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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 1.0

January 2007

FEDERATION EUROPEENNE DES FABRICANTS D'ALIMENTS COMPOSES POUR ANIMAUX

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CONTENT

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 & 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 developed 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 practice 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).

From 2002 on, FEFAC organised annual meetings with other partners of the chain upstream (AAF, CEFS, CIAA, CIDE, EFPRA, EMFEMA, EUROMALT, FEDIOL, FEFANA, GAM, IFAH-Europe, IFFO and COCERAL) and downstream (COPA-COGECA, AVEC, EDA, EEPA and UECBV). 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 (BEUC), retailers (EUROCOMMERCE) and modern restaurants (EMRA), 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 stakeholder's 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, e.g. obligation for suppliers of feed materials and feed additives to implement feed safety assurance systems. 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. It was assessed by the Standing Committee on the Food Chain at its meeting on 29 January 2007. The Title "European Feed Manufacturers Guide (EFMC): a community guide to good practice for the industrial EU compound feed & premixtures manufacturing sector for food producing animals" and the references of the EFMC were published in the OJEC No C…, page…

A special Committee, 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, where necessary, 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 do 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 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.

Although medicated feed are subject to a specific legislation, i.e. Directive 90/167/EEC, they are supposed to meet also the feed hygiene standards applying to conventional feed and are often produced in the same plant as conventional feed. The good practices hereafter apply therefore also to the manufacturing of medicated feed. Additional requirements laid down in Directive 90/167/EEC applying to the manufacturing of medicated feed have been inserted in the EFMC. 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, medicated feed
- the operations covered:
  - the sourcing of feed materials, premixtures, medicated premixtures and feed additives
  - the production, storage, transport and distribution of premixtures, compound feed and medicated feed;
- a risk analysis based on “HACCP” 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, the implementation of which are 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 1.0 January 2007

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, including medicated feed. To facilitate the reading and use of the Guide, any provision applying to compound feed applies also to medicated feed. 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, premixtures and medicated feed. The Guide does not cover the production of medicated premixtures. 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) N°1774/2002).

Compound feedingstuffs: mixtures of feed materials, whether or not containing additives, for oral animal feeding in the form of complete or complementary feedingstuffs (Directive 79/373/EEC);

Complete feedingstuffs: mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration (Directive 79/373/EEC);

Complementary feedingstuffs: mixtures of feedingstuffs which have a high content of certain substances but which, by reason of their composition, are sufficient for a daily ration only if used in combination with other feedingstuffs (Directive 79/373/EEC);

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 material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions:

a) Favourably affect the characteristics of feed
b) Favourably affect the characteristics of animal products
c) Favourably affect the colour of ornamental fish and birds
d) Satisfy the nutritional needs of animals
e) Favourably affect the environmental consequences of animal production
f) Favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs,
g) Have a coccidiostatic or histomonostatic effect (Regulation (EC) No 1831/2003).

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).

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

Veterinary medicinal product: Any substance or combination of substances presented for treating or preventing disease in animals. (Directive 2001/82/EC). Any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals is likewise considered a veterinary medicinal product.

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) N° 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).

1.3. Other definitions

Carry-over: Contamination of a material or product with another material or product that originates from previous use of equipment.

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

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 (Codex): 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 medicated feed and to premixture manufactured by the compound feed manufacturer for his personal use.

"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. By extension, it also covers medicated premixtures.

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

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

Returns: Compound feedingstuffs, medicated feed 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 - good housekeeping must keep this to a minimum in factories, stores, retail premises, and on farm.

(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 the manufacture of food or drink and safe returns complying with the EU feed safety legislation shall not be regarded as waste.

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 standards of feed safety 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** (FSMS) must be established, documented, implemented and maintained. The system must be adapted to regulatory and other feed safety developments.
- The structure of the FSMS 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 FSMS 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 FSMS.

