Community Guide to Good Practice
For
Feed Additive and Premixture Operators

INTRODUCTION

This European Guide of Practice for Animal Feed Additive and Premixture Operators ('**Guide**') responds to the Regulation of the European Parliament and the Council laying down requirements for feed hygiene, (183/2005/EC), articles 20 to 22 of which encourage the development of guides to good practice for hygiene and the application of HACCP principles.

Implementation of the guide aims to ensure the safety of feed additives and premixtures, the operation of businesses in accordance with European feed hygiene requirements, and improved traceability. The guide also applies to import from third countries of feed additives and premixtures.

In order to align the Guide with current animal feed legislation and various activities on national, industrial and/or association levels, it takes into account the principles of feed and food safety as well as HACCP principles that are set out in:

- The European Commission's White Paper on Food Safety (COM (1999) 719 final)

  http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub06_en.pdf

- European Council Directives 95/69/EEC and 98/51/EEC, laying down conditions and arrangements for approving and registering establishments and intermediaries in the animal feed sector (repealed by Regulation 183/2005).

  http://www.europa.eu.int/comm/food/food/animalnutrition/approval/approval01_en.pdf

  http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_208/l_20819980724en00430048.pdf

- Regulation of the European Parliament and of the Council on additives for use in animal nutrition. (1831/2003/EC).

  http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00290043.pdf

- Regulation of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority. (178/2002/EC).

  http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf

- Regulation of the European Parliament and of the Council laying down requirements for feed hygiene. (183/2005/EC).

  http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_035/l_03520050208en00010022.pdf

- The relevant codes of practice of the Codex Alimentarius.

  http://www.codexalimentarius.net/.

- The principles of HACCP, re. Codex Alimentarius, General principles of Food Hygiene, (CAC/RCP 1-1969, Rev. 4-2003 Amd. (1999), Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application), http://www.codexalimentarius.net/.

- Management systems developed by associations, for instance:

Code of Practice (FEFAC, EU)

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

FEMAS (AIC, UK)

http://www.agindustries.org.uk/content.template/30/30/Home/Home/Home.mspx)

GMP (OVOCOM, B)

http://www.ovocom.be/intro_fr.htm

GMP+ (PDV, NI)

http://www.pdv.nl/index_eng.php?switch=1

Q+S (DVT, D).

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

FAMI-QS (EU)

http://www.fami-qs.org

FEFANA (EU)

http://www.fefana.org

The combination of the above principles provides guidance for feed additive and premixture operators in implementing the measures necessary to ensure feed safety in European and international manufacturing and trade. In order to facilitate implementation of the Guide, the structure of ISO 9001:2000, Quality Management Systems, is used.

In the exceptional case where a direct or indirect risk to human or animal health is related to a product manufactured and marketed under the Guide, the information and recall procedures (including the rapid alert system) defined in Regulation 178/2002/EC shall apply.

The text of the Guide is designed to set out general requirements and to be used by operators as a tool to develop their own procedures. It is freely available to all feed business operators who want to develop their own procedures to comply with the requirements of the Feed Hygiene Regulation. The Guide has been developed by FAMI-QS Asbl (Feed Additive and premixture Quality System European Association) on the basis of its Code of Practice. FAMI-QS Asbl is in charge of the run and management of the Code, a system of independent and voluntary certification recognized by operators down the supply chain. FEFANA Asbl has actively promoted the development of the Guide and is in full support of it.

A compilation of guidance is provided as annex to the Guide. These are covering topics of special importance, providing information in a more detailed and practical way and if applicable may serve as additional assistance. These guidance are not exhaustive; they are no intended to replace the implementation of a proper HACCP system but should help operators to implement it. If the operator decides to follow the procedures described in the Guidance, this will become a part of its Safety System. In case that, for good reasons, he uses different procedures, he must be able to provide evidence that he is complying with the requirements of the Guide as well.

Both the guide and annexes will be submitted to periodical revision in case of relevant technological, scientific and legislative developments or statutory modification in the sector. In these cases, the European Commission will be informed

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Annexes

1 Scope

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

- minimizing the risk, that adulterated feed additives and premixtures enter the feed chain;
- enabling an operator to implement the objectives of the feed hygiene regulation (183/2005/EC); and
- providing measures to ensure that other applicable feed safety regulatory requirements are met.

Feed is considered unsafe for its intended use if it has adverse effect on human or animal health, or if the food derived from food-producing animals is unsafe for human consumption.

This Guide shall apply to feed additives and premixture operators at all stages from the first placing on the market of feed additives and premixtures based on current EU legislation. Therefore it also applies to the placing on the market of feed additives and premixtures after import from third countries.

Compliance with this Guide does not exonerate the operator from meeting the statutory or regulatory requirements in each country in which the operator is active. A tool for checking the regulatory status of feed additives is the Register of Feed Additives:

(http://europa.eu.int/comm/food/food/animalnutrition/feedadditives/registeradditives_en.htm)

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

2 Terms and definitions

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

Adequate: The terminologies “adequate”, “where appropriate”, “where necessary”, or “sufficient” mean that it is up to the business operator in first instance to decide whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives of the Regulation. In determining whether a requirement is adequate, appropriate, necessary, or sufficient, account should be taken of the nature of the feed and of its intended use*(adopted from EC Guidance Document 2005 on Regulation 852/2004/EC and modified).*

Agent: An individual or firm authorized to act on behalf of an operator such as by executing commercial transactions without ever taking legal responsibility of the product and the way it is supplied and provided into the feed chain.

Authorised personnel: Persons who have skills, permission and purpose as specified by job descriptions, process descriptions or management.

Batch (or lot): A specific quantity of a material produced in a process or series of processes so that it is expected to be homogeneous and have uniform character and quality. In case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval. In case of a delivery (in-coming material) the batch size can be defined either by the amount of delivery or by splitting up the delivery in fractions each corresponding to the suppliers number of batches. *(Adopted from ICH Guideline Q7A and modified).*

Batch number (or lot number): A unique combination of numbers, letters, and/or symbols that identifies a batch (or lot) and from which the delivery, production and distribution history can be determined. *(Adopted from ICH Guideline Q7A and modified)*.

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

Carry-over: Contamination of a material or product with another material or product that originates from previous use of equipment and would alter the quality and safety beyond the established specifications.

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

Guide to Good Practice: Document identifying the principles of feed hygiene essential to ensure the safety of feed for animals and in turn the safety of animal products intended for human consumption.

Contamination: The undesired introduction of impurities of a chemical or microbiological nature or of foreign matter, into or onto a raw material, intermediate, feed additive or premixture during production, sampling, packaging or repackaging, storage or transport.

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

Establishment: Any unit of a feed business that carries out the manufacture/production and/or the placing on the market of feed additives and premixtures *(Regulation 183/2005/EC and adapted).*

Export: The release for free circulation of a product or the intention to release a product for free circulation into a non EU member state, which is manufactured in a EU member state.

Feed additives: Substances, micro organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or

more of the following functions:

favourably affect the characteristics of feed;

favourably affect the characteristics of animal products;

favourably affect the colour of ornamental fish and birds;

satisfy the nutritional needs of animals;

favourably affect the environmental consequences of animal production;

favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs; or

have a coccidiostatic or histomonostatic effect.

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

Feed business: Any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing or distribution of feed additives and premixtures. *(Regulation178/2002/EC and adapted)*. See 'Stages of production, processing and distribution'

Feed business operator: 'The natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control*. (Regulation178/2002/EC and adapted).* See 'Feed business'.

Feed hygiene: The measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed additive or a premixture, taking into account its intended use. *(Regulation 183/2005/EC).*

Feed material: Various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof. Organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures*. (Regulation 1831/2003/EC)*

Feed Safety: High level of assurance that the feed (feedingstuff, feed additive, or premixture) will neither cause harm to the farm animals when prepared or consumed according to the intended use, or to the final consumer. Throughout the Guide, the word 'safety' is taken to have the same meaning as 'Feed Safety'.

First placing on the market: The initial placing on the European Union market of an additive or premixture after its manufacture or the import of an additive or premixture. (See placing on the market). *(Regulation 1831/2003/EC)*

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

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

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

Hazard: Biological, chemical or physical agent in the feed chain with the potential to cause an adverse health effect for animals or consumers*. (Regulation178/2002/EC)*

Import: The release for free circulation of a product or the intention to release a product for free circulation into an EU member state, which is manufactured in a non EU member state. *(Regulation 882/2004/EC and modified)*

Incoming material: A general term used to denote raw materials delivered at the beginning of the production chain (e.g. reagents, solvents, processing aids, feed materials, feed additives and

premixtures).

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

Lot: See batch.

Lot number: See batch number.

Manufacture/production: All operations encompassing receipt of materials, processing, packaging, repackaging, labelling, relabelling, quality control, release, storage, and distribution of feed additives and premixtures and related controls.

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

Operator: See feed business operator.

Placing on the market: Holding products for the purposes of sale, including offering for sale or for the purposes of any other form of transfer, whether or not free of charge, to third parties, and the sale and other forms of transfer themselves. *(Regulation178/2002/EC)* (See first placing on the market).

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

Premixtures: Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended to direct feeding to animals. *(Regulation 1831/2003/EC)*

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

Processing aids: Any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technological unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have any adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed. *(Regulation 1831/2003/EC)*

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

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

Record: Written documents containing actual data.

Reworking: Any appropriate manipulation steps in order to ensure a feed additive or premixture will conform to specifications.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard. *(Regulation178/2002/EC)*

Safety: See feed safety.

Shall: Compliance with a requirement which is mandatory for compliance with this standard. (Obligation to follow the exact requirement as stated by this Guide).

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

Should: Means "must" and the activities, descriptions or specifications accompanied by the word "should" are intended to be mandatory, unless the manufacturer is able to demonstrate that the activity, description or specification is inapplicable or can be replaced by an alternative which must be demonstrated to provide at least an equivalent level of quality and safety assurance. (Operators are obligated to achieve the goal of the Guide by appropriate means).

Sign / signature: Confirmation of an authorised person in writing or by electronic means with controlled access.

Specification: A list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the test described. It establishes the set of criteria to which a material shall conform to be considered acceptable for its intended use. "Compliance to specification" means that the material, when tested according to the listed analytical procedures, meets the listed acceptance criteria.

Sufficient: See "Adequate".

Stages of production, processing and distribution: Any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed. *(Regulation178/2002/EC)*

Traceability: The ability to trace and follow a food, feed, food producing animal or substance intended to be, or expected to be incorporated into a food or feed through all stages of production, processing and distribution. *(Regulation178/2002/EC)*

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

Where appropriate: See"adequate".

Where necessary: See "Adequate".

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

3 Management System (MS)

3.1. General requirements

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

The MS shall be continually adapted to consider regulatory developments.

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

The MS shall ensure that all activities carried out by the operator that could impact on the quality and feed safety of the product are consistently defined, implemented and maintained at all levels in the organisation.

The MS shall include quality procedures to ensure that the product consistently conforms to the authorization of the feed additive and the specification of the premixture.

Ensure that:

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

3.2. Management Principles

Operators should be able to demonstrate the awareness of all employees of their contribution to feed safety.

Each operator shall perform and record the evaluation of risks and subsequently define controls to be applied to the manufacturing process based on HACCP principles.

All quality and safety related activities shall be recorded directly after they are performed.

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

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

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

Ensure that:

- *employees are committed to quality and feed safety*
- *HACCP principles are applied*
- *An effective change control system is implemented*
- *Information of management in case of threats to product quality and feed safety*
- *A system is in place to ensure that management is kept up-dated on all relevant legislation, feed and food safety issues, and other relevant guidelines*

3.3. General documentation requirements

The operator shall have a system of documentation which reflects all aspects of this Guide. The system of documentation shall reflect in particular the application of HACCP principles as part of a quality control plan.

Records shall contain all relevant data that will permit investigation of any non-conformance or deviation from planned procedure.

The design and nature of use of records is at the discretion of the operator.

MS documentation should include:

a) a written quality and safety policy, re. section 4.2;

b) a quality manual;

c) documented procedures and records; and

d) information needed by the operator to ensure the effective planning, operation, and control of its processes.

