recall.
- The user of this Guide must establish a documented procedure for the dealing with non-complying feed: there must be an identification of the affected finished feed. The managing and recording of non-conforming feed must be documented. The cause of non-compliance must be evaluated and affected batches must be segregated. There also has to be communication with relevant authorities and parties.
- The responsibility for review and disposal of non-conforming feed must be defined.
- The recording of all incidences and action decisions must only be made by nominated staff.
- Non-conforming finished feed should be dealt with through disposal, rework or downgrading.
- All requirements for reprocessing and re-evaluation on completion must be documented.

2.2.10. Complaints Procedure in Relation to Safety

- The complaint procedure in relation to safety must include systems for:
  - The allocation of responsibility for the management of complaints
  - The recording of the name of the complaining customer
  - The recording of the finished feed under complaint
  - An investigation into the cause of the complaint
  - A reply to the customer and
  - All necessary corrective actions in a timely and effective manner.

2.3. Feed Safety Control Laboratory

- The user of this Guide must possess a properly equipped control laboratory or make use of an external laboratory, preferably accredited.
- The laboratory must demonstrate the reproducibility and accuracy of its results.
- The relevant methods of analysis must be regularly reviewed and approved by:
  - Accreditation by a nationally recognised accreditation authority according to EN 17025
  - Validation through the participation in a recognised ring test
  - Alternatively, validation through other recognised means (e.g. a comparison with the results of a recognised laboratory).

2.3.1. Inspection, Sampling and Testing

- Inspection, sampling and testing must be done through competent staff. There must be records of adequate staff training, its experience and qualifications.

2.3.1.1. Physical Inspection

- A physical inspection must check the colour, physical form, odour, and freedom from contamination by insect pests, from mould and excessive damage of the incoming and finished feed. The goods must comply with the incoming feed and finished feed specifications.
- Incoming batches of additives must be examined visually, on receipt, for damage to the containers. Any damage thought likely to have affected the quality of the product must be reported to the Feed Safety Manager.

2.3.1.2. Sampling

- The sampling schedules are the responsibility of the Feed Safety Manager. There must be documentation of the location, method and frequencies of sampling.
- Sampling of all incoming and finished feed has to be done with adequate techniques. The sampling regime must be appropriate to the volume and nature of the incoming and finished feed (see guidance in Annex III F).
- The samples of incoming and finished feed must be retained for a period appropriate to the use for which the feed is placed on the market.
- The samples must be kept in appropriate, sealed and labelled containers and be disposed of in a controlled way.

2.3.1.3. Chemical Analysis

- Adequate testing must be done using the appropriate methodology.
- Testing schedules are the responsibility of the Feed Safety Manager.
- Tests on incoming feed must ensure the safety of any finished feed, which is produced thereof.
- The nature and frequency of the tests must consider the volume and potential risk in the final product.

2.3.1.4. Microbiological Analysis

- The microbiological analysis must be the responsibility of the Feed Safety Manager.
- The level of tests must be defined in accordance with the results of the HACCP study and ensure the safety of any supplied finished feed.
- There must be occasional testing on equipment, which has to be recorded.

3. GOOD HYGIENE PRACTICES

3.1. General Requirements

- A hazard analysis study ("HACCP") of the whole production process (i.e. from sourcing of incoming feed, through to farm delivery of finished feed including operations of transport, storage and manufacturing) must be done in order to identify potential associated hazards for consumer and animal health.

3.2. Control of Contaminants and Carry-over

- Controls to protect incoming and finished feed from contamination must take place. In particular, intake points, processing equipment, conveying systems and storage facilities must be designed and operated to minimise the possibility of ingress.
- The control of contaminants must be carried out by trained personnel.

3.2.1. Carry-over

- Control of carry-over must always be considered within the HACCP study. Attention should be paid to each additive, added separately or in the form of a premixture with a view to establish a list of critical substances for the purpose of control of carry-over. Each part of the process, loading and delivery must be considered in the HACCP study. Specific attention must be paid to the plant design (see 3.4.1), the dust management (see 3.4.1.4), the cleanliness of equipment (see 3.4.2.1) and scheduling (see 3.6.1).
- Carry-over has to be measured with an appropriate method at least once a year or after adaptation of the facilities.
- Where a hazard presents a significant risk to the product, control measures to reduce or minimise it (scheduling of manufacturing) must be established and documented.
- The Critical Control Points for hazards must be identified and particular emphasis be laid upon documenting control procedures and corrective actions.
- Further guidance on the measurement and the control of carry-over is provided in Annex III E.

3.2.2. Undesirable Substances and Products / Biological Hazards / Negative List

3.2.2.1. Control Measures for Undesirable Substances

- During the production of finished feed, the manufacturer must apply control measures to ensure that maximum permitted levels are not exceeded.
- The delivery point of incoming feed is a critical point for the presence of undesirable substances. Feed Safety Assurance Systems at the level of suppliers must therefore be taken into account.

3.2.2.2. Control Measures for Biological Hazards

- The possible microbiological contamination must be monitored and controlled in accordance with microbiological criteria defined as part of the HACCP study and in accordance with Article 3 of the Feed Hygiene Regulation.

3.2.2.3. Control Measures for Prohibited Materials and for Feed Materials subject to Legal Restrictions

- The EU legislation has established a list of prohibited materials. Manufacturers must ensure that products on this list are not used at all or not used for species for which they are prohibited.
- Control measures must show reference to the relevant provisions of Regulation (EC) No 999/2001 on BSE-related provisions, in particular the total feed ban (Annex IV of Regulation (EC) No 999/2001).
- Control measures must also show reference to the relevant provisions of Regulation (EC) No 1774/2002, in particular the ban on catering waste and the ban on intra-species recycling.

3.3. Additives

- Additives and premixtures must be mixed in appropriate quantity and in a homogeneous way following the manufacturer's instructions of use to ensure that finished feed contains the quantity as specified.
- Companies using these products must comply with the legal criteria regarding the facilities, the management and administration of the plant, as well as with the qualification of the employees.

3.4. Plant Design and Maintenance / Personal Hygiene

3.4.1. Storage, Production Facilities and Manufacturing Equipment

- Storage, production facilities and manufacturing equipment must be clean and in a good state.
- Appropriate and regular checks in accordance with “HACCP” must take place as well as a risk assessment using information the manufacturer of equipment can provide. All checks must be carried out in accordance with written procedures.
- The process flow within the manufacturing facility must be designed to minimise the potential for contamination and carry-over.
- Storage, production facilities and manufacturing equipment must be free of chemicals, chemical fertilisers, pesticides or other potential contaminants.
- Procedures should be established to keep to a minimum the proportion of out-of-date stocks (e.g. first-in-first-out principle) by applying a careful stock rotation. Materials must be stored in such a way that they are clearly identifiable, and that their intake identification is easily visible. The effectiveness of the stock rotation must be monitored by the Feed Safety Manager.
- Layout, design and the operation of all facilities and equipment must be such that they:
  - Minimise the risk of error
  - Permit effective cleaning and maintenance
  - Avoid contamination and carry-over

- Minimise condensation
- Allow the disposal of sewage, waste and rain water without contamination
- Allow the mixing of homogeneous products. The dosing, weighing and transport equipment for additives must be adapted to the level of concentration of the feed materials, feed additives and premixtures to be weighed.

3.4.1.1. Perimeter and Grounds

All grounds within the site must be finished and maintained to an appropriate standard:

- Where natural drainage is inadequate, external drainage must be installed
- Where external storage is necessary, items must be protected from contamination and deterioration
- Where possible, all buildings should be surrounded by clear space, which should be regularly maintained
- Waste must be collected in a well-defined area
- Control measures must prevent the presence of domestic, feral and wild animals.

3.4.1.2. Off-site Storage Facilities

- Compliance of off-site storage facilities (including third party stores) for incoming and finished feed before putting on the market must be ensured.
- Third party stores must comply with an approved national or international guide of practice unless formally audited each year by the feed manufacturer.

3.4.1.3. Sieves, Screens, Filters and Separators

- Sieves, screens, filters and separators must be regularly checked for damages and their effective operation.

3.4.1.4. Dust Control

- Reasonable precautions must be taken against dust accumulation and other residual materials where incoming and finished feed are processed or stored. The company must define a “dust management plan” which should include procedures for the cleaning and sanitisation of the facilities and the equipment. Specific attention must be paid to those feed additives and premixtures with high propensity to generate dust. Specific measures must be defined for such feed additives and premixtures to minimise the impact of such dust on the level of carry-over. This should include provisions regarding dust disposal or rework.

3.4.1.5. Air Movement

- Where air is used for conveying or cooling, there must be a regular evaluation of the risk of this air to become a vehicle for pathogens. Any necessary precautions to prevent this must be taken.

3.4.1.6. Intake and Loading Facilities

- Intake and loading facilities must be designed and constructed to maintain the safety of incoming and finished feed.
- Contamination through weather, birds’ access etc. must be avoided.

3.4.1.7. Conveyors and Handling Equipment

- Conveyors and handling equipment must be maintained in a sufficiently clean and hygienic condition to avoid theirm adversely affecting incoming and finished feed.