2.1.1. Risk analysis and HACCP

- An “HACCP” team must be appointed to produce an effective HACCP Plan. The team must include personnel from all of the relevant operations and functions within the company and at least one member with demonstrably effective HACCP training. The members of the HACCP team must be recorded within the HACCP Plan.
- The Process steps must be defined by the “HACCP” Team.
- The “HACCP” Team must identify and record any possible chemical, physical or microbiological hazards.
- For each process stage, a separate hazard analysis must be done.
- Control measures must exist for each stage of the process.
- Critical limits must be identified by the “HACCP” Team and the suitability of these limits has to be shown.
- Critical Control points must be monitored under a documented schedule.
- Preventative and corrective actions have to be suitable, prompt and an effective remedial action. The preventive and corrective actions must be recorded.
- The “HACCP” system must be reviewed regularly, i.e. at least one complete review per year must take place, which must be recorded.

2.1.2. Management Responsibilities

- The Management (from CEO to the operational management) must be committed to the implementation of this Guide and the operation of effective feed safety systems, which have to be documented.
- The Management must:
  - Define the scope of the "HACCP" 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 at defined intervals of not more than 12 months, and when major or significant changes to plant or products occur, to ensure suitability and effectiveness of feed safety management systems (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

- Appropriate training to raise and keep up the awareness of staff on their responsibility for feed safety assurance must be provided.
- Appropriate training for all employees must be provided to ensure conformity with product requirements:
  - The staff must be adequately trained on a continuous basis according to appropriate procedures and
  - 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.
- 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 premixtures and medicated premixtures manufacturers or intermediaries, including batch number
- 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 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.
- For medicated feed delivered directly to the livestock holder, the prescription and the name and address of the prescribing veterinarian.

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 FSMS 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 3.5.1) 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, Community code related to veterinary medicinal products) 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 sectoral guides to good practice where exists, 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 specification 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. Directive 90/167/EEC requests that records related to the manufacturing of medicated premixtures should be kept for 3 years at least.
- 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 complies with the specifications defined by the manufacturer and the relevant legislation.
  - Address the nature, content and homogeneous dispersion of the additives and veterinary medicinal products concerned in the finished feed. Homogeneity tests shall be conducted frequently at the most relevant stage of the process (see Annex II D).
  - 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 and analytical constituents (Directive 79/373/EEC) of finished feed and undesirable substances they contain are recorded.
- The feed safety control plans 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 plans 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 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 controller.

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 for 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.
- The samples of incoming and finished feed must be retained for a period appropriate for the use to 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 therefrom.
- 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

- 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 done 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, and each veterinary medicinal substance added in the form of a medicated 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 (every 2 years) or after adaptation of the installation.
- 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.

3.2.2. Undesirable substances and products / Pathogenic agents / 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 pathogenic agents

- The possible contamination with pathogens (e.g. the BSE agent) must be controlled through the use of “HACCP” based Feed Safety Assurance Systems.

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 used for species for which they are prohibited.
- Control measures must show reference to the relevant provisions of Regulation (EC) N° 999/2001 on BSE-related provisions, in particular the total feed ban (Annex IV of Regulation (EC) N° 999/2001).
- Control measures must also show reference to the relevant provisions of Regulation (EC) N° 1774/2002, in particular the ban on catering waste and the ban on intra-species recycling.

3.3. Additives and veterinary medicinal products

- Veterinary medicinal substances must only be incorporated in medicated feed in the form of authorised medicated premixtures in accordance with Directive 2001/82/EC on the Community code relating to veterinary medicinal products.
- Additives, premixtures and medicated premixtures must be mixed in appropriate quantity and in a homogeneous way following the manufacturer's instructions of use to ensure that finished feed contain the quantity as specified.
- Companies using these products must comply with the legal criteria regarding the installations, the management and administration of the plant, as well as with the qualification of the employees.

3.4. Plant Design and Maintenance and 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.
- 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 product. The dosing, weighing and transport equipment for additives must be adapted to the level of concentration of the feed materials, feed additives, premixtures and medicated 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) of 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 annually formally audited 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 medicated premixtures with high propensity to generate dust. Specific measures must be defined for such feed additives and medicated 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 them 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 of the maintenance on 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 programs must ensure the maintaining of incoming and finished feed safety at all times. The cleaning programs 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.
- Personnel 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 temporary 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, premixtures and medicated premixtures

- There must be specifications of feed materials, feed additives and premixtures to be suitable for purchasing
- For medicated premixtures, specifications are established in the marketing authorisations.
- 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 feedstuffs in which its use is approved,
  - Notes on any hazards or limitations on its use and any special characteristics of the incoming feed.