Document control. Documents should

a) have unambiguous contents: the title, nature and purpose shall be clearly stated;

b) be approved, signed and dated by appropriate authorised persons. No document shall be changed without authorisation; and

c) be kept up to date.

Minimum documents required are:

a) specifications and testing procedures for incoming materials and finished product;

b) master formulae and operating instructions for each product or group of products;

c) batch processing records for each product; and

d) Standard Operating Procedures (SOPs).

The Quality Manual should include:

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

b) quality procedures established as part of the MS, or reference to them.

c) quality procedures to cover the prerequisite program in support of the HACCP program

d) HACCP procedures to ensure feed safety.

Ensure that:

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

4 Management Responsibility

4.1. Management commitment

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

Documentation shall be provided to evidence this.

Ensure that:

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

4.2. Quality and safety policy

Management shall:

a) establish a quality and safety policy and ensure that objectives are established;

b) define the scope of the HACCP system, by identifying the products/product categories and production sites which are covered by the system and ensuring that safety objectives are established as part of the system; and

c) ensure that these objectives and policies are in compliance with business goals of the operator, statutory and regulatory requirements, and any specific additional safety requirements from customers.

Ensure that:

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

4.3. Responsibility, authority and communication

Management shall ensure that responsibility and authority are defined, in written form, and communicated within the organisation.

Staff appointed by senior management should have defined responsibility and authority to:

a) identify and record any problems with regard to product quality, safety and the operator's HACCP system;

b) initiate remedial measures and control of any such problems;

c) initiate action to prevent the occurrence of nonconformities relating to product quality and safety; and

d) appoint a HACCP team and team leader.

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

Ensure that:

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

4.4. Management representative

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

a) ensuring that processes needed for the management and HACCP systems are established, implemented and maintained;

b) reporting to top management on the performance of the management systems and any need for improvement; and

c) ensuring the promotion of awareness of customer requirements throughout the operator.

Ensure that:

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

4.5. Management review

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

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

Ensure that:

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

5 Resource management

5.1. Provision of resources

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

To accomplish this, management shall:

a) provide sufficient and appropriately designed equipment & premises;

b) employ sufficient numbers of appropriately trained staff; and

c) clearly assign the responsibility and authority for ensuring compliance with regulatory requirements and industry guides of practice to competent persons. Issue, maintain and make available to the operator and external bodies an organisational chart and job descriptions.

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

Ensure that:

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

5.2. Human resources

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

In particular:

a) staff shall be adequately educated and trained in the appropriate procedures;

b) education and training shall be documented and maintained; and

c) staff shall be trained in appropriate standards of hygienic behaviour in order to contribute to overall feed safety, as part of the food chain.

Ensure that:

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

5.3. Infrastructure

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

In particular this should include:

a) adequate buildings;

b) adequate utilities; and

c) adequate process equipment.

This means that,

- the facilities and manufacturing equipment should be located, designed, constructed and maintained to suit the manufacture of the products concerned.
- the lay-out, design and operation of the facilities and equipment should minimise the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination, carry-over and any adverse effects generally on the quality and safety of the products.

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

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

Ensure that:

- *The building is suitable for the purpose to minimize risks.*
- *The building is durable to minimize maintenance and feed safety risks.*
- *The building is well maintained by a preventive maintenance program.*
- *Necessary utilities are available, e.g.*
  - *Potable water or other water quality*
  - *Steam*
  - *Pressured air*
  - *Heating system*
  - *Extraction units*
  - *Other relevant utility system*
- *Waste materials are properly identified to avoid mix-up with production materials.*
- *Waste is handled properly to avoid risks for workers or environment, both internally and externally.*

5.4. Work environment

Where applicable, the operator shall provide adequate work environment in accordance with local regulations to achieve product conformity. For example:

a) Adequate ventilation;

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

b) Adequate control of humidity;

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

c) Adequate control of temperature;

   If necessary, heating, cooling or air-conditioning systems shall be designed and installed so that air-intake or exhaust vents do not cause contamination of products, equipment or utensils.

d) Adequate lighting; and/or

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

e) Adequate hygienic design of plants and equipment.

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

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

Ensure that:

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

6 Product realisation

6.1. Product requirements

6.1.1. Determination of requirements related to the product

The operator shall determine:

a) statutory and regulatory requirements related to the product;

b) requirements specified by the customer, including requirements related to delivery and post-delivery activities; and

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

Ensure that:

- *A system to identify external requirements is implemented.*
- *The external requirements are communicated and complied with.*
- *Requirements and compliance are documented.*
- *Requirements specified by customers are controlled and implemented.*

6.1.2. Compliance of the product to the requirements

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

a) product requirements are defined;

b) the operator has the ability to meet the defined requirements; and

c) the existence and handling of products for export outside the EU and which cannot, from a regulatory point of view, be placed on the EU market, is described in the operator's MS. If the operator markets such non-EU compliant products, the operator should maintain a list of products which may be marketed in the EU and which may be marketed outside the EU only.

Should product requirements change, the operator shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. (See also section 6.3.2).

Ensure that:

- *Procedures are in place to comply with identified requirements.*

6.1.3. Customer communication

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

a) product information;

b) enquiries, contracts or order handling, including amendments; and

c) customer feedback, including complaints.

Ensure that:

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

6.2. HACCP Program

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

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

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

It is recommended that operators follow the guidance for application of HACCP provided in the Codex Alimentarius Guidelines, which are based on the following 7 principles:

1. Conduct a hazard analysis.
2. Determine the critical control points (CCPs).
3. Establish critical limits.
4. Establish a system to monitor the control of each CCP.
5. Establish the corrective action to be taken if controls should fail
6. Establish a procedure to verify that all the aspects of the HACCP system are working effectively.
7. Document all procedure and records to demonstrate the HACCP system is working effectively.

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

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

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

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

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

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

Ensure that:

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

6.3. Design and development

6.3.1. Development of new products and processes

The operator shall plan and control the design and development of products or processes related to safety.

The safety of feed additives shall be taken into account during the development process of a new product by applying HACCP principles.

Ensure that:

- *Development plans are issued prior to relevant phases of the development process.*
- *The development plan considers risks related to safety.*
- *HACCP is considered,*

6.3.2. Change control

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

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

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

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

Ensure that:

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

6.4. Handling of incoming materials

6.4.1. Sourcing of incoming materials

Purchasing information shall describe the product to be purchased, including, where appropriate, requirements for approval of product.

Selection and approval of all raw materials shall consider their origin, transport, storage, processing and handling.

Every raw material shall be evaluated to assess any potential hazard associated with it.

Each raw material shall have a written specification which is amended when any change takes place. In addition to the analytical characteristics of the product, the specification should include, where appropriate, details of any undesirable substance with which the product may typically be associated, and any other hazards or limitations associated with the product which have been considered in the operator's HACCP system.

In case the material is a feed additive or premixture imported from outside the European Union, a written confirmation of the compliance with the EU current feed regulations issued by the supplier is needed.

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

There shall be a list of internally approved suppliers and each supplier shall be subject to review periodically.

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

Records of the results of evaluations and necessary actions arising from the evaluation shall be maintained.

Ensure that:

- *New suppliers are covered by an approval process.*
- *Approved suppliers are documented, reviewed, re-evaluated and the documentation is up-to-date.*
- *The review is done periodically at a predetermined interval.*
- *Purchased incoming material has an agreed specification.*
- *Specifications comply with feed safety topics and legislative requirements,*

6.4.2. Verification of incoming materials

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

If the incoming material is delivered in bulk and stored either in silos or floor storages an adequate separation procedure must be in place. If silos are emptied, this shall be registered.

Incoming materials should be checked and formally approved prior to use according to written procedures. Where appropriate, a retained sample shall be available for the at least the shelf life of the incoming material, either at the supplier or the operator. For more detailed information on possible sampling procedures see the “Guidance on sampling” (Annex 7).

Handling of incoming product should be in accordance with its status, for example, a received product which is deemed unfit for use must be identified as such and segregated from those products released for use.

If incoming materials are rejected and not incorporated for any reason related to product quality and safety, their disposal, destination, or return to supplier shall be recorded.

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

Ensure that:

- *A written procedure on handling of incoming materials exists.*
- *Incoming materials are registered uniquely and include:*
  - *Supplier's name and lot/batch number*
  - *Operator's lot/batch number*
  - *Name of material*
  - *Quantity and date of receipt*
  - *Possible expiry date.*
- *Materials are inspected before, during and after unloading.*
- *The inspection includes contamination, pest infestation and documentation of findings.*
- *Non-conformities are recorded.*
- *Records of inspection results are documented and archived.*
- *Records of supplier guarantees and other relevant supplier documentation kept.*
- *Incoming materials are released before use.*
- *Documentation is maintained in case a product is returned to the supplier.*

6.5. Production of finished goods

6.5.1. Quality Control and Production

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

Controlled conditions should include, as applicable:

a) The availability of information that describes the characteristics of the finished product.
   - Each product shall have a written specification, which is amended when any change takes place.
   - Each product shall have a unique name or code.
   - Details of packaging and labelling shall be available. Product labelling shall be in accordance with the relevant EU feed legislation.
   - Each package shall be labelled by a unique identifier (which can be a combination of codes) in order that the batch to which it belongs can subsequently be identified and traced.

- All finished product should be inspected prior to dispatch, in accordance with written procedures, to ensure it meets specification. A retention sample adequate size shall be taken of each batch and held, as a minimum, for a time equivalent to the defined shelf life of the product. The samples must be sealed and labelled, stored in a manner that prevent abnormal change, and kept at the disposal of the authorities for a period appropriate to the use.

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

- If products are rejected and not put into circulation for any reason related to product quality and safety, their disposal, destination, or return to supplier shall be recorded. Further details are found in section 8 (Control of non-conforming products).

b) The availability of work instructions:

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

- Records shall be kept which confirm that procedures are followed and/or identify any deviation from them. Procedures shall be subject to regular critical appraisal to ensure that they continue to be effective.

c) Rules governing packaging:

- Where products are packaged, care shall be taken to avoid contamination during the packaging process, and to ensure that packaged products are correctly identified and labelled in compliance with the provisions of relevant feed regulations.

- Packaging shall be appropriate to product type, with the objective being to maintain contents for their intended shelf life. Packaging shall be considered under HACCP analysis.

- Pallets shall be serviceable, clean and dry. All pallets which are returned shall be inspected and if necessary cleaned before re-use.

d) Rules controlling storage:

- Finished product shall be clearly identified and stored in clean dry conditions. Access to these materials should be restricted to authorised personnel only.

- Incoming materials, active substances, carrier substances, products which meet the specifications – and those which do not – shall be stored in suitable places designed, adapted and maintained, in order to ensure appropriate storage conditions which manage the risks of contamination and the presence of harmful organisms. Packed materials shall be stored in appropriate packaging.

- Materials should be stored in a manner which enables easy identification, avoids cross-contamination and prevents deterioration. A stock rotation system should be in place.

- The storage environment should be set up in a manner which minimises the risk of damage to packaging and spillage of material.

e) Rules concerning loading and delivery:

- Products shall be delivered with the protection of animal and human health as prime considerations.

- Containers and equipment used for internal transport, storage, conveying handling and weighing shall be kept clean. Cleaning procedures should consider such containers and equipment.
- A final inspection shall take place to ensure delivery of correct product

Ensure that:

- *Production areas are accessible to authorized personnel only.*
- *Production is run according to formal production planning.*
- *The production plan is distributed to relevant persons.*
- *Production records are kept prove compliance with master formula.*
- *Cross-contamination is prevented or controlled.*
- *Each product has a specification, unique name and/or code.*
- *Each product has a predefined label.*
- *Finished products are clearly marked and identified.*
- *Each product has a predefined packaging instruction.*
- *The packaging process is controlled to avoid contamination and mix-up.*
- *Deliveries are inspected prior to dispatch.*
- *This inspection is documented.*
- *Non-conforming products are segregated and stored in a manner to prevent failures.*
- *Storage facilities are adequate to the purpose.*
- *Storage facilities are operated in a manner to prevent failures during handling.*
- *Storage facilities are suitable to the purpose, e.g. cleanliness, ventilation, dry, and temperature controlled.*
- *A defined stock rotation system is in place, e.g. FIFO.*
- *Outdated stock is controlled and segregated.*
- *Loose bulk materials are controlled and segregated from other loose bulk material.*

6.5.2. Verification of processes for production

The operator shall verify any processes for production where the resulting output cannot be controlled by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or has been delivered.