3.4.2. Planned Maintenance

- The equipment must be subject to a programme of planned maintenance, in particular to avoid adverse effects on the feed safety and hygiene of working conditions.
- Records must be kept on the maintenance of all equipment critical to the production of safe finished feed.

3.4.2.1. Cleaning

- Cleaning methods and material must be chosen depending on the characteristics of the business.
- Documented cleaning programmes must ensure maintaining the safety of incoming and finished feed at all times. The cleaning programmes must be monitored and recorded.
- Cleaning and disinfection agents must be food and feed compatible and stored separately.

3.4.2.2. Waste Management

- Any waste must be visually marked and promptly segregated to eliminate the likelihood of accidental or inadvertent use.
- Waste shall be collected or stored in dedicated waste containers. Waste containers must be covered where possible and stored away from incoming and finished feed storage or production areas.
- Waste must be disposed of legally.

3.4.2.3. Pest Control

- A pest control plan must be drawn up and contain active measures – including inspection - to control and limit pest activity throughout the part of the supply chain for which the feed business is responsible.
- Only approved pesticides handled by trained operators shall be used for pest control.
- Pest control procedures must be taken throughout the part of the supply chain for which the feed business is responsible under avoidance of contamination. Records of the pest control procedures must be kept.

3.4.3. Personal Hygiene

- There must be adequate washing facilities.
- Protective clothing must be worn in production and loading areas.
- There must be clear policies on smoking and eating or drinking on site.
- The staff must get appropriate hygiene training for the direct handling of incoming and finished feed.
- A procedure must be developed establishing hygiene requirements for visitors, contractors and any other person, including staff members, only temporarily on site.

3.5. Purchase, Delivery, Intake of Incoming Feed

3.5.1. Purchase

- The plant must have a standard specification mentioning the characteristics required for each incoming feed bought outside.
- A standard specification must indicate when and to what extent deviations may be accepted.

3.5.2. Specifications of Feed Materials, Feed Additives and Premixtures

- There must be specifications for feed materials, feed additives and premixtures to be suitable for purchasing.
- Specifications must at least cover:
  - Analytical characteristics of the incoming feed
  - The results of the risk analysis carried out for each incoming feed, e.g. the product specification and monitoring programme for undesirable substances
  - The list of approved geographic origins and sources
  - The types of feedingstuffs in which their use is approved
  - Notes on any hazards or limitations on their use and any special characteristics of the incoming feed.

3.5.3. Delivery, Intake and Storage of Incoming Feed

- Each batch of feed materials, feed additives and premixtures delivered to a plant must be traceable.
- Incoming feed must be stored in dry, hygienic conditions, free from vermin and birds.
- There must be a system of site allocation for safe storage (easily identifiable, no mixing with other feed additives, intake identification easily visible). In case of doubt on the identity of a product during storage (damaged packaging), a procedure must be established whereby the Feed Safety Manager must decide about the destination of the product (re-identification, clearance for use, disposal, etc.). Records must be kept about the action taken.
- Sampling and analyses of incoming feed must be done in accordance with the control plan defined under 2.2.7.
- Designated and trained staff must be present at the point of delivery and intake.
- Water used as an ingredient in the manufacturing process must be suitable for animals. If not from human drinking water sources, it should be included in the scope of the HACCP study. The conduits for water should be of an inert nature.
- Feed materials, feed additives and premixtures that have been rejected by the Feed Safety Manager must be clearly identified and segregated from other materials in a manner which precludes their unauthorised used. Disposal of rejected feed additives and premixtures should be undertaken only after consultation with the manufacturer and/or supplier.

3.6. Manufacturing Process, Storage and Delivery of Compound Feed and Premixtures

3.6.1. Manufacturing

3.6.1.1. General Requirements

- A trained employee must be designated as the person responsible for the production process.
- The manufacturer must ensure that the different production stages are carried out according to pre-established written procedures and instructions.
- In order to obtain the desired safety of feed, these procedures must define, control and master critical points of the manufacturing process listed below.
- Both technical and organisational measures must be taken to eliminate as much as possible bacteriological contamination, carry-over and human errors to maintain the hygiene and safety standards.
- Tolerances must be defined for the dosing of each feed material and feed additive.
- A production schedule must be established in order to minimise the risk for public health in relation to carry-over.
- Where required, equipment must be cleaned and/or flushed so as to avoid contamination between batches.
- Flushing must be collected into clearly identified containers and dealt with in accordance with written procedures, unless flushed into the original batch.

3.6.1.2. Calibration

- All inspection, measuring and test equipment used must be calibrated.
- A calibration plan must be established which specifies a. o.
    - o the required calibration accuracy
    - o the frequency of calibration
    - o the calibration reference standards.
- Records must be kept on calibration and all equipment must be uniquely identifiable and traceable to calibration records.

3.6.1.3. Incorporation of Feed Additives

- Additives must be incorporated in animal feed in accordance with the legal requirements. A specific attention should be paid to those additives which the legislation requires to be incorporated in animal feed in the form of premixtures (liquid or solid), i.e. vVitamins A and D, cupper, selenium, coccidiostats and histomonostats.
- Where dosage silos are used for feed additives, the equipment must include adequate dosing and locking systems. The sequence of operations for the transport of additives must be established beforehand and shall be recorded in a written procedure.
- Daily administrative records must be kept on (i) the types of feed manufactured (name) and (ii) the quantity of additives (or premixtures containing additives) of the categories mentioned in Annex IV of the Additives Regulation (EC) No 1831/2003.
- The composition of a batch of animal feeds to which additives are added must respect the fixed tolerances set in the product specifications.

3.6.1.3.1. Incorporation of Additives and Premixtures into Compound Feed

- Feed additives and premixtures may be added by hand. However, there must be a communication system designed to ensure that additives are correctly added in accordance with the product specifications.
- Feed additives may also be added to the appropriate feed by means of spraying: all precautions must be taken to ensure that the exact dosage is administered (as well as the spraying equipment tested and inspected according to a plan on a regular basis).
- The inclusion rate of the premixture into the compound feed should be predefined on the basis of the assessment of the efficiency of each production line, taking into account the specifications of the equipment manufacturer, the accuracy of calibration and the results of homogeneity tests.

3.6.1.3.2 Incorporation of Feed Additives into Premixtures

- The transport of feed additives in their original packaging or storage silo to the weighing and dosage equipment must be ensured by adequate conveying means.
- The incorporation of feed additives into premixtures requires a locking or warning system in order to ensure that the targeted feed additive is included into the target premixture at the suitable dose. This procedure must be consigned in writing.

3.6.1.4. Weighing

- A regular maintenance programme must ensure that the weighing equipment is kept clean and worn parts are replaced as necessary.
- The weighing equipment must be fit for the purpose and easily cleanable.
- The weighing accuracy must be fit for the quantities of products to be weighed.
- Acceptable deviations to the predefined dose should be established.
- As regards manual addition, a procedure should be established for ensuring that the right products are weighed within predefined tolerances.

3.6.1.5. Mixing

- Cleanliness of the mixer is essential.
- Written maintenance schedules must exist for the examination of the mixer to ensure that wear of the equipment does not lead to build-up of residues when the mixer is emptied.
- Mixers must operate for a pre-set time, which tests have shown to be adequate in order to ensure the appropriate mixing of feedingstuffs and feed additives.
- The accuracy and efficiency of the mixing process must be regularly checked at intervals of not more than six months to ensure that feed additives are evenly dispersed throughout the mix.

3.6.1.6. Temperature and Time Control – Pelleting and Cooling

- Where the temperatures of the finished feed, process and/or environment are critical to the product's safety and legality, this must be adequately controlled, monitored and the control measures be recorded.
- A written procedure must exist to ensure the regular cleaning of the cooler.
- Air drawn into the cooler is a potential source of bacterial contamination. Therefore, it should as far as possible be drawn from clean areas of the mill, and in particular not be drawn from intake areas.
- The pelleting conditions must be adapted to the stability of the incorporated feed additives.

3.6.1.7. Metal Detection and Magnets

- Metal detection equipment and magnets must be included in the processing systems where necessary and regularly checked for their effective operation. Records of the checks must be kept.

3.6.1.8. Management of Returns

- The production of finished feed must be organised, both on an internal and external level, with an eye to limit possible returns to a minimum.
- Approval of any return for rework must be formal, recorded, and is a function of the Feed Safety Manager.
- Returns (internal) must, whenever possible, be reincorporated into their original batch or "run". The re-incorporation process must take place in accordance with determined rules.
- If returns (internal) cannot be reincorporated into their original batch or “run”, the manufacturer must clearly indicate in which suitable containers the feed returns must be stored.
- Procedural rules must lay down in which feed formulation returns may be incorporated and the maximum percentage of returns in the respective feed type. In no case a product containing an ingredient subject to restrictions of use must be reprocessed into a batch designed for a species for which this material is prohibited.
- The quantity of returns, which have been reprocessed, must be recorded on a daily basis. These administrative registers must also indicate the batches of the respective feed type, in which these returned products were reprocessed.