3.5.3. Delivery, intake and storage of 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
- For additives and medicated premixtures, the following additional records must be kept:
  - Where relevant, the name of market authorisation / product licence number holder
  - Manufacturers' batch number(s) and number of containers from each batch
  - Generic name of the additives or legal E number as mentioned in the EU register of feed additives
  - Generic name of the medicated premixtures and veterinary medicinal substance
  - Average quantities of active substances guaranteed by the supplier
  - Instructions of use

- Shelf life time

- Each batch of additives, premixtures and medicated premixtures delivered to plant must be traceable.
- Incoming feed must be stored in dry, hygienic conditions, free from vermin and birds.
- Medicated premixtures must be stored in a secured section in the storage area. Access to medicated premixtures must be restricted to authorised persons.
- There must be a system of site allocation for safe storage (easily identifiable, no mixing with other additives / medicated premixtures, 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 controller 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 personnel must be present for 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 additives, premixtures or medicated premixtures that have been rejected by the feed safety controller must be clearly identified and segregated from other materials in a manner which precludes their unauthorised used. Disposal of rejected feed additives, premixtures or medicated 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.
    - the required calibration accuracy,
    - the frequency of calibration,
    - the calibration reference standards.
- Records must be kept of calibration and all equipment must be uniquely identifiable and traceable to calibration records.

3.6.1.3. Incorporation of additives and medicated premixtures into animal feeds

- 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. Vitamins A and D, cupper, selenium, coccidiostats and histomonostats;
- Veterinary medicinal substances may only be incorporated in animal feed in the form of premixtures in accordance with Directive 2001/82/EC on the Community code relating to veterinary medicinal products;
- Where dosage silos are used for additives and medicated premixtures, 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 of: (i) the types of feed manufactured (name), (ii) the quantity of additives (or premixtures containing additives) of the categories mentioned in Annex IV of the Additives Regulation (EC) No 1831/2003 and (iii) all medicated premixtures that have been incorporated into these feeds. The latter information must be recorded chronologically.
- The composition of a batch of animal feeds to which additives and medicated premixtures are added must respect the fixed tolerances set in the product specifications and in the marketing authorisations of medicated premixtures.

3.6.1.3.1. Incorporation of additives, premixtures and medicated premixtures into compound feed

- Additives, premixtures and medicated premixtures may be added by hand. However, there must be a communication system designed to ensure that additives and/or medicated premixtures are correctly added in accordance with the product specifications and the marketing authorisations of medicated premixtures.
- 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.
- The inclusion rate of the medicated premixture is established in the market authorisation.

3.6.1.3.2 Incorporation of additives into premixtures

- The transport of additives in their original packaging or storage silo to the weighing and dosage equipment must be ensured by adequate conveying means.
- The incorporation of additives into premixtures requires a locking or warning system in order to ensure that the targeted additive is included in 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 for ensuring that the right products are weighed within predefined tolerances should be established.

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 feedstuffs and additives.
- The accuracy and efficiency of the mixing process must be regularly checked at intervals of not more than six months to ensure that additives are evenly dispersed throughout the mix.

3.6.1.6. Temperature and Time control – Pelleting and Cooling

- Where the temperature of the finished feed, process and/or environment is critical to the product 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 most particularly not be drawn from intake areas.
- The pelleting conditions must be adapted to the stability of the incorporated additives and veterinary medicinal substances.

3.6.1.7. Metal detection & 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 re-work must be formal, recorded, and 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 returns of the feeds 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.
- Returns of medicated feed must be subject to specific rules in accordance with national good practices for the implementation of Directive 90/167/EEC.

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 maintained 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 additives.
- Medicated feed must be stored in separate, secured storage area or container.
- Compound feedingstuffs intended to be put into circulation, must comply with the provisions laid down in Directive 79/373/EEC 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.
- 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.