Verification should demonstrate the ability of these processes to achieve planned results.

The operator shall establish arrangements for these processes including:

a) defined criteria for review and approval of the manufacturing processes;

b) approval of equipment;

c) qualification of personnel;

d) use of specific methods and procedures; and

e) requirements for records.

Ensure that:

- *A written verification procedure is in place.*

6.5.3. Identification and traceability

To ensure traceability, the operator shall:

a) identify and record the product by suitable means throughout product realisation; and

b) maintain a register, that contains:

- the names and addresses of manufacturers of incoming materials, additives or of intermediaries. Incoming materials shall be verified according to section 6.4.2.
- the nature and quantity of the additives and premixes produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacturing, and the name and addresses of the intermediaries or manufacturers or users to whom the additives or premixes have been delivered.

Ensure that:

- *A traceability system is in place, including tracing back from the final product through quality control data and batch records to the raw materials used and the suppliers.*
- *Deliveries can be traced to customers, including customer name, date, batch and amount.*

6.5.4. Preservation of product

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

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

Ensure that:

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

6.6. Transport

Where third party distribution or haulage is used, this shall be selected on the basis that the haulier can satisfy safety and reliability criteria. Special attention shall be paid to vehicle hygiene and cleanliness, correct loading and avoidance of contamination and cross-contamination. This shall be verified by visual inspection prior to loading.

In respect of bulk deliveries, the transportation agent shall provide information about at least the last previous load. In cases where the last previous load consisted of product/s which may compromise the safety of the final product, or are products not permitted for inclusion in feedingstuffs according to existing regulations, the transportation agent shall provide a cleaning certificate, information about the means of cleaning and drying and guarantee that a clean, empty, dry and odourless cargo compartment and discharge equipment is made available.

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

Ensure that:

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

6.7. Control of monitoring and measuring devices

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

Where necessary to ensure valid results, measuring equipment shall:

a) be calibrated or verified at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards. Where no standards exist, the basis for calibration or verification shall be recorded;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable the calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result; and

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

In addition, the operator shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The operator shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

A documented plant maintenance program shall be in operation. A record shall be kept of work carried out.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application should be verified. This verification should be undertaken prior to initial use and reconfirmed as necessary.

Ensure that:

- *A formal calibration system is in place.*
- *This includes items to be calibrated.*
- *Appropriate calibration intervals are defined.*
- *Calibration results are documented.*
- *A formal preventive maintenance system exists.*
- *Appropriate maintenance intervals are defined.*
- *Maintenance work is documented.*
- *Maintenance work does not interfere with product safety.*

6.8. Cleaning

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

Ensure that:

- *A formal cleaning program exists, covering*
  - *Daily house-keeping*
  - *Periodic deep cleaning*
  - *Cleaning after maintenance*
- *The program defines responsibility.*
- *Post evaluation is covered.*
- *Cleaning records are filled-in currently.*
- *Procedures on cleaning of equipment exist, and support hygiene and feed safety.*
- *Employees are trained in cleaning procedures and the training is documented.*

6.9. Pest control

There should be a written plan for pest control including description of periodic inspections. Results of such inspections shall be recorded. Details of any fumigation or use of chemicals such as pesticides shall be recorded.

The HACCP plan shall consider the risk of cross-contamination due to infestation or use of pesticides.

Ensure that:

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

7 System Review

7.1. General requirements

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

Ensure that:

- *A formal review system exists.*
- *The system includes collection of data.*
- *The system includes analysis of the data.*
- *The system includes a conclusion.*
- *The system includes improvements originates from the conclusion.*

7.2. Internal audits

The operator shall ensure that internal audits are performed to verify that the management system is:

a) effectively implemented and maintained; and

b) in compliance with regulatory and other defined requirements.

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

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

a) preparation and issue of audit plans;

b) scope of audits;

c) frequency of audits;

d) methods used to conduct the audits;

e) reporting of findings;

f) distribution of reports;

g) implementation of corrective actions and follow-up activities; and

h) selection and training of competent auditors.

Ensure that:

- *An audit system is in place.*
- *Internal audits are carried out.*
- *A scheduled audit program is ain place.*
- *The auditors are suitably trained.*
- *Audits done are reported and documented.*
- *The audits contain a define scope.*
- *Feed safety issues are included in scope.*
- *Identified non-conformities are reported.*
- *A formal follow-up is reported.*
- *Corrected non-conformities are verified.*

8 Control of non-conforming products

8.1. General requirements

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

The procedure should include:

a) identification of product and batch code;

b) documentation of any non-conformance, corrective action/s and verification steps;

c) evaluation of the cause of the non-conformance;

d) segregation of affected batch or batches;

e) provision for disposal of products where appropriate; and

f) recording of internal information of relevant parties.

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

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

a) rework;

b) reclassification or dispensation; or

c) rejection and subsequent destruction or disposal.

d) Records of all non-conformances must be maintained in accordance with document control procedures and archived for an appropriate time.

The approval and use of reworks (e.g. from rejects, customer returns or spillage) shall be considered within the HACCP system. Potential reworks which are not approved become waste material and should be dealt with according to waste disposal procedures.

Ensure that:

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

8.2. Complaint handling system

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

a) allocate responsibility for controlling complaints;

b) record name of complaining customer;

c) record product name and identification code;

d) identify and record the cause of each complaint; and

e) reply to the complaining customer.

Corrective actions should be carried out in a timely and effective manner, with consideration given to the frequency and seriousness of complaints.

Where possible, complaint information shall be used to avoid recurrence and implement ongoing improvements.

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

Ensure that:

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

8.3. Recall – Withdrawal

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

The recall procedure should include requirements to:

a) define and allocate responsibility for the recall process;

b) identify the non-conforming product and batch, including consequences to other products, batches or raw materials;

c) identify the destination of affected lots;

d) describe procedures for disposal of returned product/s, including segregation from other products; and

e) maintain registers of information tracing the product and its components from production to customers.

In case of a serious risk to human or animal health the recall procedure shall include requirements to notify local authorities, as defined in relevant legislation.

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

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

Ensure that:

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

9 Statistical techniques

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

Ensure that:

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

Annex 1: GUIDANCE ON THE IMPLEMENTATION OF HACCP

Introduction:

HACCP is a Hazard Analysis of Critical Control Points that helps an operator identify safety hazards and quantify the risk associated with their product and process. The system then enables the operator to document, control and verify the affect of these control measures.

General requirements:

Ensure you have a robust system in place to manage the daily tasks of good manufacturing practice (GMP or prerequisites). The prerequisites are the backbone of any quality or safety system and without them no management program will be successful. These procedures will give you a solid operating foundation allowing your HACCP team to focus on the few critical issues that may not be addressed as part of your daily program but still require special care.

Examples of common prerequisites are cleaning and sanitation, approved/controlled suppliers, employee training, stock control, preventative maintenance, product identification and traceability etc.

For each of these prerequisites, and any not specified here, you should have a written procedure on how to carry it out, how its efficacy is verified and how it's audited. Remember, as far as an auditor is concerned, if its not written down it doesn't exist!

Specific requirements for HACCP – the 7 principles:

1. Conduct a hazard analysis.
2. Determine the critical control points (CCPs).
3. Establish critical limits.
4. Establish a system to monitor the control of each CCP.
5. Establish the corrective action to be taken if controls should fail
6. Establish a procedure to verify that all the aspects of the HACCP system are working effectively.
7. Document all procedure and records to demonstrate the HACCP system is working effectively.

The following paragraphs provide guidance for operators on the implementation of the above guidelines.

1. Assemble a HACCP team

Form a small multi-disciplinary team that will that will have responsibility for establishing, developing, maintaining and reviewing the HACCP system. It is vital this group has the full support of the operator's senior management and ideally a management representative should lead the team. The team should include people who are very familiar with the products, processes and associated risks.

2. Formulate the finished product specifications

Detailed information regarding each product is required in order to assess hazards presented by the process or delivery to the end user. Be sure to consider the product raw materials, nutritional value and application of the finished product by your customers.

For practical reasons it is advisable to group similar products where appropriate.

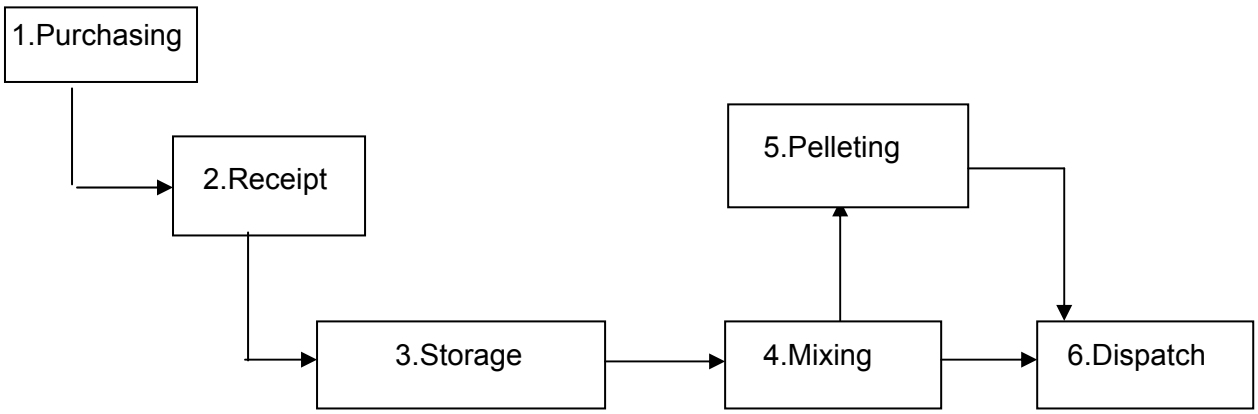
3. Identify the product's intended use

The product specification must detail the target groups for which it's intended. It should also specify the animal species, directions for use, storage and shelf life guaranteed analysis etc. The more information you can identify and add to your specification the better.

4. Construct a diagram of the process flow

Draw up a process flow diagram for each product group. This diagram should indicate the steps used to produce the product and should include details of by products, intermediate products, storage, transport etc. One block in the process flow should reflect each step in the process.

Make the diagram as simple as possible, with clear diagrams and unambiguous terms. A very basic example is given here:



5. Confirm the accuracy of the process flow diagram in situ

If the diagram is drawn up in an office make sure it is accurate by checking it against the actual operating process in your facility. This will help make sure you don't miss any steps.

6. Identify and analyse the hazards

Use the diagram to access potential hazards at each process step from the perspective of:

- Chemical – Pesticides, lubricants, dioxins, heavy metals, cleaning agents etc.
- Biological – Undesirable microorganisms such as salmonella, E. coli etc.
- Physical - Foreign bodies such as glass, wood, jewellery, stones etc.

For example, for Step 1, your first consideration should always be, “How good is the material being supplied to me?”

You must consider the chemical, biological and chemical hazards associated with each material you’re bringing on site. Potential chemical, biological and physical hazards must be considered for each subsequent step in the process, in each case taking the particular circumstances of the step into account.

7. Determine the CCP and control measure/s

After hazard identification it is important to evaluate whether or not a hazard is a risk or not. If a hazard needs a specific control and there is no point further down stream in the process that can reduce or eliminate it, it is a Critical Control Point (CCP). If it's not a CCP then no control or the correct application of your prerequisite program will suffice. Useful questions to ask yourself when you’re establishing CCPs are:

- If I don’t control this risk, is the safety of the end user compromised?
- If I don’t apply controls to this hazard at this step, are there other controls further on in the process that will ensure consumer safety?