3.6.2. Storage of finished feed

3.6.2.1. General Requirements

- Finished feed, which meet the specifications, must be stored in suitable packaging materials or containers.
- The finished feed must be kept in good hygienic storage places and only be accessible to persons who are granted an authorisation by the manufacturer.
- Storage areas must be constructed to insure maximum prevention against the entrance of domestic, feral and wild animals.
- To reduce chances of contamination, trained personnel must carry out routine checks, eliminating, to the best of their ability, the presence of these undesirables.
- The finished feed must be stored as to make them easily identifiable (product name, number, date and time of manufacture).
- The way in which finished products are stored must in no way lead to confusion or contamination between different finished feed, between feed materials or feed additives containing high levels of undesirable substances and finished feed or between supplemented feedingstuffs and feed additives.
- Compound feedingstuffs intended to be put into circulation, must comply with the provisions laid down in Regulation (EC) No 767/2009 on compound feed.
- The storage facilities must be cleared completely and cleaned on a regular basis. The cleaning procedures must follow a planned and recorded cleaning programme.
- The storage areas must enable goods to be stored in clean, dry and orderly conditions.

3.6.2.2. Finished Feed Packaging

- Finished feed packaging must meet either internal or customer specifications and be suitable for the means of delivery and transport used and the type of finished feed. The packaging must be designed to protect finished feed.
- The packaging as well as the delivery documents must be clear and unambiguous. All relevant legal information must be included on delivery documents or attached labels to the product packaging.
- Finished feed sold in bulk and bags must include any details required under the labelling regulations in the country of production and receipt.
- Pallets must be clean and in good state and must be stored in a dry environment.

3.6.2.3. Finished Feed Labelling

- Finished feed must be labelled in accordance with the relevant legislation, i.e. Regulation (EC) No 1831/2003 for premixtures and Regulation (EC) No 767/2009 for compound feed. Additional provisions laid down in Articles 24 and 25 of Regulation (EC) No 1829/2003 on GM feed and food and Annex IV of Regulation (EC) No 999/2001 on TSE should also be complied with.

3.6.2.4. Storage at the Customer's Premises

- In order to avoid undesirable effects on the safety of the feed, the manufacturer must inform his customers about the storage conditions of the feed, if the nature of the compound feed and premixtures delivered should require this.

3.7. Transport and Delivery

- The transport of incoming as well as finished feed must be made by using only hygienic vehicles and in compliance, where existing, with a transport guide or relevant transport sections of sectoral guides developed in accordance with Article 22 of Regulation (EC) No 183/2005.
- All means of transport whether owned or contracted, whether in bulk or packed, must be appropriate and adequately controlled with specific regard to hygiene and potential contamination.
- To facilitate the traceability of finished products during or after transport, the individual load compartments used must be recorded.
- The feed manufacturer must develop a system for order taking and fulfilment to ensure that the customer receives the type of feed he ordered, that the feed is properly labelled in accordance with the legal requirements and that all measures have been taken to ensure the safety of the feed delivered.
- Before the feed is loaded, no materials from previous loadings must remain in the container (tank truck, boxes) which must be clean and dry.
- All vehicles used for delivery of feed must be kept clean and operated according to a transport gGuide:
  - The transport guide must prescribe that all vehicles used for the transport of incoming and finished feed must be subject to regular cleaning and sanitising programmes ensuring that these are in a clean state, with no accumulation of residual waste material
  - If these vehicles are used for the transport of goods or materials presenting a health risk - as defined by the person in charge of feed safety control - the vehicles must be cleaned thoroughly, sanitised and dried as required by the guide and taking into account the HACCP study before they are used for the transport of incoming and finished feed
- In the absence of transport guides for finished feed, other proofs of hygiene and traceability of previous loads must be specified

- Incoming and finished feed must be protected from contamination and kept dry during transport. Enclosed vehicles or containers must be used whenever possible for loose bulk, but where this is impracticable, the loads must be covered. The cover used must be maintained in a clean condition by being regularly cleaned, sanitised and dried.

3.8. Product Traceability Records

3.8.1. Incoming Feed

- Records must be kept of the following details for each delivery of incoming feed:
  - Date/time of intake
  - Delivery vehicle identification
  - Name of incoming feed
  - Quantity delivered
  - Name of supplier
  - Delivery order or reference
  - Analytical results relevant for the feed safety management
  - Country of origin
  - Registration number where relevant
  - Identifier of storage allocation

- For purchased premixtures, the following additional records must be kept
  - Approval or registration number where relevant
  - Manufacturers' batch number(s) and number of containers for each batch

- For additives, the following additional records must be kept:
  - Approval or registration number where relevant
  - Manufacturers' batch number(s) and number of containers for each batch
  - Generic name of the feed additives or legal E number as mentioned in the EU register of feed additives
  - Average quantities of active substances guaranteed by the supplier
  - Instructions of use
  - Shelf life time

3.8.2. Finished Feed

- Records must be kept of following details for each batch of manufactured products:
  - Nature of the feed (product number, species of destination)
  - Batch number
  - Manufacturing date/time
  - Nature and proportion of feed materials, premixtures and feed additives used in accordance with the actual formula
  - Procedures followed to ensure safety requirements and avoidance of carry-over
  - Identifier of storage allocation.

3.8.3. Delivery

- Records must be kept regarding the customer to whom the final product was sold to:
  - Nature of the feed (product number, species of destination)
  - Batch number
  - Name and address of the customer
  - Date/time of delivery
  - Delivery order or reference
  - Delivery vehicle identification.

4. NORMATIVE DOCUMENTS

4.1. EU Food and Feed Legislation (non exhaustive list)

- The General Food Law Regulation (**(EC) No 178/2002**)
- The Feed Hygiene Regulation (**(EC) No 183/2005**)
- The Marketing of Feed Regulation (**(EC) No 767/2009/EEC**)
- The Official Control Regulation (**(EC) No 882/2004**)
- The Directive on the Circulation of Feed Materials (**96/25/EEC**)
- The Additives Regulation (**(EC) No 1831/2003**)
- The Certain Constituents Directive (**82/471/EEC**)
- The Dietetic Feeds Directive (**93/74/EEC**)
- The Directive on Packaging and Packaging Waste (**94/62/EC**)
- The Directive on Undesirable Ssubstances in Animal Nutrition (**2002/32/EC** including Commission Directive **2009/8/EC**)
- The Decision establishing a list of materials whose use is prohibited (**2004/217/EC**)
- The Regulation laying down the rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ((EC) No°**999/2001**)
- The Regulation laying down health rules concerning animal by-products not intended for human consumption ((EC) No **1774/2002**)
- The Medicated Feed Directive (**90/167/EEC**)

4.2. International Standards

- **"HACCP"** Guidelines - CODEX Alimentarius Food Hygiene Basic Texts
- **"HACCP"** Handbook
- EU Commission guidance document for the implementation of procedures based on the HACCP principles and facilitation of the implementation of the HACCP principles in certain food businesses.
- **CODEX Code of Practice on Good Animal Feeding**

ANNEX I: GUIDANCE FOR THE APPLICATION OF HACCP PRINCIPLES

1. INTRODUCTION

Hazard Analysis and Critical Control Points (HACCP) is a system that was devised to identify, evaluate and control hazards that are significant for food and feed safety. This Guidance is designed to help operators using HACCP principles within their businesses in the following operations, although its use must be supported by thorough training by those experienced in the practical application of the principles:

- Purchase of feed materials, premixtures, feed additives and additive- like substances
- Production of compound feeds and/or premixtures
- Storage, packing and delivering of compound feed and/or premixtures.

In its purest form, HACCP is concerned solely with food safety and only with food intended for human consumption. The methodology behind HACCP is however suitable for much wider application, e.g. in the feed sector, when considering potential hazards to both human and animal health. With the introduction of the EU Feed Hygiene Regulation (EC) No 183/2005, feed may not be placed on the market or fed to any food producing animal if they are unsafe and adherence to HACCP principles is a legal obligation for all "feed business operators". The techniques associated with HACCP can also be used to consider additional issues that may not strictly be hazardous, but are of critical interest to the feed industry. This Guidance is intended to optimise the benefits of developing HACCP systems into practical and beneficial tools for feed businesses. In so doing, the methodology used for HACCP is utilised to consider wider issues than would be the case in textbook HACCP studies. For this reason, references in this Guidance to "HACCP" should be interpreted as meaning 'HACCP principles' as described in CODEX Alimentarius and "HACCP methodology" rather than "pure" HACCP.

This Guidance is designed for use both by companies for whom HACCP may be a completely new concept and also for those companies with prior experience of HACCP. Companies already operating a HACCP system will find this Guidance particularly useful if they are seeking certification against an accredited feed industry assurance scheme or have found that their existing HACCP system does not bring significant benefits to the business. HACCP systems can be effectively implemented to provide benefits to companies of all sizes, from one-man operations to multi-national corporations. This Guidance is therefore intended for use by businesses both large and small but is not meant to cover all specific situations and circumstances faced by feed business operators in all EU Member States. For this reason, practical HACCP examples were not introduced as such in this Guidance in order to prevent any inappropriate transposition of these examples into individual HACCP plans.

2. THE AIM OF HACCP IN COMPOUND FEED AND PREMIXTURE SECTORS

It is important, right at the outset, to consider what is to be achieved by using HACCP principles and then to keep this in mind throughout the whole process of developing and maintaining a risk management system.