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 Directive 79/373/EEC for compound feed. Additional provisions laid down in articles 24 and 25 of Regulation (EC) No 1829/2003 on GM feed & food, Annex IV of Regulation (EC) No 999/2001 on TSE or in article 6, par. 1 of Directive 90/167/EEC on medicated feed shall also apply, when required.

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 its customers about the storage conditions of the feed, if the nature of the compound feed and premixtures delivered requires this.

3.7. Transport Requirements

- 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.
- No materials from previous loading must remain in the container (tank truck, boxes) before it is loaded with the feed. The container must be clean and dry.
- All vehicles used for delivery of feed must be kept clean and operated according to a transport Guide:
  - 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 medicated feed or other 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 cleaned, sanitised and dried regularly.

4. NORMATIVE DOCUMENTS

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

- The General food law Regulation ((EC) N° **178/2002**)
- The Feed Hygiene Regulation (**(EC) No 183/2005**)
- The Marketing of Compound Feedingstuffs Directive (**79/373/EEC**)
- The Official Control Regulation (EC) N° 882/2004)
- The Directive on the Circulation of Feed Materials (**96/25/EEC**)
- The Additives Regulation ((EC) N^{o} **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 substances in animal nutrition (**2002/32/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) N° **999/2001**)
- The Regulation laying down health rules concerning animal by-products not intended for human consumption ((EC) N° **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 1: LIST OF NATIONAL GUIDES TO GOOD PRACTICE BASED ON THE EFMC

- **Portugal (IACA)**: Código de boas práticas para o fabrico de prémisturas e de alimentos para animais
- **The Netherlands (Productschap Diervoeder)**: GMP+-certificatieschema diervoedersector 2006 – Productie & bewerking diervoeders voor lanbouwhuisdieren – 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/SYNCOPAC)**: Guide de Bonnes Pratiques de la Fabrication des Aliments Composés pour Animaux (contact SNIA for more information)
- **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)**: Code of good manufacturing and hygiene practice for the manufacturers of premixtures and compound feedingstuffs containing premixtures or complementary feedingstuffs for farm animal nutrition (contact CMSO-ZZN for more information)
- **Denmark (DAKOFO)**: EFMC has been translated in the national language and will serve as the reference code for the organization 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 (contact VFÖ for more information)
- **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 organization 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)
- **Switzerland (VSF):** SFPS Schweizerischer Futtermittel Produktions-Standard (Leitlinien für eine gute Verfahrenspraxis für die Herstellung von Futtermitteln) (contact VSF for more information)

ANNEX 2: GUIDELINES FOR IMPLEMENTATION OF CERTAIN SECTIONS OF THE EFMC

A. GUIDANCE FOR THE OPERATION OF THE HACCP STUDY

As a basis for carrying out the HACCP study, the operator may refer to the 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: http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf.
The purpose of the present annex is to provide additional sector notes taking into account the specificities of the compound feed and premixtures manufacturing industry.

1. HACCP study

1.1 Assembly of a multidisciplinary team (HACCP team)

The HACCP team may include, where appropriate, expertise in feed production & technology, feed logistics, veterinary matters (including veterinary medicine), microbiology and analytical chemistry. Where such expertise is not available on site or within the company, expert advice may be obtained from other sources, such as, trade and industry associations, independent experts, regulatory authorities and HACCP literature.

1.2 Description of the product

Products may be grouped by categories, providing that differences in composition or processing steps do not lead to additional hazards.

1.3 Identification of Intended use

The animal species, the age of the animal and the directions for use (including storage conditions) must be described. Where needed for ensuring the safe use as intended, the natural variation between animal species and individual animals in transfer rates from feed to food should be identified.

1.4. Construction of a flow diagram (description of manufacturing process)

The flow diagram should cover all steps in the operation for a specific product (or a group of products undergoing similar processing steps), including interactions and reworks.