There are two recognised guidance methods to apply when determining CCPs:

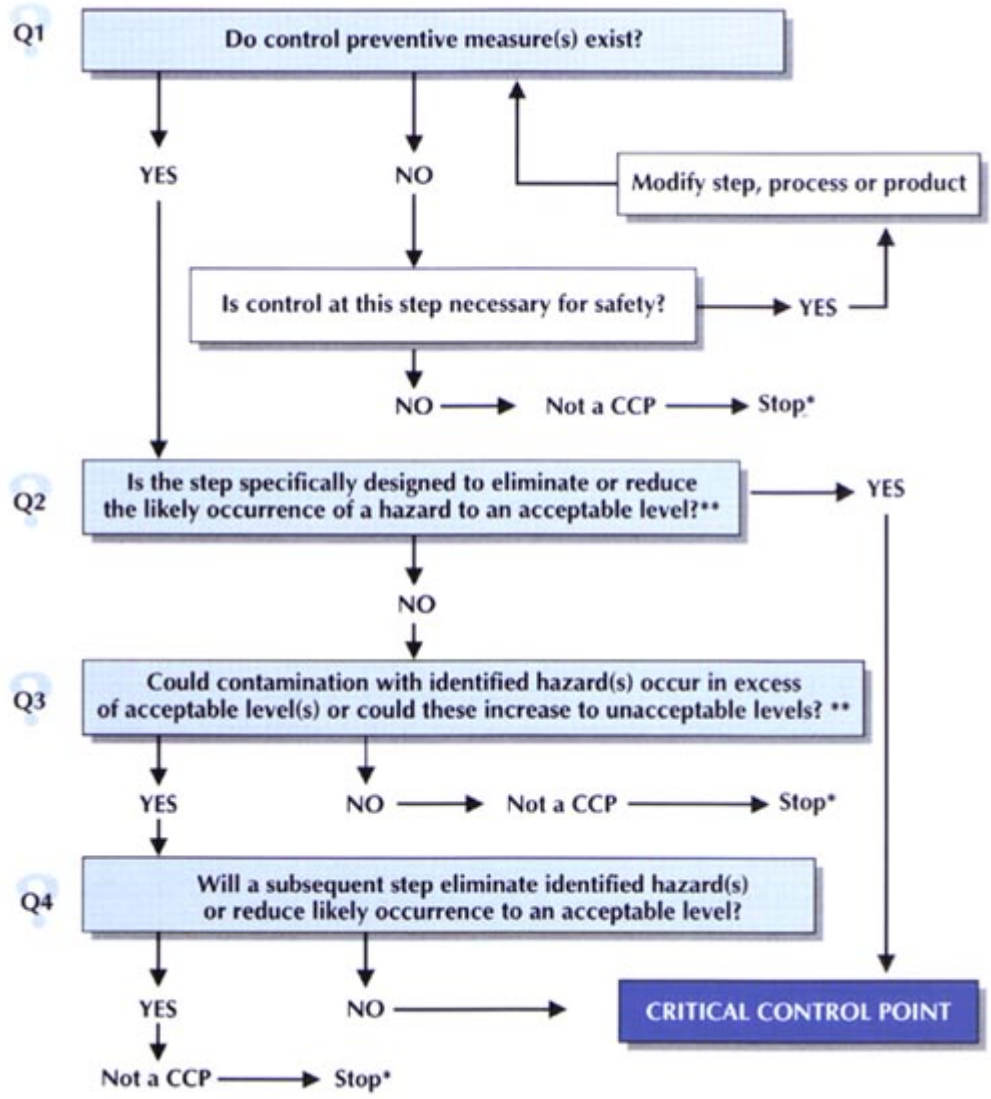
Severity ↓			
Large	3	4	4
Moderate	2	3	4
Small	1	2	3
Risk → of occurrence	Small	Moderate	Large

One is using a decision matrix, that will help you to decide how severe the potential risk is and how likely it is to occur. It is based in the concept that the risk level is the result of the probability that a hazard will occur and the severity if it occurs

Risk level 1: no need for measures
Risk level 2: once-only periodical measures
Risk level 3: general control measures, control of points of attention
Risk level 4: specific control measures → control at critical control points (CCPs)

Four risk levels can be determined with the risk evaluation model. In the event of risk level 1, no measures are necessary. In the event of risk level 2, periodic measures – often activities to be performed just once - have to be carried out. Risk level 3 requires general control measures, such as hygiene programs, maintenance and calibration, purchasing procedures, etc .In the event of risk level 4, specific control measures are necessary for that particular situation.

The determination of a CCP in the HACCP system can also be facilitated by the application of a decision tree (see figure below), which indicates, by means of four questions, a logic reasoning approach.



The number of CCPs you have will depend on your system but try and keep the total number as low as possible. You can monitor a few key CCPs much more effectively than a vast array

Once you have identified a hazard that needs a specific control you must identify the process step that will carry the control measure. Keep in mind that control must be possible and measurable, the control must eliminate or reduce the risk to an acceptable level, and if a CCP fails immediate corrective action must be possible.

8. Determine the target values and critical limits for the CCP

Establish a target value you expect as an average and a critical limit that will divide the acceptable from the unacceptable. These limits must comply with all legislative obligations but if there are no legal limits one's own research; analytical and bibliographic, and

experience (either your own or a consultant's) should be used to strike the right balance between safety and operability.

9. Construct monitoring procedures for the CCP

Monitoring of a CCP is planned measurement of the process parameters to establish if a CCP is under control. It must have a schedule, limits as defined above, a written procedure, responsible employees with appropriate training and a written record of the measurements/observations/results.

10. Determine corrective actions

These are the decisions that must be taken once a critical limit has been breached. For example, a faulty raw material or finished good may be placed on hold, reworked, destroyed etc. A written procedure must be in place that details how this process should be undertaken and someone must have responsibility for this process.

Example:

Step	Hazard	Category	CCP	Monitoring				Critical limit	Corrective action	Record & verification
				What	How	When	Who			
4.Mixing	Any form of physical contamination	Physical	3 (3rd in process)	Sieve	Inspected to ensure it is operating and in good condition	Daily	Maintenance Dept.	All holes < 2 mm Sieve is rotating at 50 revs'/ minute	Replace or repair sieve if any holes >2mm or reset its speed if its out of spec.	Results of monitoring and corrective action

11. Verify the system

The system must be verified periodically to ensure it is effective and up to date. This review should cover all aspects of the HACCP system including the prerequisites, deviations and customer complaints. All records of this review should be in writing and ideally be part of the company's internal audit schedule.

12. Draw up the necessary documentation

There are a number of documents that will be necessary as part of your HACCP system. A minimal list is prescribed here:

- HACCP team (members and expertise).
- End product specifications.
- Process diagrams.
- Prerequisites.
- Risk analysis tables.
- Operating procedures for CCP's.
- Corrective actions and associated documents.

- Verification procedures and results for all of the above.

13. References

Formal guidance on the implementation of HACCP principles is available from the Codex Alimentarius (www.codexalimentarius.net). General principles of Food Hygiene (CAC/RCP 1 – 1969, Rev 4 – 2003. Annex on Hazard Analysis Critical Control Point (HACCP) System & Guidelines for its Application.

Annex 2: GUIDANCE ON THE IMPLEMENTATION OF BASIC HYGIENE RULES

Introduction:

This guidance provides assistance and gives practical examples to conduct and implement measures within manufacturing, storage and transport processes that are essential to comply with the requirements for feed hygiene.

The plant, buildings, facilities and equipment should be designed suitable for the intended use as well as to prevent contamination and to ensure the production of safe feed additives and premixtures. A maintenance system in place including cleaning program and pest control makes sure that appropriate hygiene standards are met at all times. Regular training of the personnel as well as evaluation of the applied programs for suitability and effectiveness are also very important and have to be documented.

1. Buildings and Facilities

- Design and construct all buildings and facilities for manufacture, packaging and storage according to its intended use in a manner that maintenance and cleaning is facilitated.
- Provide buildings and working spaces of sufficient size to allow orderly storage of equipment and materials.
- Construct floors, walls, ceilings and windows of smooth, easily cleanable surfaces.
- Construct ceilings, overhead fixtures and pipes so that the build up of dirt and condensation is minimised.
- Design and construct adequate drainage and waste disposal systems.

2. Personnel Hygiene Facilities

- Ensure that personnel hygiene facilities are suitably designated, located and maintained. They should include:

  a) adequate changing and washing facilities;
  b) adequate number of toilets;
  c) adequate facilities for hand washing and drying;
  d) a constant supply of potable water.

3. Equipment

- Ensure that all equipment is kept clean and adequately maintained.
- Place equipment away from walls to allow easy access for cleaning and to prevent the infestation of pests.

4. Maintenance and Cleaning

- Ensure that all inside and outside areas, buildings, facilities and equipment are kept clean and in good state to function as intended and to prevent contamination.
- Maintain grass areas regularly.
- Cleaning and / or disinfection should remove dirt and residues which may be a source of contamination.

- Cleaning can be carried out by e.g. physical methods like scrubbing and vacuum cleaning and chemical methods using alkaline or acidic agents and methods without the use of water.
- Where appropriate disinfection may be necessary after cleaning.

Cleaning program

Write and implement a cleaning program and specify the following items. Where appropriate consult experts to draw up the program.

a) areas, facilities and equipment to be cleaned
b) method and frequency of cleaning
   - establish a schedule
c) agents used
   - use and store according to the manufacturer's instruction
   - ensure clear labelling of the containers
   - store separate from raw materials and finished products
   - apply properly so as not to contaminate raw materials and finished products
d) responsibilities for the tasks
e) inspection and evaluation
   - perform periodic checks and verify the procedure for suitability and effectiveness
f) training of the personnel
g) record-keeping of all cleaning, inspections and evaluation

5. Pest control

- Ensure that all inside and outside areas, facilities and equipment are in an appropriate condition to avoid creating an environment conductive to pests.
- The following preventive measures can minimise the likelihood of infestation and thus limit the use of pesticides.

  a) check that exterior walls are free of holes
  b) keep doors to the exterior closed when not in use
  c) keep holes and drains sealed or close up with a mesh screen
  d) eliminate potential breeding sites
  e) remove trash daily and store in exterior dumpsters
  f) remove dead insects and spider webs
  g) inspect storage areas regularly for indications of infestation of pests

Pest control plan

Write and implement a pest control plan and specify the following items. Where appropriate consult experts to draw up the plan.

a) areas, facilities and equipment to be inspected
b) methods and / or preventive measures
   - install rodent traps (interior) or rodent bait stations (exterior) and inspect regularly
   - map the positions of traps and bait stations
   - install flying insects defence traps and inspect regularly
   - fit windows with removable and cleanable insect-proof screens
c) pesticides used
   - check and record that they are suitable and comply with local regulations
   - record details of used materials including safety data sheets

- store separate in a secured area

d) responsibilities for the tasks
e) inspection and evaluation
- perform periodic checks and implement corrective actions

f) training of the personnel
g) record-keeping of all applied methods and inspections

6. Waste and drainage

- Identify waste clearly and dispose in a manner which avoids contamination of raw materials and finished products.
- Ensure that drainage lines and sewage systems are watertight and of sufficient capacity.
- Store waste in closed or covered containers at defined waste accumulating areas
- Clean waste accumulating areas regularly.
- Waste containers should be clearly marked and designated for that purpose only.
- Dispose waste and sewage according to local regulations.

7. Personal Hygiene

- Provide workwear such as protective clothing and safety footwear and maintain in hygienic condition.
- If gloves are worn control that there is no risk of contamniation of the finished product.
- Establish clear rules on smoking and eating / drinking on site. If necessary provide separate facilities.

8. Storage

- Prevent cross-contamination by separate storage of raw materials and finished products
- Keep packaging dust-free.
- Store raw materials and finished products under cool and dry conditions to prevent the growth of mould. Control temperature and humidity.
- Keep temperatures as low as possible to avoid condensation.

9. Transport

Please refer to annex 4

10. Evaluation

- Check procedures and programs for suitability and effectiveness and implement corrective actions routinely.

11. Training

- Perform training programs of the personnel regularly and keep records.
- Train the staff that they are aware of their responsibility for feed safety and quality.