Most businesses will be familiar with ISO 9000, which focuses on systems and procedures;, however HACCP is different - – it focuses on the product. Systems, procedures and records will inevitably play a part in delivering the controls required by HACCP, but systems and procedures

are only required by HACCP where they help to maintain the integrity of the product. ISO 9000 and similar standards are not an essential requirement for a successful HACCP.

By definition, HACCP is intended to control hazards, typically divided into physical, chemical and biological hazards.

In the context of the feed supply chain, the hazards to be considered fall into two main groups:

- ***Hazards that have the potential to cause direct harm to animals eating feedingstuffs or humans consuming agricultural plant products***.

These may be physical (e.g. stones are a choking hazard, wire may pierce the gut wall, glass may cut the gut, etc.), chemical (e.g. mycotoxins produced from fungal activity, fertilisers or pesticides used in the growing of crops, etc.) or biological (e.g. various diseases, salmonellae or other pathogens).

Although compound feeds are usually designed for specific animal species of animals, the same feed materials/additives may be fed to many animal species of animals. The sensitivity and tolerance of different livestock species to nutrients or anti-nutrients is extremely variable. Any consideration of hazards therefore has to include the particular needs and sensitivities of all the species for which the feedstuff is intended.

- ***Hazards that have potential to cause actual (or perceived) harm to humans consuming animal products.***

The hazards most likely to affect humans through this route are of chemical or biological origin. For example, chemicals hazardous to humans include Aflatoxin B1 that may be present in certain feed materials, synthesised in the gut of dairy cows and excreted into milk as Aflatoxin M1. The most notorious biological hazards are probably the various types of salmonella that can be present in feed materials and feed products, ingested by livestock and subsequently contaminate eggs or carcasses. In addition, it may be that regulations, the media or consumers regard an aspect of a feed product or feed material as ”hazardous” although there is no factual basis for concern. An example is the EU ban of meat fit for human consumption from any livestock feeds, where the legal framework assumes the feeding of meat is potentially hazardous and therefore the feed business operator must do the same. Control of these kinds of issues may need to be included in the HACCP Plan.

In the compound feed and premixture sectors, the aim of HACCP is to identify what hazards exist and their inherent risks having a detrimental effect on both animals and humans, and then to implement controls, so that any potential effect can be prevented or reduced to an acceptable level.

It is important to remember that potential hazards may be inherent to the products themselves (e.g. mycotoxins in crops or heavy metals in minerals) or to their production processes (e.g. by adding fertilizers or pesticides to growing crops, through combustion gases from direct flame driers and solvent residues from oil extraction). They may also be introduced subsequently during transport, storage and handling (e.g. through contamination, weather damage, pest damage or chemicals used in pest control).

In a business environment of limited financial and personnel resources, HACCP methodology helps to focus attention on the areas of the business that really matter if hazards and the risks of them occur and are to be controlled. Consequently, there is a business advantage in developing a HACCP system - it ensures right-targeted spending of money and time to assure the products’ safety.

3. THE HACCP PRINCIPLES

The Codex Alimentarius Commission of the World Health Organisation has issued a list of seven HACCP principles (CAC/RCP 1 - 1969, rev. 4 - 2003), which have been adopted widely and form the basis of most HACCP guidelines.

These principles are:

1) Conduct a hazard analysis

2) Determine the Critical Control Points (CCPs)

3) Establish critical limit(s)

4) Establish a system to monitor control of the CCPs

5) Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control

6) Establish procedures for verification to confirm that the HACCP system is working effectively

7) Establish documentation concerning all procedures and records appropriate to these principles and their application.

These principles will be used to lead us through the development of a HACCP system in the following sections of this Guidance.

4. PREPARATION FOR THE HACCP STUDY

4.1. Selecting the HACCP Team

In a classic HACCP Team the following disciplines will be represented but not necessarily by different persons in every case:

- Team Leader. This may be one of the persons identified below and ideally will be someone who has been trained in HACCP principles and has experience of applying them.
- Quality Assurance/Quality Control/Technical. This will require someone who understands the products under consideration and the historical hazards and critical issues associated with them.
- Production. This will require someone who is closely involved with the production process and has an intimate knowledge of what happens where in the process.
- Engineering. This will require someone who understands the mechanics of the processing plant, where material may accumulate inside machinery, where heat or moisture may be applied and how to gain access to machinery.
- Additional, Part-Time Expertise. This may require specialists who offer technical or specific expertise on purchasing, operational activities, distribution, microbiology, specific species requirements, etc.

It is essential that Team members are familiar with what actually happens in the business and are not too far away from day- to- day activities. They must be given the authority to carry the project forward, but may not necessarily themselves be amongst the most senior members of the company.

It is important to have a person available who is competent in HACCP techniques if no member of the Team has the necessary training and experience.

There will necessarily be a lot of documentation generated by the HACCP Study. The inclusion in the Team of someone with skills to record all this information will allow the Team to focus on the task.

For complex businesses the core HACCP Team should ideally be supplemented with:

- A qualified HACCP expert (if no member of the core Team is already qualified)
- Secretarial/computing services.

Once the HACCP Team has been appointed, it can then move on to consider the HACCP study.

4.2. HACCP Study Documentation

It is important that all parts of the HACCP Study are recorded and documented. This will provide information for the Project as it develops and references for future HACCP reviews.

4.3. Scope of the Hazard Analysis

The business can ultimately only exercise direct control over those areas where the product is owned by the business. Not all potential hazards may however be identified in this part of the supply chain and it is important for the study to consider all potential hazards, whether they are introduced in areas where the business has direct control or outside of these. This is particularly true for feed materials/additives where it will be necessary to gain an understanding of how and where these are produced and what happens to them between the point of production and their delivery to compound feed / premixtures manufacturers. Identifying the potential hazards in feed materials/additives will play a significant part in determining specifications and contractual requirements imposed upon suppliers by the business.

4.4. Products to be included in the HACCP Study and Product Descriptions

The HACCP Team must consider and document all products that are to be included in the study, as well as all locations and processes relevant to them. This should include different physical forms of products, products intended for different species and products produced by different processes. The HACCP Team must also understand the intended use of the products by the customer.

Where product specifications already exist the HACCP Team should refer to these. Where they do not already exist, the Team must work with the relevant departments of the business to develop product specifications. It is possible that the HACCP risk assessment will uncover potential hazards that need to be included in the product specifications (e. g. limitations in the way products are used).

4.5. Prerequisite Programmes

Before undertaking a HACCP Study a company should have in place basic operating procedures validated as effective by internal auditing systems. These procedures are referred to as “prerequisites” (i.e. “required as a prior condition”) for the HACCP system.

Some examples of prerequisite programmes include:

- Smoking, eating and drinking policy
- Cleaning schedules and hygiene audits
- Pest control programme
- Supplier approval procedures
- Plant operating procedures and instructions
- Job descriptions and responsibilities
- Staff training

The establishment and the validation of effective procedures to control potential hazards in these areas allow the HACCP System to focus on those hazards not controlled by other means. Subsequent HACCP reviews must revisit prerequisites as well as the HACCP System itself to ensure that large areas with potential hazards are not ignored.

4.6. Producing Flow Diagrams

A flow diagram (or series of flow diagrams for ease of use) should be created dividing the business process into a series of numbered steps (for ease of reference), from the start of the operation, through processing (where applicable) to distribution to the customer, taking into account any storage, transport or handling involved.

For any manufacturing business, a current engineering flow diagram should be available to the HACCP Team. The HACCP Team should confirm the details of any engineering flow diagrams produced by physically checking them against the process being studied, prior to progressing to the next stage.

Flow diagrams should include (where relevant):

- All administrative processes such as order receipt and product formulation
- All relevant inputs to the process flow, including raw materials and any products purchased for re-sale
- All mechanical process steps
- Passive equipment (such as stone traps and magnets)
- Recycle and return loops where fractions are returned to the process
- Potential areas for cross-contamination
- All areas where product is not enclosed
- Storage, packing and transport steps
- Steps where fractions are removed from the process (and do not return)

This list is not necessarily exhaustive.

The overview flow diagram will subsequently need to be broken down into smaller and more detailed sections for working purposes and the determination of potential hazards.

4.7. Description of the Business Process

It is useful to describe the business processes in simple terms. This ensures that all members of the HACCP Team fully understand the process flow. Process descriptions are helpful for external auditors and enforcement officers with statutory authority.

5. THE HACCP STUDY

5.1. Hazard Analysis (Codex Principle 1)

Hazard – "a biological, chemical or physical agent or condition with the potential to cause an adverse effect"

HACCP concerns the product. It is essential to bear in mind both the process of production and expected use of the product.

5.1.1. Identifying Hazards

At each step of the process, the HACCP Team should list all the potential hazards that might reasonably be expected to present a threat. At this stage all hazards should be listed and any that may be removed from the study as prerequisites can be identified at a later stage.

Key considerations are:

- Hazards inherent to the product
- Hazards that may be introduced at the process step in question
- Hazards that may increase at the process step in question

5.1.2. Risk Assessment

The HACCP Team should next undertake a risk analysis of all the hazards identified. The aim is to identify those that have the highest impact on feed or food safety by assessing the likelihood of each occurring and the severity of its effect. Existing controls should be ignored in this exercise.