1.5 On-site confirmation of flow diagram (for the record)

1.6 Listing of hazards and control measures

1.6.1 Listing of hazards

Three major types of hazards are distinguished:

- Chemical hazards are undesirable chemical elements which may make the product unsafe for consumption. They may be present in the incoming feed (residues of pesticides, naturally occurring antinutrients, residues of veterinary medicinal substances, heavy metals, POPs,

mycotoxins) or may contaminate the product during the production process through carry over (feed additives for non-target species, veterinary medicinal substances for non target species or for non-medicated feed) or contact (cleansing agents, lubricants, mineral oils) or result from interactions between veterinary medicinal products, additives and feedingstuffs once ingested by the animal. Too high concentration of desirable elements can also be a hazard and may make the product unsafe for consumption.

- Microbiological hazards are related to the presence of undesirable micro-organisms either present in incoming feed or may contaminate the product during the manufacturing process. Examples are pathogens bacteria (Salmonella,), moulds and yeasts, TSE agents, etc.
- Physical hazards are foreign bodies such as glass, plastic, metal components, stones, bones, etc., which may be present in raw materials or may contaminate the product. This makes the product unsafe for consumption.

Every company must evaluate its own situation to determine which (additional) hazards the company is confronted with. It is recommended to draw up a list of concrete hazards from the point of view of product specifications and (business) expertise which is specific to the company. This list is the basis for going through the decision tree.

1.6.2 Determination of control measures

Consideration should be given to those existing control measures which can be applied for each hazard. For each hazard the control measures that impact its level should be identified. The performance of each control measure against the relevant hazard should be identified, taking into consideration:

a) The likelihood of occurrence and level of the hazard to be controlled at this step;
b) The likelihood of failure of the control measure and the possible level(s) of hazard in case of such failure
c) The likelihood of re-occurrence of the hazard after the step;
d) The severity of the impact if the hazard is introduced to the animal

An appropriate method should be used taking into account the likelihood of a risk and its seriousness.

1.7 Identification of Critical Control Points (CCP)

This step identifies critical areas or points of the flow of a food product that are required to control the identified hazard. If the hazard can be controlled adequately, is not better controlled at another step and is essential for food safety, then this step is a CCP for the specified hazard. Other steps may be subject to control and the loss of control does not necessarily result in an increased health risk. These steps called control points (CPs) may also be identified in the HACCP programme. A CCP is different from a CP. Feed safety relies on identification and control of CCPs, while CPs may be used for quality specifications. CCPs must be identified at processing steps where the step(s) has significant impact on the presence of the hazard taking into account the performance needed to achieve the required outcome. An appropriate method for the identification should be described, e.g. a decision tree (see model in the EU Commission guidance document – page 14).

1.8 Critical limits at critical control points

The critical limits should be measurable and observable to enable monitoring. Measurable parameters in the feed sector are for example specifications of incoming feed, feed formulation, temperature, time, moisture level, pH, visual appearance, texture, quality and condition.

1.9 Monitoring procedures at critical control points

Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product.

1.10 Corrective actions (for the record)

1.11 Verification procedures (for the record)

1.12 Documentation and record keeping (for the record)

B. 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 ways 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 must specify:

- The responsible person / organisation;
- The product manufacturing, storage and transport facilities areas as well as manufacturing equipment that must be kept cleaned;
- 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.

C. 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 personnel / organisation involved in pest control activities;
- A list of targeted pests (rodents, birds, insects, …)
- The product manufacturing, storage and transport facilities areas that must be inspected;
- The frequency of inspection;
- The method for prevention of pest intrusion (traps…);
- The method for elimination of 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 with which they are baited
- The storage area of the chemical agents where relevant;
- Records of any pest found;
- Details of corrective actions implemented.

D. GUIDANCE FOR HOMOGENEITY TESTS

Purpose of the homogeneity test: to check the dispersion of feed additives and veterinary medicinal substances 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 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 % 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.

E. GUIDANCE FOR CALIBRATION PROCEDURES

The calibration procedure should include the following elements

- Responsible person 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,);

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

Several factors may influence the level of carry-over in a feed mill: the installation itself (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, the carry-over target and the sampling stage must be determined in accordance with the risk assessment.
- 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 or veterinary medicinal substances) and a batch for a non target species or for animals during the withdrawal period or for food exporting 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.

G. 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 points in the delivery;
- 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 to reduce deterioration to a minimum (cool, dry and free from pests and insects);
- samples must be disposed of safely