Annex 3: GUIDANCE ON THE IMPLEMENTATION OF A COMPLAINT HANDLING SYSTEM

Introduction:

This guidance provides assistance to describe and implement a complaint handling system in case of non-conforming products. It highlights key areas which have to be covered to achieve an effective and efficient procedure for feed additive and premixture operators.

Area	Suggested Action
1. Make information visible to the customers about how and where to complain. Publicise the system to encourage the customers to voice their dissatisfaction and to make the good intentions of the operator apparent.	Publicise your system e.g. • on company invoices • in use and care instructions • on product packaging and labelling • on company internet home page Prepare a form for the complainant (customer) to submit the details required to handle the complaint adequately (see Annex A: Form for complaints)
2. Collect and record complaints	File the forms
3. Acknowledge the receipt of the complaint to the customer immediately	• If possible by phone or in person • By e-mail or post, but avoid impersonal form letters
4. Assess the complaint for validity and evaluate the cause for further handling	Categorise according to e.g. • Severity • Environmental, health and safety risks • Complexity • Impact • Immediate action needed • Immediate action possible
5. Assign the complaint to the person who is the best to deal with	Allocate the responsibilities for handling and controlling the complaints
6. Resolve as soon as possible or further investigate the complaint.	Investigate and analyse all the relevant circumstances and information in an objective manner by getting both sides of the complaint. Keep records of all findings.
7. Make a prompt decision about what to do	Adopt a customer-focused approach. e.g. correct the problem and prevent it happening in the future
8. Communicate the decision to the customer and evaluate the response	
9. If the customer accepts the proposed decision carry out the action timely and effectively	Keep records of the outcome e.g. according to Annex A

Area	Suggested Action
10. If the customer rejects the proposed decision give alternative internal and external options of recourse	Keep records
11. Monitor the progress of the complaint	Until all reasonable internal and external options of recourse are exhausted or the complainant is satisfied
12. Close the complaint	
13. Review complaints regularly. Define the responsibility for review.	A brief review e.g. each month helps to act upon any obvious things that could be changed immediately. A more detailed annual review helps to identify any trends and thus to implement ongoing improvements of the product quality.
14. Establish and implement an action plan for complaint prevention	Summarise corrective actions

Annex A: Form for complaints

Annex A

Form for complaints

Part 1: Information from the complainant

1. Details of complainant
Name / Organisation _____
Address _____
Postal code, town _____
Country _____
Phone No. _____
Fax No. _____
E-Mail
Details of person acting on behalf of complaint (if applicable)
Person to be contacted (if different from above)
2. Product description
Reference number of product/order (if known) _____
Description _____
3. Problem encountered
Date of occurrence _____
Description _____
4. Remedy requested
yes ☐ no ☐
5. Date, signature
Date _____ Signature _____
6. Enclosure
List of enclosed documents

Part 2: Complaint follow-up

1. Details of complaint receipt

Date of complaint _____

Name of recipient _____

Complaint medium phone □ e-mail □ internet □ personally □ postal mail □ other □

Reference number of complaint _____

2. Problem encountered

Date of problem _____

Recurrent problem yes □ no □

Problem category _____

_____

_____

3. Complaint assessment

Severity _____

Complexity _____

Impact _____

Need for immediate action yes □ no □

Availability of immediate action yes □ no □

Likelihood of compensation yes □ no □

4. Complaint resolution

Remedy requested yes □ no □

Action to be taken _____

_____

5. Tracking complaint

Action taken	Date	Name	Remarks
Complaint acknowledged to complainant			
Complaint assessment			
Investigation of complaint			
Information to complainant			
Correction			
Correction verified			
Complaint closed			

Annex 4: GUIDANCE ON TRANSPORT

Introduction:

Transportation of finished goods as well as goods received e.g. raw materials can be a major critical point. Impurities may get into the product that is hazardous to humans or animals. Thus measures must be taken to ensure that the transportation of goods is adequate and minimizes the risk of contamination. Goods received must be checked to find out whether they have been transported in a safe way.

Basically two major categories have to be considered: transportation of packed goods and transportation of loose bulk materials, either liquid or solid.

1. Packaged goods

- If goods are packed in appropriate durable containers they are well protected against the risk of cross contamination with impurities coming from other goods loaded on the same truck/container. This requires that the packaging material is strong enough. The package should provide adequate protection against deterioration of the product that may occur during transportation.
- In order to increase the safety level it is advisable to check transporters for cleanliness. Even though goods are packed there may be items like sharp edges or rusty nails that may damage the packaging.
- All products intended for the usage in the feed or food chain should not be loaded together with other goods that are hazardous. Dust, droplets or gases coming from such goods may contaminate the packaging of feed materials and when these are opened my get into the feed material itself. Thus feed additives or premixtures should be loaded, even if packed, only with goods that do not smell, color and are not hazardous to humans and animals.
- The above-mentioned aspects are to be considered for both, goods delivered and received. In both cases other goods loaded together with feed material and the condition of the transporter may have a serious effect on the integrity of the packaging and the safety of the product.

2. Bulk Transportation

- In case of transporting loose goods in bulk containers cleanliness of the container and loading or unloading equipment is very important.
- The clean status of the containers used can be assured by several steps. First of all ideally a haulier should have sufficient knowledge about handling feed materials. In the best case this is proven by a certification according to a quality standard which is good enough to cover feed transportation.
- Ideally only bulk transporters are used which specifically carry only safe feed ingredients. If this is the case, guaranteed by the container provider and verified by its user through spot checks of information about goods previously transported no other measures need to be taken.
- If a container may be used for transportation of goods hazardous to humans or animals the provider of the transporter shall have cleaning certificates and guarantee that the container is clean. Such cleaning certificates shall be dated and signed and state the method of

cleaning. In addition knowledge of at least the previous load is required. It is even better to know the two or even three last loads.

- Equipment used to load or unload bulk transporters must be checked for cleanliness prior to usage. There could be residual amounts of other products in e.g. pipes that can contaminate the whole load.

3. HACCP

The process of selecting transporters as well as checking of carriers for cleanliness and goods for damage cause by transportation shall be included in the HACCP considerations of an operation. Appropriate steps must be taken to minimize the risk for the product safety due to transportation

Annex 5: GUIDANCE ON HOMOGENEITY

Introduction:

This example procedure can be used to determine the efficacy of blending procedures at producing a product within which all ingredients are uniformly distributed.

As a basic guide, homogeneity trials should carried out biannually. Frequency should be amended according to results. ie. Where mixing times have been adjusted following unacceptable results in a homogeneity trial, the frequency of testing should be increased. Where homogeneity has proven satisfactory over a long period of time frequency may be reduced, bearing in mind that the frequency of testing should always be in line with the frequency noted in quality policies and procedures.

Procedure:

	Instruction	Guidance
1.	Determine product/raw materials to be tested.	Minerals are suggested as an appropriate active ingredient as they are easily assayed and subject to relatively narrow limits of variation.
2.	Take and test retention samples of each raw material before production commences.	
3.	Mix the raw materials in accordance with normal procedure	Mixing times should reflect those used in the normal course of production
4.	When the product and packaged (but not sealed) representative samples should be removed from the batch. A sample must be taken from the first 25Kg of product made and regularly thereafter.	For example, were product packaged into 40 x 25Kg bags, samples should be taken from the first bag and every fifth bag thereafter, (ie every 125Kg) and labelled in accordance with the bag they were removed from, ie, 1, 5, 10, 15, 20, 25, etc.
5.	Each retention sample must be tested for the active ingredients and results recorded.	
6.	The efficacy of the mixing process should be determined by calculating the standard deviation and coefficient of variation of the results.	Standard deviation measures the spread of data about a mean (average) value. The formula is given below. The Coefficient of Variation is the standard deviation expressed as a percentage. Each statistic gives us an impression of how much the distribution of product varies from the mean value. Formula is given below. Quality procedures must define an acceptable limit of variation for Coefficient of Variation.
7.	Records of testing should be maintained in accordance with documented procedures.	

CALCULATION OF STANDARD DEVIATION:

The formula for calculating standard deviation is:

$$\sigma = \sqrt{\frac{\Sigma(x - \bar{x})^2}{n - 1}}$$

σ = lower case sigma

Σ = capital sigma

$\bar{x}$ = x bar

Lower case sigma = 'standard deviation'

Capital sigma = 'the sum of'

x bar = 'the mean'

'n' = number of values

To calculate the Standard Deviation of a group of results, for example, 4, 9, 11, 12, 17, 5, 8, 12, 14

1. Calculate the mean: $\frac{(4 + 9 + 11 + 12 + 17 + 5 + 8 + 12 + 14)}{9}$

$= \frac{92}{9}$

$= 10.222$

2. Subtract the mean individually from each result and square the result.

x	4	9	11	12	17	5	8	12	14
$(x - \bar{x})^2$	38.7	1.49	0.60	3.16	45.9	27.3	4.94	3.16	14.3

3. Add the results in step 2.

$\Sigma(x - \bar{x})^2 = 139.55$

4. Divide by n-1.

$$\sigma = \frac{\Sigma(x - \bar{x})^2}{n - 1} = \frac{139.55}{8}$$

$\sigma = 17.44$

5. Square root:

$$\sigma = \sqrt{\frac{\Sigma(x - \bar{x})^2}{n - 1}} = 4.18$$

CALCULATION OF CO-EFFICIENT OF VARIATION:

1. Co-efficient of variation (CV) is the standard deviation expressed as a percentage of the mean.

In this example CV = 40%

As a guide, a CV of less than 10% is desirable with respect to homogeneity of additive mixes. Operators should establish an acceptable limit for CV based on scientific research and in consideration of specific mixers (refer to HACCP Principles!). Where the CV is greater than the limit set by the operator, corrective action should be implemented. This may include increasing mixing time, looking for worn equipment or overfilling of mixer, or amending the order in which ingredients are added to the mixer.

Annex 6: GUIDANCE ON CARRY-OVER

Cross-contamination or carry over is the contamination of a material or product with another material or product that originates from previous use of equipment.

Cross-contamination has to be controlled during the production process in order to minimize and avoid it, until an acceptable level of carry-over is reached. The operator should follow procedures, documented in records, with all the actions that have been taken to prevent cross contamination.

In order to prevent cross-contamination, special attention should be paid to these processes:

- Transport (contamination with previous cargoes)
- Dosage
- Transport through the circuits within the factory.
- Mixing.
- Preparation and storage.

Operators must ensure that formal systems are in place to minimize the risk of cross-contamination of feed additives and premixtures between them and/or with other products. Operators are required to take measures to avoid this cross-contamination by providing, among others:

- clear labelling
- thorough and complete cleaning of all equipment used between batches;
- use of suitable sequencing and flushing techniques to prevent traces of restricted material entering the production line; and
- use of separate dedicated storage bins to store stock feed additives and premixtures, and to label each bin.

The operator should also be able to provide written procedures specifying:

- Control of the cross-contamination critical points.
- Sampling and analytical results.
- Cleaning of the equipment when changing to a product with different characteristics from the product previously manufactured.
- Verification of the adequate maintenance and cleaning of the equipment (verification of the mixer total opening, verification of the cleaning program, etc.).
- Record the corrective measures taken, including their efficiency, in order to prevent or eliminate cross-contamination.

Practical example:

This example procedure can be used to determine the efficiency of production procedures at preventing the passage of raw materials from one batch of product to subsequent batches of product, such that the efficacy, safety and specification of either product it is not threatened.

Carry-over and cross contamination of batches must be addressed via your HACCP program.

Where process lines may sometimes carry non-EU authorised products, this process must be used to demonstrate that there is no carry-over of this unapproved material into EU destined products.

The basis of this procedure is the production on one production line of a batch of material containing a traceable, easily tested active ingredient, (Batch A) followed by the production of a second batch of product (Batch B), which does not contain the same active ingredient.

This procedure should reflect the actual practices in place on the production line. For example, where it is customary for a flush to take please in between production of batches, this should take place as usual.