Some practitioners find it helpful to use a simple model for scoring hazards. A practical tool that can be used to manage the risk assessment exercise is suggested in the risk score table at the end of this guidance.

Whether or not a risk scoring method is used, it is necessary to ensure that the most significant risks receive the most attention.

5.1.3. Tabulating the HACCP Study

For ease of reference it is beneficial to use a HACCP table to summarise the data accumulated from the HACCP Study. When using such a table, it is important that the details include actions, responsibilities and timescales.

5.1.4. Creating Control Measures

Control Measure – "a control measure is any action and/or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level"

It is important to apply a control measure or measures wherever there is a hazard with a high risk score (3 or above) to eliminate it or reduce it to an acceptable level. The control measure(s) can take several forms but must be practical and achievable. When determining control measures the following considerations apply:

- Can the hazard be eliminated?
- Can the hazard be removed by engineering design?
- Can the hazard be managed by automated process control systems?
- Can the hazard be managed by staff action?

5.1.5. Validation

Any controls applied must be validated to ensure they are effective. For example, this means demonstrating by analytical or other means that a statement made about a control is true and the control works as intended. Records of this must be kept for future reference.

5.2. Determining the Critical Control Points (Codex Principle 2)

Critical Control Point (CCP) - "a step at which control can be applied and is essential to prevent or eliminate a hazard or to reduce it to an acceptable level"

Critical controls points (CCPs) are those that are essential for excluding hazards or for maintaining them at acceptable levels and where no subsequent process or procedure will be able to control the hazard adequately in the event of a failure. Determining whether control points are "critical" can be done using a decision tree. An example of a decision tree is shown in the chart at the end of this guidance.

Having determined and confirmed the CCPs it is important to identify them clearly in all HACCP-related documentation. In the case of physical equipment these should be clearly labelled or otherwise identified.

5.3. Establishing the Critical Limits (Codex Principle 3)

Critical Limit – "a criterion separating acceptability from unacceptability"

Having determined all the CCPs in the process under study, the HACCP Team must detail the critical limits for the control measures at each of these. The critical limit is what separates the acceptable from the unacceptable. Some critical limits will be determined by legislative requirements, while others will be determined by experience or scientific research.

5.4. Establishing a Monitoring System (Codex Principle 4)

Monitoring – "the act of conducting a planned sequence of observations or measurements to assess whether a control measure is operating within specified parameters"

Businesses must be aware when critical limits have been breached or where there is a trend indicating that they may be breached. Achieving this may require automatic recording, observation and/or testing. Whichever methodology is most appropriate, monitoring must be recorded.

Ideally, monitoring systems must be designed to identify as quickly as possible any controls that are becoming ineffective, prior to their failure. Therefore, the frequency of any monitoring is also important and should be specified as part of the HACCP System.

It is essential that properly qualified and authorised staff undertake monitoring activities and those authorised to undertake monitoring must be specified in the HACCP System. For example, if testing forms part of the monitoring activity, the HACCP System must define how samples are taken, and by whom, as well as who monitors the test results. The monitoring frequency must also be specified in the HACCP System.

5.5. Establishing a Corrective Action Plan (Codex Principle 5)

Corrective Action – "an action to be taken when monitoring indicates a loss of control"

The HACCP Team must specify the actions to be taken in the event of a CCP going out of control. Responsibilities for implementing corrective actions must be clearly assigned and documented.

It is important to ensure procedures also consider action to be taken with regard to any product processed since controls were last confirmed as operating within acceptable limits. This may require bonding of stock or even recall of products from customers or intermediaries.

5.6. Verification (Codex Principle 6)

Verification – "the application of methods, procedures, tests and other evaluations, in addition to monitoring, to ensure compliance with the HACCP Plan"

Verification systems must be implemented by the HACCP Team to ensure not only that all personnel staff are complying with the requirements of the System, but also that the System is effective. Verification systems must review the whole HACCP System and its associated records. There may be several CCP's in the HACCP Plan to control one hazard type each with its own appropriate monitoring. However the verification activity should cover the control of that hazard throughout the whole process. When establishing verification systems the following should be considered:

- Sampling & Testing
- Complaints Monitoring
- Internal Auditing of the HACCP System
- External Auditing of the HACCP System

5.7. Establishing Documentation (Codex principle 7)

No HACCP System will work effectively unless the controls it identifies as necessary are properly implemented. In most circumstances this will require the establishment of procedures and records. Therefore a HACCP System must include two types of documentation.

- The HACCP Plan itself - this encompasses all the details previously described in this Guidance.
- Procedures and Records - these include written procedures detailing control measures and other aspects of the HACCP Plan, together with associated records. These may form part of a quality system (such as ISO 9001/2), or may solely be connected to the HACCP Plan. For practical purposes, it is usually most effective to integrate HACCP Procedures and Records into the overall quality system of the business, wherever possible.

6. HACCP SYSTEM REVIEW AFTER IMPLEMENTATION

6.1. Immediate HACCP System Review

There are a number of circumstances under which sections of the HACCP System, or even the whole HACCP System, may need to be reviewed immediately. In particular, where any changes are being considered, the HACCP Review must always form part of the planning process. In such circumstances the HACCP Team must instigate an immediate review to ensure all identified hazards will still be under control and no new ones result from the changes. Minutes of Immediate Reviews must be kept for future reference and be considered as part of the Scheduled Review. Some examples of circumstances that may require an Immediate Review of part or all of the HACCP System are noted below (this list is not exhaustive):

- Changes in raw materials, suppliers or sources
- Changes in formulation
- Changes in factory equipment or layout
- Proposed modifications or replacement of process and handling equipment
- Changes in cleaning or maintenance practices
- Changes in packaging, transport or storage
- Changes in personnel, whether replacement or reduction in numbers
- Changes in product type or use
- Changes in customer basis that may affect the hazard analysis
- Changes in legislation/other requirements
- A breach of HACCP critical limits
- Feedback/complaints from customers
- New knowledge regarding potential hazards

6.2. Scheduled HACCP System Review

At least annually, the HACCP Team must meet to discuss the HACCP System from start to finish in a scheduled HACCP Review. Minutes must be kept of Scheduled Reviews for future reference. Among the issues to be considered are:

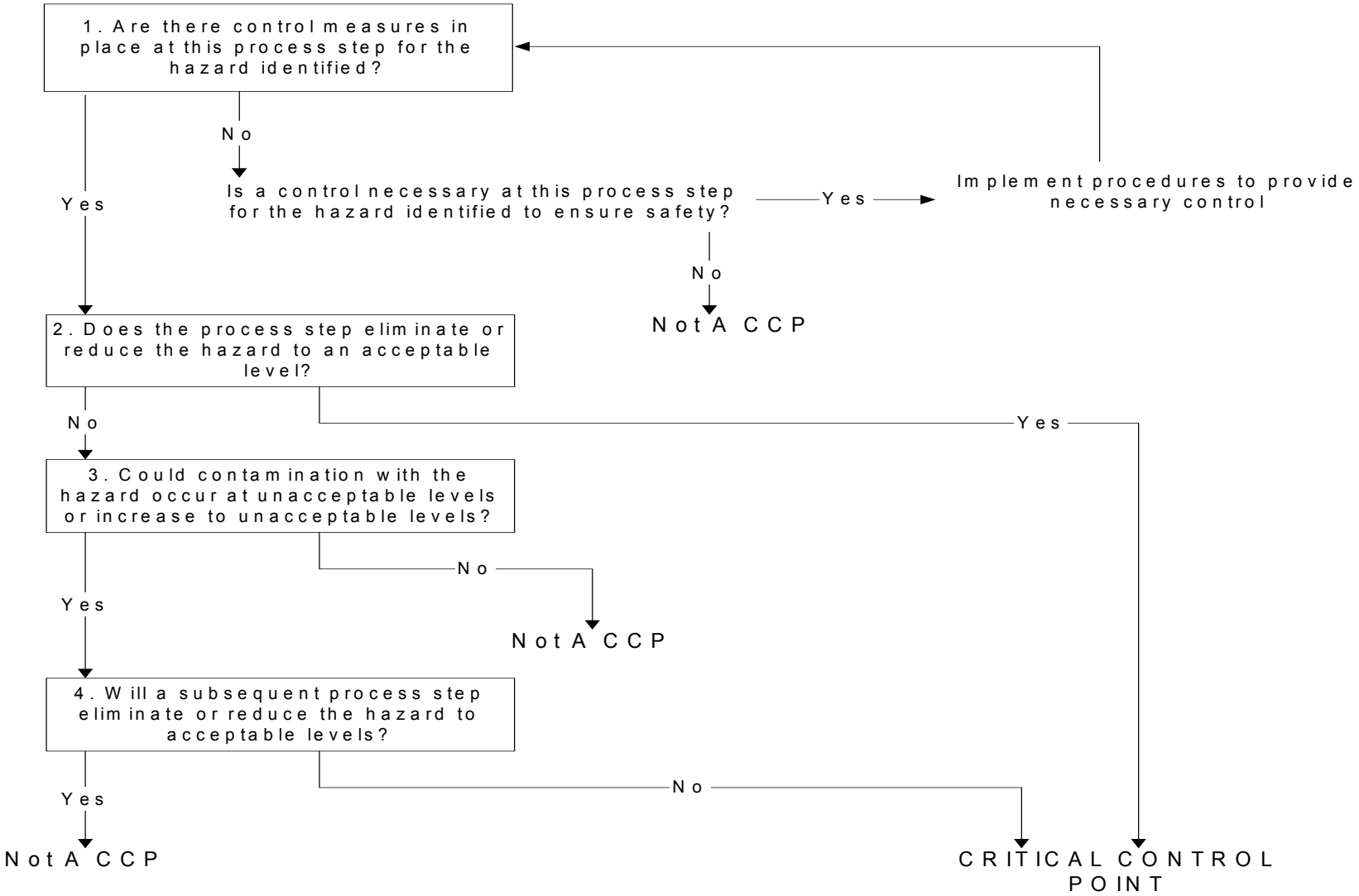
- The records of any breaches of critical limits, corrective actions that were implemented at the time and the lessons to be drawn from this. The aim should be to ensure that critical limits are never breached.
- Records of any deviations from targets and the lessons to be drawn from this. Excessive deviation from targets may indicate controls are too loose and need to be tightened. Very few deviations from target may suggest controls are too tight and excessive costs could be incurred as a consequence.