Procedure:

	Instruction	Guidance
1.	Determine materials to be used to test	Minerals are suggested as an appropriate active ingredient as they are easily assayed and subject to relatively narrow limits of variation.
2.	Retain samples of all raw materials to be used in the test.	Retention samples to be used in production of Batch B should be taken before production commences and labelled with product name and batch number.
3.	Batch A containing the selected active raw material, must be produced in accordance with normal production procedures.	For example, blending times should reflect normal blending times. Where a flush is normally carried out between batches of production, this should be completed as normal.
4.	A sample of Batch A must be tested and retained.	
5.	If a flush takes place between Batches A and B, samples of the flush material should be taken from the first 25 Kg of flushed product and from the last 25Kg.	For example, were 100 Kg of flush material used and packaged into 25Kg bags, samples should be taken from the first bag and from the fourth bag. Labelling of the samples should identify their source bag.
6.	When Batch B is completely mixed and packaged (but not sealed) representative samples should be removed from the batch. Samples should be taken from the first 3rd and 5th bags. A sample must be taken from the first 25Kg of product made.	Assay each sample individually for the target material. Use your HACCP system to consider if there is a significant risk to the end user, from any one of these results.
7.	All samples (including samples of flush materials) must be tested in accordance with prescribed procedures.	

8.	Batch B should not contain levels of the active ingredient contained in Batch A to an extent that poses a risk to the end user. (Apply your HACCP principles!).	Should Batch B test positive for levels of active ingredient to an extent that causes concern, procedures should be reviewed. For example, procedures for flushing between Batches A and B or production scheduling procedures.
9.	Records of testing should be maintained in accordance with documented procedures	

NOTE: This is a basic example and is intended as guidance only. As the operator, you know your machinery and its limitations better than anyone.

Use results in conjunction with your HACCP program to demonstrate product safety.

Annex 7: GUIDANCE ON SAMPLING

Introduction: (General considerations)

The sampling procedure must be adapted to the purpose of sampling, to the type of controls intended to be applied to the samples, and to the material to be sampled. The procedure should be described in writing. All operation related to sampling should be performed with care, using proper equipment and tools. Any contamination of the sample by dust or other foreign material is liable to jeopardize the validity of the subsequent analyses.

1. Purpose of sampling

Sampling may be required for different purposes such as: acceptance of consignments, batch release testing, in-process-control, special controls, deterioration, adulteration, obtaining retention sample, etc.

2. Sampling facilities

Where possible sampling should be performed in a defined area. Sampling from large containers of starting material or bulk products can present difficulties. Whenever possible this work should be carried out within the warehouse in order to reduce the risk of contamination by dust of either the sample or the remaining material in the container, or cross-contamination.

3. Qualification of the sampler

Everyone called upon to take samples should be trained in the practical aspects of sampling and should have sufficient knowledge of the materials or products to execute the work effectively and safely. A conscientious approach, with meticulous attention to detail and cleanliness, is essential. The sampler must remain alert to any signs of contamination, deterioration or tampering.

4. Health and safety

It is the responsibility of the sampler to read the relevant health and safety information i.e. Material Safety Data Sheet before sampling the material or product. The information must include necessary safety precautions and requirements for both the sampler and the environment. The sampler must wear appropriate protective clothing for the task.

Sampling process:

For the sampling of products the sampler should have at his/her disposal all the tools needed to open the packages, barrels, containers, etc. and material to re-close the packages as well as labels to indicate that a part of the contents has been removed from the package or container. Cleaning of containers due to be sampled should be performed prior to sampling if necessary. All tools and implements should be made of inert materials and kept clean. After use, or before re-use, they should be thoroughly washed, rinsed and dried. They must be stored in clean condition. The use of disposable sampling materials has distinct advantages.

1. Sampling operation and precautions

The sampling procedure should be such that any non-uniformity of the material can be detected. Signs of non-uniformity include differences in shape, size or color of particles in crystalline, granular, or powdered solid substances, moist crusts on hygroscopic substances, deposits of solid material or stratification in liquid products. Such changes, some of which may be readily reversible, can occur during prolonged storage or exposure to extreme temperatures during transportation. Non-homogeneous portions of the material should be sampled separately from the rest of the

material that has a normal appearance. Compositing of the samples from the different portions should be avoided, since it can mask quality problems.

Labeling of samples should indicate appropriate details such as product name or identification code, batch/lot number, quantity, date of sampling, storage conditions, handling precautions, container number, etc. Labels should be applied at the time of sampling.

2. Storage and retention

The container used to store the sample should not interact with the sampled material nor allow contamination. It should also protect the sample from light, air, moisture etc. as required by the storage conditions. Any headspace should be kept to a minimum in case of any degradation through oxidation. Adequate storage conditions must be ensured for the rooms where samples are stored.

Sampling on receipt (for acceptance):

1. Raw materials

If the material of a consignment can be regarded as uniform the sample can be taken from any part of the consignment. If, however, the material is not physically uniform special sampling tools may be required to withdraw a cross-sectional portion of the material. In some instances, however, an attempt can be made to restore the uniformity of the material before sampling, based on information concerning the subsequent handling and manufacturing steps. Thus, a stratified liquid may be stirred, or a solid deposit in a liquid may be dissolved by gentle warming and stirring. Such interventions should not be attempted without adequate knowledge of the properties of the contents and appropriate discussions with owner of the goods.

All partially processed natural products should be treated as intrinsically non-uniform. Special procedures requiring considerable practice are used to prepare representative samples from such consignments.

Sampling plans for raw materials and finished products:

From a practical point it is not prudent to open all containers for sampling.

The number of units depends on different assumptions following the three plans.

2. The n-plan (Assuming a uniform material from a recognized source where there is a high degree of confidence in the source) *

Samples can be withdrawn from any part of the container; usually from the top layer. The n-plan is based on the formula $n = \sqrt{N+1}$, where N is the number of sampling units in the consignment. The value of n is rounded up to the next higher integer. According to this plan samples are taken from n sampling units selected at random and these are subsequently place in separate sample containers. The control laboratory inspects the appearance of the material and tests the identity of each original sample according to the relevant specification. If the results are concordant the original samples are pooled into a final sample from which the analytical sample is prepared, the remaining part being kept as a retention sample.

3. The p-plan (Assuming a uniform material from a recognized source with the main purpose to check identity) *

The p-plan is based on the formula $p = 0.4\sqrt{N}$, where N is the number of sampling units. According to this plan samples are taken from each of the N sampling units of the consignment and placed in separate sample containers. These original samples are visually inspected and tested for identity by a simplified method. If the results are concordant p final samples are conformed by pooling of the original samples.

4. The r-plan (Assuming the material is non-uniform and/or from a source that is not well known) *

The r-plan is based on the formula $r = 1.5\sqrt{N}$, where N is the number of sampling units. Samples are taken from each of the N sampling units of the consignment and placed in separate sample containers. These original samples are transferred to the control laboratory and tested for identity. If the results are concordant r samples are randomly selected and individually subject to testing. If the results are concordant the r samples are pooled for the retention sample.

** Source of the statistical plans: 'WHO GUIDELINE FOR SAMPLING OF PHARMACEUTICALS AND RELATED MATERIALS'*

Annex 8: GUIDANCE ON BIOLOGICAL HAZARDS

1. Microorganisms

The growth of microorganisms is depending on temperature, pH and the media (nutrients).

A special group of microorganisms are the zoonotic pathogens which are the major part of food borne diseases. Therefore, it is important to eliminate those microorganisms in the feedingstuffs, including additives and premixtures. The zoonotic microorganisms are mostly found in the animals' digestive tract and from there transferred to humans via meat, raw milk and eggs. Therefore, the risk of zoonotic microorganisms should be avoided in the manufacture by designing process steps which limit or prohibit growth, kill or remove the organisms.

The operator is responsible for evaluating if other microorganisms may show a risk to feed and food safety, depending on the manufacturing methods, the use and the animal species.

The following zoonotic microorganisms show the major risks linked to feeding of domestic animals:

- ***Salmonella*-**Characteristics:
  - Normal occurrence in the digestive tract in warm-blooded and poikilothermal animals.
  - Growth optimum at 37°C (range 5-46°C).
  - Does not survive pasteurization
  - Relative resistant to freezing processes.
  - pH optimum at 6,5 – 7,5 (range 4,5 – 9,5)
  - Water activity a_w below about 0,95 eliminates growth.
  - ***In general, a food hazard from eggs, poultry, swine, and possible but seldom in cattle.***

- ***Campolybacter*-**Characteristics:
  - Normal occurrence is the digestive tract in warm-blooded animals, including birds.
  - May be found in surface water due to fecal contamination from animals, birds and humans, or from canals leading from fields fertilized with slurry.
  - In general, no growth below 30°C, and not above 43-34°C.
  - Does not grow in products stored at cool temperatures.
  - Sensitive to heating, dehydration, and concentrations of salts above 0.5%.
  - Growth optimum at pH 6,5 – 7,5.
  - ***In general, a food hazard from cattle and poultry.***

- ***Yersinia enterocolitica***
  - Characteristics:
  - Frequent occurrence is in swine.
  - Can grow at low temperature like 0°C and salt concentrations below 5-7%.
  - Growth optimum at pH 7,2 – 7,2 (range pH 4 – 9).
  - ***Swine are healthy carriers, and therefore pork meat presents a food hazard.***

- ***E. Coli*, verotoxin-producing (O157)-**Characteristics:
  - *E. Coli* is a normal bacteria in the digestive tract in humans and most warm-blooded animals.
  - The verotoxin-producing E.Coli is found in cattle, sheep and deer.
  - Growth optimum at 8-45°C, but survive cooling and freezing temperatures almost without decimation, but temperatures above 75°C are killing.

- Lower limit for growth is pH 4 – 4,5, but special species may grow at pH 2.
- ***An uncommon food hazard from cattle.***

2. Viruses

Viruses are linked to materials of animal origin. Such raw materials should not be part of feed additives or premixtures.

3. Pests

Rodents and insects should be controlled, and excluded from access to production areas. An efficient preventive pest control program should be in place.

Annex 9: GUIDANCE ON COMPLIANCE WITH THE EU LEGISLATION ON FEED ADDITIVES AND PREMIXTURES FOR PRODUCT REALISATION

Introduction

This guidance provides assistance in order to assure compliance of the products with the EU legislation as generally required under this guide to good practice:

- Section 6.1 Product Requirements
- Section 6.1.1 Determination of Requirements
- Section 6.1.2 Compliance.
- Section 6.4.1 Sourcing of incoming materials

This document highlights the aspects that have to be covered in order to achieve compliance with statutory and regulatory requirements related to the products as well as to the establishments.

It is important to notice that definitions are found in relevant legislative documents and must be understood before working with this guidance. A collection of the most important definitions are also found in this guide to good practice.

In some countries, some specific statutory or regulatory requirements may come on top of the EU ones, but this is expected to be rather limited as the feed additives and premixtures legislation is a highly integrated area.

1. Products

In the European Union the placing on the market of feed additives and premixtures is ruled by Regulation 1831/2003/EC. The coverage of the Guide to Good Practice is restricted to the additives and premixtures (as defined in Art. 2 of Reg. 1831/2003/EC) that are allowed to be put on the EU market.

1.1. Authorised additives

Only the additives that have been duly authorised by the EU Commission and included in the Register mentioned in Article 17, i.e. the EU Positive List, can be put on the market, at the exclusion of any other additive.

Further to be included in the Register, the additives shall fit to the

- definition,
- specifications and purity criteria,
- labelling requirements, and
- conditions of use that are defined in the authorisation of the additive:
  - animals categories for which the additive is authorised,
  - category and functional group of the additive, and
  - use levels

This has to be considered as requirements at the level of the operator.

Although Reg. 1831/2003/EC is in force, the additive legislation is in practice currently in a transition phase between Directive 70/524/EEC and Regulation 1831/2003/EC. All the information mentioned above may not yet have been included in the Register, because

they were not necessarily part of the original authorisation. The lacking information in the Register shall progressively be completed through the re-authorisation process, at latest by November 2010.

The Community Register of feed additives is available at the following address:

http://europa.eu.int/comm/food/food/animalnutrition/feedadditives/registeradditives_en.htm

The operator shall ascertain and document through a list of additives manufactured, held or managed on the premises, that the additives covered under the this Guide process are only those authorised in the EU. This shall also imply regular update of this documentation in order to adapt to the evolution of the Register and so the requirements of the product, e.g. more precise definition of the additive, change of specifications, etc.