- The results of any internal or external audits and any lessons to be drawn from these. (It is however essential not to use an impending review as an excuse to leave corrective actions unresolved).
- The continued validity of the principles upon which the HACCP System has been built. Do changes in regulations, industry and company practices, equipment or personnel require changes to be made at the level of the HACCP System? (This is to ensure that no changes have escaped Immediate Review.)

In any effective HACCP System fully integrated within a business, the above areas should be addressed on a routine basis and not be left for the Scheduled HACCP System Review.

HACCP Critical Control Point Decision Tree

Questions should be followed in sequence for each hazard identified at each process step



Risk Score (the combined value of severity and probability of occurrence)

Risk Assessment		Probability of Occurrence (if not controlled)		
		High (3)	Medium (2)	Low (1)
Severity Of Occurrence	High (3)	**9**	**6**	**3**
	Medium (2)	**6**	**4**	**2**
	Low (1)	**3**	**2**	**1**

This table is based on two basic elements for risk characterisation, i.e. severity and probability. Where appropriate, additional parameters such as the detectability or additional ranking category ("very high" for instance) may be included in order to allow a specific adaptation of the risk assessment on a case by case basis.

ANNEX II: SPECIFIC REQUIREMENTS FOR MEDICATED FEED

Preamble:

On request of the EU Commission this Annex is provided to assist feed business operators producing medicated feed in complying with additional feed safety requirements laid down in EU Directive 90/167/EC on medicated feed. These additional requirements have been classified along the structure of the EFMC for easy reading. Requirements laid down in Directive 90/167/EEC applying not only to the manufacturing of medicated feed have been directly inserted in the EFMC. Any requirement in the core part of the EFMC applying to incoming feed applies also by extension to pre-mix for medicated feedingstuffs. Likewise, any requirement applying to finished feed applies also by extension to medicated feed.

1.1. Scope

- This Annex is relevant to companies involved in the processing or producing of medicated feed on the same plant as conventional compound feed.

1.2. Legal Definitions

Pre-mix for medicated feedingstuffs: Any veterinary medicinal product prepared in advance with a view to the subsequent manufacture of medicated feedingstuffs (Directive 2001/82/EC).

Veterinary medicinal product:

a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

b) any substance or combination of substances which may be used in or administered to animals with a view either to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis (Directive 2001/82/EC as amended by Directive 2004/28/EC).

2.1.2. Management Responsibilities

- A Medicated Feed Manager with proven and adequate qualifications must be appointed as responsible for medicated feed in the company.
- This Medicated Feed Manager is in particular responsible for the control of orders of premix for medicated feedingstuffs and the validation of the list of authorised pre-mix for medicated feedingstuffs (authorised at either EU or national level) and the list of approved suppliers of premix for medicated feedingstuffs. He is also responsible for the scheduling programme established under 3.6.1 and the validation of the register (see 3.8) and must assure that controls are operated as foreseen.

2.1.4. Training

- Training must include safety precautions to be taken in handling veterinary medicinal products and medicated premixtures as indicated by their manufacturer.

2.2.4.2. Supplier Assessment

- A list of approved suppliers of premix for medicated feedingstuffs must be established and maintained under the supervision of the Medicated Feed Manager.
- Incoming premix for medicated feedingstuffs must be delivered by suppliers approved or registered according to the Community code related to veterinary medicinal products.

2.2.6. Record Keeping

- The records compiled in the register (see 3.8) must be kept for at least three years after the date of the last entry and must be available at any time to the competent authorities in case of checking.

2.2.7. Control plan

- The control plan for medicated feed, must address the nature, the shelf life and the inclusion rate of the pre-mix for medicated feedingstuffs as well as the homogeneous dispersion of veterinary medicinal products concerned in the finished feed. A particular attention shall be paid to carry-over of veterinary medicinal products into following batches of feed.
- To establish the frequency of the controls, the operators shall take into account the following criteria:
  - quantity of the production of medicated feed per year;
  - variety of medicated feed produced.

  In any case, homogeneity, stability and carry-over tests shall be conducted at regular intervals at the most relevant stage of the process at least every three years.
- The results of the controls must be recorded and must contain:
  - name of the product;
  - batch number;
  - reference to specifications and modalities of control of the product;
  - where relevant, analytical results;
  - date of the control;
  - details of the person in charge of the control;
  - action taken in case of non conformity.

2.2.9. Non-conforming Feed and Product Recall

- Non-conforming finished medicated feed recalled from customers should be disposed of.
- Non-conforming feed stored in the manufacturing plant should be dealt with disposal or rework under the responsibility of the Medicated Feed Manager.
- Returns of medicated feed from customers must not be accepted.

2.3.1.2. Sampling

- Samples are taken for each batch of pre-mix for medicated feedingstuffs and retained for a period appropriate for the use to which the feed is placed on the market.
- The following information must be mentioned on the sample label:
  - generic name of the premix for medicated feedingstuffs
  - date of reception of the premix for medicated feedingstuffs
  - batch number of the supplier or internal batch number if different from the supplier's batch number
  - quantity.
- Samples are taken for each batch of manufactured medicated feed and retained for a period appropriate for the use to which the feed is placed on the market.
- The following information must be mentioned on the sample label:
  - name of the medicated feed
  - batch number of the medicated feed
  - manufacturing date
  - quantity
  - batch number and name of the incorporated premix for medicated feedingstuffs
  - active substance level.
- By derogation, the label may only contain the batch number provided all other information items are collated together and available in a (electronic) file.

3.2.1. Carry-over

- Each medicated premixture must be regarded as critical substance for the purpose of control of carry-over.
- The scheduling programme defined in 3.6.1 must avoid the manufacturing of withdrawal feed or feed for continuous food producing animals such as dairy cows or laying hens after the manufacturing of medicated feed. Cleaning procedures and instructions after production of medicated feed and before resuming production of conventional compound feed must be available to the workers on their working place.
- In order to further reduce the risk of carry-over, the following measures shall among others be considered:
  - use of premix for medicated feedingstuffs formulated in such a way as to lower dust emission
  - specific areas and equipment dedicated to the weighing of premix for medicated feedingstuffs
  - use of equipment with full emptying.

3.3. Veterinary Medicinal Products

- Veterinary medicinal substances must only be incorporated in medicated feed in the form of authorised premix for medicated feedingstuffs in accordance with Directive 2001/82/EC on the Community code relating to veterinary medicinal products. When provided for under national law, veterinary medicinal products may be incorporated in the medicated feed in the form of intermediate products prepared from such premix for medicated feedingstuffs and from one or more feed materials.
- Premix for medicated feedingstuffs must be mixed in appropriate quantity and in a homogeneous and stable way following the manufacturer's instructions of use to ensure that medicated feed contain the quantity as specified.

3.4.1. Storage, Production Facilities and Manufacturing Equipment

- The dosing, weighing and transport equipment for premix for medicated feedingstuffs must be adapted to the level of concentration of the premix for medicated feedingstuffs to be weighed.

3.4.1.4. Dust Control

- Specific attention must be paid to those premix for medicated feedingstuffs with high propensity to generate dust. Specific measures must be defined for such premix for medicated feedingstuffs to minimise the impact of such dust on the level of carry-over. This should include provisions regarding dust disposal or rework.
- The incorporation device for premix for medicated feedingstuffs must be designed in such a way as to reduce dust emissions and to facilitate the cleaning and the maintenance.
- The efficiency of dust controls on premix for medicated feedingstuffs must be checked at least once a year. If appropriate the criteria of these dust controls may be adapted accordingly.

3.5.2. Specifications of Premix for Medicated Feedingstuffs

- A list of authorised premix for medicated feedingstuffs must be established and checked frequently. The list must include the denomination of the premix for medicated feedingstuffs and their authorisation numbers.