The applicant for an authorisation or his representative shall be established in the Community.

1.2. Premixtures

According to Regulation 1831/2003/EC, premixtures[1] of additives do not require specific product authorisation. They can be manufactured and put on the market, provided they only contain additives duly authorised, and carriers that comply with the EU legislation[2]. The operator shall document that he complies with these requirements.

2. Undesirable substances.

Beside the criteria included in the authorisation of an additive under Regulation 1831/2003/EC, some additives are also covered by the provisions of Directive 2002/32/EC on Undesirable Substances. The operator shall document the relevance or non-relevance of these requirements and, as the case may be, and document compliance. This evaluation shall be included in the HACCP analysis.

3. Products intended for export

An operator may manufacture and hold products that are not in compliance with the EU requirements and not intended for the EU feed market, but for export[3] only. In that case, the operator shall maintain a list of those products that are not intended for the EU market, or intended for other applications.

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1 Definition on premixtures, see definitions.
2 See guidance on carriers, the Annex is under preparation.
3 Definition on export, see definitions.

4. Products intended for import

Products manufactured by any EU member state can freely be transferred from one state to another, provided compliance with Community regulation.

In accordance with Regulation 183/2005/EC, an operator may import[4] products from third countries provided that

- the country appears on a list, drawn in accordance with Article 48 of Regulation 882/2004/EC
- the establishment of dispatch appears on a list, drawn up and maintained by the third country in accordance with Article 48 of Regulation 882/2004/EC
- the feed was produced by the establishment of dispatch
- the feed satisfies the requirements laid down in Community legislation, or those conditions recognised by the Community to be at least equivalent thereto, or where a specific agreement between the Community and the exporting country exists.

Due to interim measures, derogation from the above mentioned requirements is feasible provided that:

- the establishments in the third countries have a representative based within the Community
- the representatives submit to the competent authority in the relevant Member State where they are located:
  - a declaration which ensures that the establishment in the third country fulfils the conditions laid down in the current Feed Hygiene Regulation 183/2005/EC[5].
  - if the appropriate representative is exercising this activity for the first time, the declaration must be accompanied by a commitment to maintain a register of the imported products.

5. Authorised operators.

The Regulation 183/2005/EC on feed hygiene imposes all feed business operators either to be approved or registered prior to the placing on the market of their products.

All additive or premixture operators have to be covered by one or more of the regime as described below and document that they are duly approved or registered.

[4] Definition on import, see definitions.

[5] Before the appearance of Regulation 183/2005/EC the conditions were provided in Directive 95/69/EC.

5.1. Activities requiring approval of the establishment:

Categories	Functional groups	Products
Additives re Regulation 1831/2003/EC		
Nutritional additives	(a)	Vitamins, pro-vitamins, vitamins, pro-vitamins and chemically defined substances having a similar effect
	(b)	Compounds of trace elements
	(c)	Amino acids, their salts and analogues
	(d)	Urea and its derivatives
Zootechnical additives	(a)	Digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials
	(b)	gut flora stabilisers: micro-organisms or other chemically defined substances, when fed to animals, have a positive effect on the gut flora
	(c)	Substances which favourably affect the environment
	(d)	Other zootechnical additives
Technological additives	(b)	Antioxidants with a fixed maximum content in feed only, like propyl gallate, octyl gallate, dodecyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), ethoxyquin
Sensory additives	(a)	Colorants, but only carotenoids and xanttophylls
Products re. Directive 82/471/EEC		
Proteins	-	Proteins obtained from micro-organisms belonging to the group of bacteria, yeasts, algae, lower fungi: all products in the group (except for subgroup 1.2.1 of Directive 82/471/EEC)
Co-products	-	co-products of the manufacture of amino acids by fermentation
Premixtures containing certain additives		
Nutritional additives	(a)	Vitamins, pro-vitamins, vitamins, pro-vitamins and chemically defined substances having a similar effect
	(b)	Compounds of trace elements
Zootechnical additives	(d)	Other zootechnical additives: antibiotics, coccidiostats and histomonostats, growth promoters

5.2. Activities requiring registration of the establishment:

Categories	Functional groups	Products
Additives re Regulation 1831/2003/EC		
Technological additives	(a)	Preservatives
	(c)	Emulsifiers
	(d)	Stabilisers
	(e)	Thickeners
	(f)	Gelling agents
	(g)	Binders
	(h)	Substances for control of radionucleide contamination: Substances that suppress absorption of radionucleides or promote their excretion
	(i)	Anticaking agents
	(j)	Acidity regulators
	(k)	Silage agents
	(l)	Denaturants: Substances which, when used for manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed material
Premixtures containing certain additives		
Categories not requiring approvals	Any functional group	Premixtures containing any feed additive, excluding - vitamin A and D - copper and selenium

6. Labelling

The Regulation 1831/2003/EC on additives for use in animal nutrition lays down the rules for the labelling of feed additives and premixtures. Labelling provisions are described in Article 16 of this Regulation.

References:

List of EU legislation related to this guidance:

- 183/2005/EC Regulation laying down requirements for feed hygiene
- 1831/2003/EC Regulation on additives for use in animal nutrition
- 2002/32/EC Directive on undesirable substances in animal feed
- 82/471/EEC Directive concerning certain products used in animal nutrition
- 70/524/EEC Directive concerning additives in feeding-stuffs

Annex 10: GUIDANCE ON CARRIERS FOR PREMIXTURES

Introduction

This guidance provides assistance to operators to comply with the requirements of the Guide to Good Practice for Feed Additives and Premixtures Operators regarding the safety of carriers[6].

For a better understanding, take into account the following concepts:

- Carrier suppliers are feed business operators included in the scope of Regulation 183/2005/EC, and consequently the establishments must be approved or registered by the competent authorities. Written declaration from the supplier of compliance with the Regulation 183/2005/EC will be required.
- The risk assessment for carriers is linked to the production process and consequently under the responsibility of the supplier.
- The operator of premixtures must evaluate and ensure that the incoming material is suitable for the purpose.
- Carriers are handled as feed materials, and belong to a group that covers a wide variety of materials of different nature[7].

Carriers are incoming materials and must comply with the specific requirements as detailed in the Guide to Good Practice for Feed Additives and Premixtures Operators sections 6.4 “Incoming materials” and 6.5.3 “Identification and traceability”, including:

- Maintain a procedure on how to approve new suppliers
- Maintain a list of approved suppliers and approved establishments (Regulation 183/2005/EC). The list should include the name, address and products they supply.
- Maintain records of conformity statements
- Maintain records of material specifications
- Maintain documents on production process description, including risk assessment, listing potential hazards of the material, control measures and corrective actions, as required in the annex of the “Recommended International Code of Practice General Principles OF Food Hygiene” of the Codex Alimentarius, CAC/RCP 1-1969, Rev. 4, 2003.

The operator has to check that the products provided by the supplier are in compliance with the EU Directive 96/25/EEC and not comprised by the prohibited materials as laid down in the Decision 2004/217/EC.

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6 **Definition on 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.

7 **List of feed materials:** The Annex Part A of the Directive 96/25/EEC contains general provisions, e.g. a list dividing feed materials into 12 subgroups. This official list is copied to this guidance, see Annex I. The Annex part B of the Directive contains a non-exclusive list of the main feed materials by listing the number, name, description and compulsory declaration.

The feed safety of the carrier must be verified when entering the operators' premises according to section 6.4.2 "Verification of incoming materials" by:

- Inspection of the incoming carrier
- Registration of
    - Name of the supplier
    - Supplier's name of the carrier
    - Supplier's lot/batch number and expiry date
    - Delivery data (quantity, date)
- Approval of the delivery
- Inspection and archival of the supplied documents.

The operator must evaluate the risks and CCPs introduced by the supplier of a carrier in order to ensure feed safety of the premixtures.

Risk assessment:

As introduced before, there is a wide variety of products and it is not a priori possible to assume that a carrier is safe or not. The supplier should provide compelling evidence that he has conducted a throughout risk assessment analysis of its product in the perspective the intended feed use, and bring enough information to identify the specific hazards of each carrier. This assessment should demonstrate that risk is under control and allow us to identify CCPs.

The following basic risks need to be considered in a HACCP study by the supplier:

1. Biological and microbiological risks
2. Chemical risks
3. Physical risks

1. Biological and microbiological risks

1.1. Contamination with microorganisms

Potential critical control points are the control of the microorganisms documented in the supplier specification, e.g. salmonella, campylobacter.

2. Chemical risks

2.1. Contamination with undesirable substances originating from raw materials (including pesticides, dioxins, heavy metals, etc)
2.2. Contamination with impurities, originating from the downstream process

Potential critical control points are the control of the chemical contamination documented in the supplier specification.

3. Physical risks

3.1. Contamination with foreign materials (particles, pest infestation, tools etc.)
3.2. Particle size of the carrier

This is a generic risk which applies to most other processes as well. Potential critical control points are filters, sieves, metal detectors as well as maintenance and packaging procedures.

4. Critical control points

The potential critical control points shall be evaluated. The conclusion being, that they are covered either by the prerequisite control program (feed hygiene procedures) or controlled as a Critical Control Point (CCP) with defined acceptance limits.

ANNEX I

Introduction to subgroups of feed materials

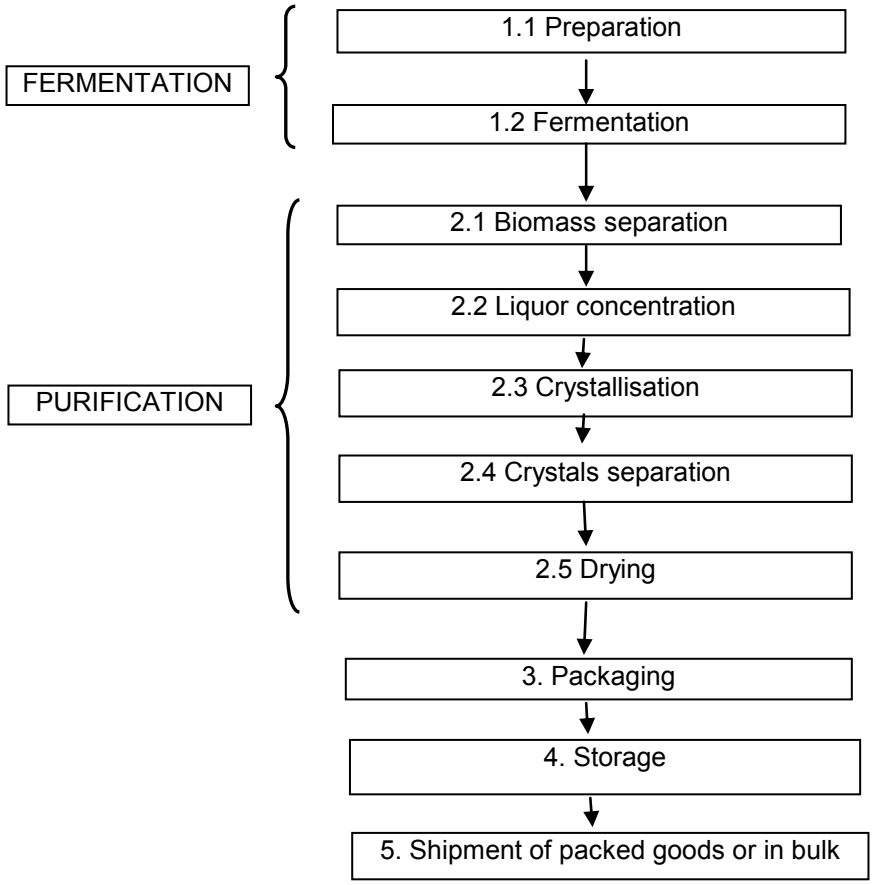
For the full understanding, it is important to look into the Directive 96/25/EC and amendments

1. Cereal grains, their products and by-products
2. Oil seeds, oil fruits, their products and by-products
3. Legume seeds, their products and by-products
4. Tubers, roots, their products and by-products
5. Other seeds and fruits, their products and by-products
6. Forages and roughage
7. Other plants, their products and by-products
8. Milk products
9. Land animal products
10. Fish, other marine animals, their products and by-products
11. Minerals[8]
12. Miscellaneous

[8] **Minerals** are in everyday usage also referred to as macrominerals to distinguish from trace elements. When consulting the Annex Part B, chapter 11, it is obvious what is included in the subgroup minerals.