3.5.3. Delivery, Intake and Storage of Incoming Feed

- Premix for medicated feedingstuffs must be stored in suitable separate and secured rooms or hermetic containers which are specifically designed for the storage of such products. Access to premix for medicated feedingstuffs must be restricted to the Medicated Feed Manager and staff members specifically authorised by him.
- Each batch of premix for medicated feedingstuffs delivered to the plant must be traceable.
- There must be a system of site allocation for safe storage (easily identifiable, no mixing with other premix for medicated feedingstuffs, first-in-first-out principle, intake identification easily visible). In case of doubt on the identity of a product during storage (damaged packaging), a procedure must be established whereby the Feed Safety Manager must decide about the destination of the product (clearance for use, disposal, etc.). Records must be kept about the action taken.

- Premix for medicated feedingstuffs that have been rejected by the Feed Safety Manager must be clearly identified and segregated from other materials in a manner which precludes their unauthorised used. Disposal of rejected premix for medicated feedingstuffs should be undertaken only after consultation with the manufacturer and/or supplier.

3.6.1.1. General Requirements

- Tolerances must be defined for the dosing of each medicated premixture.
- Medicated feed may be manufactured only by an approved manufacturer.
- Medicated feed should be delivered either directly to farmers or to approved distributors, in accordance with national law.
- Medicated feed may not be delivered to the final customer before the original of the prescription is transmitted to the person responsible for delivering the medicated feed (i.e. the manufacturer or an approved distributor).
- Unless otherwise specified under national law, medicated feed may be manufactured before the emission of a prescription.
- Unless otherwise specified under national law, the veterinary prescription:
  - must be established on the basis of the model annexed to Directive 90/167/EC
  - is valid for no more than 3 months
  - is valid for one treatment only.
- Medicated feed may be produced only from nationally or EU authorised premix for medicated feedingstuffs or intermediate products produced from the mixture of these premix for medicated feedingstuffs with feed materials. Medicated feed produced from a medicated premixture authorised in the country of production may be put on the market of another Member State if the active substance is authorised as medicated premixture in the Member State of destination.
- By derogation, medicated feed may be produced from premix for medicated feedingstuffs not authorised in the Member State of production when the medicated feed is destined to another EU Member State and the pre-mix for medicated feedingstuffs used is approved in the Member State of destination. In that case, the premix for medicated feedingstuffs and the medicated feed must be stored in separate areas with a clear indication that the product is destined to delivery to another Member State.
- Medicated feed must be produced from a single medicated premixture. By derogation, medicated feed may be produced from several premixes for medicated feedingstuffs on prescription and under the responsibility of the prescribing veterinarian provided that there is no specific authorized therapeutic agent in premixture form for the disease to be treated or for the species concerned or it is not available within the timeline required to minimize the impact on animal welfare. The number of premixes included in a medicated feed must be documented.
- The manufacturer must ensure that the medicated feed may not contain the same coccidiostat or histomonostat, incorporated as feed additives, as the active substance contained in the medicated premixture.
- The manufacturer must ensure that the daily dose of veterinary medicinal product is contained in a quantity of feed corresponding to at least half the daily feed ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirements of non mineral complementary feed.

3.6.1.3. Incorporation of Premix for Medicated Feedingstuffs into Animal Feed

- Where dosage silos are used for premix for medicated feedingstuffs, the equipment must include adequate dosing and locking systems.
- Daily administrative records must be kept of: (i) the types of feed manufactured (name) and (ii) all premix for medicated feedingstuffs that have been incorporated into these feeds. The latter information must be recorded chronologically in a register (see 3.8).
- The composition of a batch of animal feed to which premix for medicated feedingstuffs are added must respect the fixed tolerances set in the marketing authorisations of premix for medicated feedingstuffs.

3.6.1.3.1. Incorporation of Premix for Medicated Feedingstuffs into Compound Feed

- Premix for medicated feedingstuffs may be added by hand. However, there must be a communication system designed to ensure that premix for medicated feedingstuffs are correctly added in accordance with the marketing authorisations of premix for medicated feedingstuffs.

3.6.1.6. Temperature and Time Control – Pelleting and Cooling

- The pelleting conditions must be adapted to the stability of the incorporated medicated premixture.
- Dust sieving shall be suspended to avoid medicated feed being reincorporated into subsequent batches of other feed.

3.6.1.8. Management of Internal Returns

- Any rework of internal returns medicated feedingstuffs must comply with pre-established procedure and be subject to approval by the Medicated Feed Manager.

3.6.2.1. Storage - General Requirements

- The manufacturer shall have suitable and adequate storage designed in such a way as to avoid contamination with other finished feed.
- Medicated feedingstuffs shall be stored in suitable separate and secured rooms or hermetic containers which are specially designed for the storage of such products

3.6.2.2. Finished Feed Packaging

- Medicated feed may be placed on the market only in packages or containers (including individual truck load compartments) sealed in such a way that, when the package is opened, the closure of the seal is damaged and they cannot be re-used. Where the design of bulk vehicles does not permit appropriate sealing, written procedures must be implemented to protect the integrity of each parcel of a medicated feed.

3.6.2.3. Finished Feed Labelling

- The label of medicated feed must be labelled with the indication “Medicated feedingstuffs”.

3.7. Transport and Delivery

- Vehicles used for the transport of medicated feed must be cleaned as required by the Guide and taking into account the HACCP study before they are used for the transport of incoming or finished conventional feed.
- Medicated feed may only be delivered to the final customer on presentation of the prescription. The manufacturer must check that the medicated feed has been produced in accordance with the prescription.
- For medicated feed destined to another Member State, the delivery shall be accompanied by a certificate issued by the Member State of origin whenever required by the Member State of destination.

3.8. Product Traceability Records

- The manufacturer must ensure that all information relating to the purchase, manufacture and delivery of medicated feed is readily available and can be reconciled to enable traceability. The following information must be collated and recorded on a daily basis in a register:
  - For premix for medicated feedingstuffs:
    - generic name of the premix for medicated feedingstuffs and veterinary medicinal substance
    - name and address of the supplier
    - date of reception
    - where relevant, the name of market authorisation / product licence number holder
    - manufacturers' batch number(s) and number of containers for each batch
    - average quantities of active substances guaranteed by the supplier
    - shelf life
    - internal batch number if different from the supplier's batch number
    - stocks of premix for medicated feedingstuffs.
  - For medicated feed:
    - nature, quantity and batch number of the medicated feed
    - nature and quantities of medicated premixture used
    - theoretical concentration of the active substances
    - date/time of production
    - names and addresses of the customers to which the medicated feed was delivered
    - where relevant, the prescription number and the name and address of the veterinarian
    - stocks of medicated feed.
- The register may take the form of an electronic file.
- The register is kept for a period of three years at least.
- Prescriptions are kept for a period of three years at least.

ANNEX III: GUIDELINES FOR IMPLEMENTATION OF CERTAIN SECTIONS OF THE EFMC

A. GUIDANCE FOR THE DEVELOPMENT OF A CLEANING PROGRAMME

Cleaning must remove residues and dirt that may be a source of contamination. The necessary cleaning methods (e.g. physical methods such as vacuum cleaning or chemical) and materials will depend on the nature of the business and may include disinfection / sanitising, but must be compatible with feed safety legislation. Operators must ensure that at all stages of the production, storage or handling of incoming feed and final products sufficient standards of cleanliness are operated in such a way that exposure to pests and pathogens is minimised.

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 operator must ensure that control systems provide the correct and effective dilution levels at all times.

Where process machinery, conveyors or storage vessels are cleaned using wet cleaning methods, these must be dried prior to use.

The operator must establish a cleaning programme. He may contract the service to a competent organisation. The cleaning programme should specify:

- The responsible person / organisation
- The product manufacturing and storage areas as well as transport facilities and manufacturing equipment that must be kept clean
- The method for cleaning (including a description of the chemical agent used where relevant)
- The frequency of cleaning
- The authorised person for inspection
- The storage area of the chemical agents where relevant
- Records of cleaning operations and inspections.

B. GUIDANCE FOR THE DEVELOPMENT OF A PEST CONTROL PLAN

A pest control plan must be established to control and limit pest activity. Such controls must include all classes of animals (e.g. birds, insects and mammals) whether they are wild, feral or domestic.

When developing a pest control programme, the operator may either contract services to a competent pest control organisation, or shall have trained personnel, for the regular inspection and treatment of premises to stop and eradicate pest infestation. Where the services of a pest control contractor are employed, the service contracted shall be clearly defined and reflect the activities of the site.

Animals must, wherever possible, be excluded from the grounds of factories, and the area surrounding stores and processing plants. Where the presence of wild birds and other pests is unavoidable, procedures must be implemented to protect incoming feed and final products 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.

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.

Pest infestations must be dealt with promptly and any actions taken must be compatible with feed products.

The pest control plan should specify:

- Qualifications of staff / organisation involved in pest control activities
- A list of targeted pests (rodents, birds, insects, etc.)
- The product manufacturing and storage areas as well as transport facilities that must be inspected
- The frequency of inspection
- The method for preventing pest intrusion (traps, etc.)
- The method for eliminating pests (traps, pesticides)
- The type of pesticides (including safety data sheets) and their storage area
- Map(s) indicating the location of any bait stations and the baits which are used
- The storage area of the chemical agents where relevant
- Records of any pest found
- Details of corrective actions implemented.

C. GUIDANCE FOR HOMOGENEITY TESTS

Purpose of the homogeneity test: to check the dispersion of feed additives and veterinary medicinal products across appropriate batch sizes, thus allowing measuring the mixer efficiency.

The frequency of homogeneity tests must be defined. However, the frequency of tests must be intensified in case of repeated deviations.

Method of measurement: a batch of feed is manufactured, containing the target parameter, which typically could be a trace element or a mineral. A minimum of 8 samples need to be taken as close to the mixer discharge as possible and at predetermined intervals throughout the batch and put into sequentially numbered containers. The whole set of individual samples must be sent for separate analysis. The test must be conducted on the maximum batch size.

Interpretation of the data must look at variation between samples and may also look at average recovery.

Interpretation of results: a target maximum percent coefficient of variation (CV) and mean percent recovery must be established taking into account the analyte, the target levels and background values. In most cases, a target CV of less than 10% should be achieved.

In case the CV would exceed the target, corrective actions should be implemented, e.g. increasing mixing time.

The CV is expressed as the ration standard deviation (SD) / mean, expressed in percentages.

D. GUIDANCE FOR CALIBRATION PROCEDURES

The calibration procedure should include the following elements:

- Person responsible for maintenance of measurement devices
- Unique identifier of all measurement devices
- Calibration accuracy for each device
- Calibration protocol traceable to international or national measurement standards. Where no standards exist, the basis for calibration or verification must be recorded
- Frequency of calibration (should be adapted depending on the results of the previous calibration tests)
- Records of calibration results and validation
- Corrective actions (adjustment, verification of the validity of previous measurement results.

E. GUIDANCE FOR THE MEASUREMENT AND CONTROL OF CARRY-OVER

Several factors may influence the level of carry-over in a feed mill: the facilities themselves (the equipment of the facilities), the substance itself (depending on adhesive strength, electrostatic properties and the size and density of the particles) and the measures that are taken to control carry-over.

Measurement of premise bound carry-over

Several methods exist to measure the plant bound carry-over. These methods must follow the following general principles:

- The tracer (coloured “iron filings” that can be added to a feed and then detected using a magnet), the carry-over target and the sampling stage must be determined in accordance with the risk assessment and should be as close as possible to the end of the line.
- One or several batches of feed containing the tracer are manufactured.
- The measure must be carried out on at least one batch of feed manufactured after the batch containing the tracer.
- In case several batches of the same lot are produced, samples must be representative of the lot. The number of samples must be defined in such a way as to minimise the risk of misevaluation.
- When analysing the tracer, samples may be gathered.
- Results interpretation: the carry-over is calculated as a percentage of the concentration in the first batch manufactured without tracer divided by the concentration of the tracer in the last batch containing the tracer.

In case the carry-over would exceed the target, corrective actions should be implemented.

Sequence of production

Sequencing (or scheduling) of production does not allow for a reduction of carry-over but enables to manage carry-over in order to prevent any adverse impact on animal or public health.

- Each plant must establish its own rules for drawing up production schedules derived from the HACCP study taking into account the premise bound carry-over, the characteristics of the substances (depending on adhesive strength, electrostatic properties and the size and density of the particles) and the species for which they are authorised. In addition, attention should be paid to the risk for animal and public health, with the adoption, where required of scheduling exclusions (e.g. no production of horse feed after a batch of feed containing ionophores).
- In order to establish this schedule, the company must define for each substance regarded as at-risk further to the HACCP study the number of batches to be produced between a batch containing a given active substance (additive including coccidiostats and histomonostats or veterinary medicinal substances) and a batch for a non target species or for withdrawal feed or for continuous food producing animals (dairy cows, laying hens). This number of batches will be defined for each animal species, taking into account the level of carry-over of the plant, the physical characteristics of the substance and the level of risk for animal and public health.

Flushing

Where necessary, the equipment must be flushed to avoid carry-over between batches. Flushing must be done using a specified amount of wheat feed or other suitable material, proven to purge the system adequately.

F. GUIDANCE FOR SAMPLING

The control plan must establish the sampling procedures where samples have to be taken, the quantities and the frequency.

As additional guidance, attention should be paid to the following when establishing a sampling protocol:

- All incoming feed materials and final products must be sampled.
- The volume of the sample should be sufficient to carry out the required analyses; part of it should be retained for reference. A typical sample volume is around 400 g.
- The reference sample for feed ingredients should be a composite of several samples from different delivery points.
- The reference sample for finished feed may be composed of a single sample taken at the point of loading.
- The sampling equipment must be suitable to permit a representative sample to be taken in a safe manner. Attention should be paid to hygiene.
- Samples must be labelled in such a way as to ensure full traceability.
- Samples must be retained for a defined period of time. The samples of feed ingredients and final products must be retained for a period appropriate for the shelf life of the final feed and be available to the public authorities.
- Samples must be stored in conditions which aim at reducing deterioration to a minimum (cool, dry and free from pests and insects).
- Samples must be disposed of safely.

ANNEX IV: LIST OF NATIONAL GUIDES TO GOOD PRACTICE BASED ON THE EFMC

EU Member States

- **Portugal (IACA)**: Guia de Boas Práticas para os Industriais de Pré-Misturas e de alimentos compostos para animais destinados à produção de géneros alimentícios
- **The Netherlands (Productschap Diervoeder)**: GMP+-certificatie schema diervoedersector 2006 – Productie & bewerking diervoeders voor landbouwhuisdieren – GMP+ standaard B1 (EN)
- **Belgium (OVOCOM)**: Code GMP général pour le secteur de l'alimentation animale (NL)
- **Luxembourg (OVOCOM)**: Code GMP général pour le secteur de l'alimentation animale
- **Italy (ASSALZOO)**: Codex-ASSALZOO di buone pratiche per la produzione e la commercializzazione di alimenti composti per animali da reddito
- **France (SNIA/Coop de France Nutrition Animale)**: Guide de Bonnes Pratiques de la Fabrication des Aliments Composés pour Animaux
- **Germany (QS)**: QS Leitfaden für die Futtermittelwirtschaft
- **UK (AIC)**: Universal Feed Assurance Scheme (UFAS) - Code of Practice for the Manufacture of Safe Compound Animal Feedingstuffs
- **Spain (CESFAC)**: Alimentacion Animal Certificada
- **Czech Republic (CMSO ZZN)**: Pravidla správné výrobnía hygienické praxe pro výrobce premixů a krmiv s použitím premixů nebodoplnkových krmiv určených k výživě hospodářských vířat (EN).
- **Denmark (DAKOFO)**: EFMC has been translated in the national language and will serve as the reference code for the organisation's members (contact DAKOFO for more information)
- **Ireland**: Irish Feed Assurance Scheme - Code of Practice for the Manufacture of Safe Compound Animal Feedingstuffs
- **Austria (VFÖ)**: Austrian Feed Manufacturers' Code
- **Slovenia (GZS)**: Slovenian Feed Manufacturers' Code (contact GZS for more information)
- **Poland (IZBA Gospodarcza)**: EFMC has been translated in the national language and will serve as the reference code for the organisation's members (contact IZBA for more information)
- **Slovakia (AFPWTC)**: Slovak Feed Manufacturers' Code (contact AFPWTC for more information)
- **Finland (FFDIF)**: Finish Feed Manufacturers' Code (contact FFDIF for more information)

Third countries

- **Switzerland (VSF):** SFPS Schweizerischer Futtermittel Produktionsstandard (Leitlinien für eine gute Verfahrenspraxis für die Herstellung von Futtermitteln (FR)
- **Croatia (CFIA)**: Croatian version of EFMC (contact CFIA for more information)

ANNEX V: LIST OF REPRESENTATIVES OF EUROPEAN FEED BUSINESS SECTORS CONSULTED FOR THE DEVELOPMENT OF THE GUIDE

- **AAF:** Association des Amidonniers et Féculiers
- **AVEC:** Association of Poultry Processors and Poultry Trade in the EU countries
- **BEUC:** The European Consumers' Organisation
- **CEFS:** Comité Européen des Fabricants de Sucre
- **CIAA:** Confederation of the Food and Drink Industries of the European Union
- **CIDE:** European Dehydrators Association
- **COCERAL:** Comité du Commerce des Céréales, Aliments du Bétail, Oléagineux, Huile d'Olive, Huiles et Graisses et Agrofournitures
- **COPA-COGECA:** European Farmers - European Agri-Cooperatives
- **EDA:** European Dairy Association
- **EEPA:** European Egg Processors Association
- **EFPRA:** European Fat Processors and Renderers Association
- **EMFEMA:** International Association of the European Manufacturers of Major, Trace and Specific Feed Mineral Materials
- **EMRA:** European Modern Restaurant Association
- **EUROCOMMERCE:** Retail, Wholesale and International Trade Representation to the EU
- **EUROMALT:** Committee of the Malting Industry of the European Union
- **FEDIOL:** EU Oil and Protein Meal Industry
- **FEFANA:** EU Feed Additives and Premixtures Association
- **European Flour Millers Association:** European Flour Millers Association
- **IFAH-Europe:** International Federation for Animal Health - Europe
- **IFFO:** International Fish Meal and Fish Oil Organisation
- **UECBV:** European Livestock and Meat Trading Union