Annex 11: GUIDANCE ON RISK ASSESSMENT IN PRODUCTION

Standard Fermentation process for manufacturing of feed additives



Risk Assessment

- **Fermentation Processes**

Production characteristics

The typical production process consists in producing of molecules by microorganisms. The microorganisms are fed by carbon, nitrogen raw materials and micronutrients. After a growth step, the microorganisms produce the expected product. Then the target molecule is separated from the biomass and is purified.

HACCP Analysis

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
BASIC ISSUES PRERREQUISITE PROGRAM (PRP) – see also Annex 2					
Incoming materials: • **Raw materials**	Purchase & sourcing of raw materials	**Presence of foreign objects like : glass, metal parts, ropes, scoops, synthetic materials, (small) stones, tools, internal liners of equipment, insulation materials, wood, jewellery from operators.**	**P**	• **Raw material specification and receiving inspection** • **Suitable process design and downstream filtration steps**	
		Presence of undesirable substances, e.g. heavy metals, pesticides, as described in Directive 2002/32/EC and its amendments.	**C**	• **Raw material specification and receiving inspection.** • **Supplier information, e.g. certificates, conformance statements, or contractual agreements** • **Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
		Presence of micro-organisms or virus.	**B**	• **Raw material specification and receiving inspection.** • **Supplier information, e.g. certificates, conformance statements, or contractual agreements** • **Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization, heating.**	
	Purchase & sourcing of raw materials used in the downstream purification steps	**Raw materials used in the downstream purification steps, certain contaminants are considered when establishing the raw material specification, e.g. pathogenic micro-organisms, virus.**	**B**	• **Raw material specification and receiving inspection.** • **Contractual agreements**	
• **Indirect materials**	Purchase of indirect materials, e.g. lubricants, cleaning agents	**Presence of toxic substances may result in contaminated products**	**C**	• **Ensure suitable supplier documentation**	
• **Water**	Water may be supplied from communities or from wells, and used as process ingredient and cleaning	**Water pipes and reservoirs may constitute to** ▪ **growth of microbes, and** ▪ **dissolution of substances.** **In certain cases, purification systems may be established due to product quality.**	**BC**	• **When an ingredient, use potable water or a quality suitable for feeding animals** • **Prevent storage at temperatures which support growth of microbes** • **Monitor official control of potable water or the alternative water source** • **Separate non-potable water systems from potable water systems**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
• **Packaging material**	Purchase, Sourcing , Use and possible re-use of packaging	**Contamination via packaging containers or materials or parts of it.** ***Specific considerations:*** • **Special units like drying bags may present a contamination risk**	**CBP**	• **Measures to avoid contamination of empty containers, bags, lids, ect.** • **Packaging design and materials shall provide adequate protection for products to minimize product contamination during use** • **Minimize damage during handling** • **Accommodate proper labelling** • **Re-saleable packaging (also internal usage) shall be suitable durable, easy to clean and, where necessary, disinfect** • **Measures to prevent Silica gel drying bags or closing straps to contaminate the product**	
Maintenance	Maintenance work may conflict with on-going processes	**Possible contamination of equipment after maintenance**	**CP**	• **Documented cleaning after maintenance** • **Ensure that excess of lubricants are prevented from entering the process equipment**	
Cleaning	Cleaning of product contact surfaces and the production environment	**Possible contamination if equipment is not cleaned to an acceptable level.** **Possible residues of cleaning agents. The environment may cause cross contamination.** **Wet cleaning of equipment used for dry products may support growth of microbes.**	**C** **B**	• **Ensure adequate cleaning programs of equipment** • **Ensure cleaning is documented** • **Control carry-over** • **Ensure an adequate level of environmental hygiene (rooms, floors, the outside of equipment)** • **Prevent condensate from entering process equipment**	
Sampling operations		**Dirty sampling tool → Foreign body** **Glass sampling tool → Chip of glass**	**P**	• **Cleaning of sampling tool** • **Storage of sampling tool** • **Hands washing** • **Glass policy**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
Open air steps		**Use of dirty tool → Foreign body**	**P**	• **Cleaning of tool** • **Hands washing** • **Storage of tool**	
		Use of tool made up of wood → Chip of wood	**P**	• **Wood policy**	
		Loss of object → Foreign body	**P**	• **Rules about jewellery and other objects wearing (e.g. pencil)**	
		Insects / Rodents → Foreign body or bacteriological contamination	**P/B**	• **Closing of outside accesses** • **Pest control**	
		Flakes of ceiling paintwork / Flakes of rust → Foreign body	**P**	• **Infrastructure maintenance**	
Transportation (see also Annex 4) • **Incoming**	Bulk transport of incoming ingredients	**Possible contamination from previous loads**	**CBP**	▪ **Contractual agreements with suppliers** ▪ **Dedicated tank transport** ▪ **Ask for cleaning certificates and previous loads before unloading** ▪ **Use only certified and registered transporters according the requirements**	
Transportation (see also Annex 4) ▪ **Outgoing**	Bulk transport of outgoing products as well as packed products	**Possible contamination from previous loads**	**CBP**	**Bulk:** ▪ **Contractual agreements with transporters** ▪ **Inspection before loading /dedicated transport** ▪ **Require and investigate cleaning certificates before loading** ▪ **Use only certified and registered transporters according the requirements** **Packed products:** ▪ **Contractual agreements with transporters** ▪ **Inspection of truck before loading**	

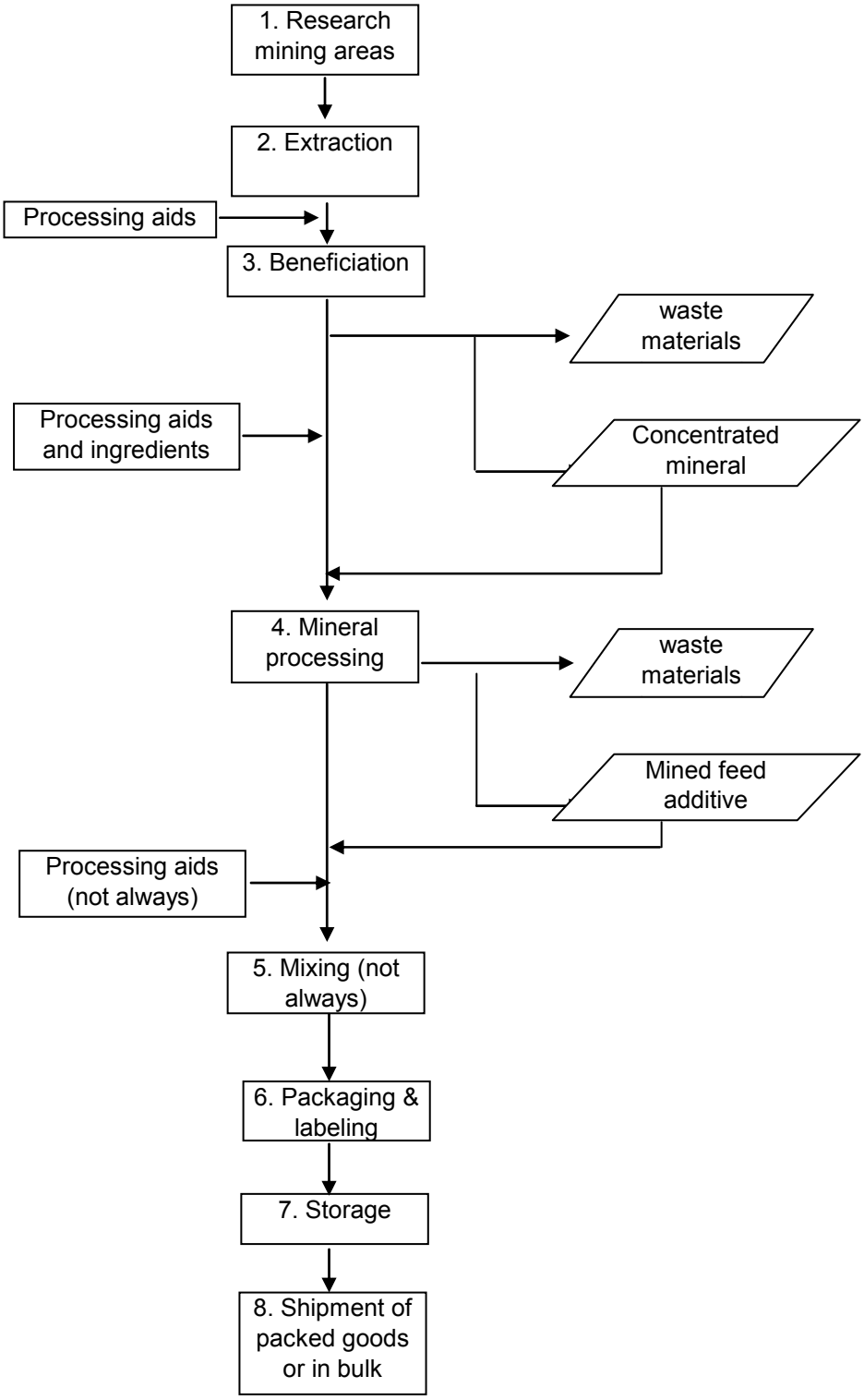
Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
PROCESS STEPS					
1.Fermentation					
1.1 Preparation	Growth of strain population	**Failure in asepsis conditions → Growth of contaminating micro organisms**	**B**	• **Process rules to avoid any contamination**	
		Growth of contaminating micro organisms → Degradation of the intended product into undesirable substances	**C/B**	• **Process rules to avoid any contamination**	
1.2 Fermentation	Production of the intended product	**Failure in asepsis conditions → Growth of contaminating micro organisms**	**B**	• **Process rules to avoid any contamination**	
		Growth of contaminating micro organisms → Degradation of the intended product into undesirable substances	**C**	**Process rules to avoid any contamination**	
		Failure in equipment maintenance → Loss of screw, bolt or part of equipment	**P**	• **Preventive maintenance program**	
2. Purification					
2.1 Biomass separation	Separation of intended product from the rest of the broth	**Favourable pH and T°C conditions→ Growth of contaminating micro organisms (e.g. attached growth)**	**B**	• **Pasteurization / sterilization of equipment / Cleaning In Place** • **pH / T°C conditions monitoring**	
		Loss of strain cells through the separation system → Bacteriological contamination	**B**	• **Preventive maintenance program** • **- Turbidity monitoring**	
		Loss of strain cells through the separation system → Cells carbonization in downstream (black spots)	**P**	• **Preventive maintenance program** • **Turbidity monitoring**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
		Lubricant leak in agitator → Undesirable substances	**C**	• **Preventive maintenance program** • **Double lubricant tightness** • **Food grade lubricant / grease**	
		Clogging of equipment by cells cream → Growth of contaminating micro organisms	**B**	• **Cleaning program**	
		Breakage of agitator system → Foreign body contamination	**P**	• **Preventive maintenance program**	
		Leak of lubricant during the greasing operation of bearings → Undesirable substances	**C**	• **Instructions** • **Food grade lubricant / grease**	
2.2 Liquor concentration	Increase of intended product concentration	**Crack in heating system → Steam contamination**	**C**	• **Preventive maintenance program** • **Monitoring of steam treatment products**	
		Deterioration of joints → Foreign bodies	**P**	• **Preventive maintenance program**	
		Carbonization of deposit → Black spots	**P**	• **Cleaning program**	
		Deposit → Growth of undesirable micro organisms	**B**	• **Cleaning program**	
2.3 Crystallization	Getting crystals by using the physical and chemical properties of intended product	**Crack in cooling system → Contamination by not drinking water**	**C / B**	• **Preventive maintenance program**	
		Leak of lubricant in speed reducer → Undesirable substances	**C**	• **Man hole protection (edge)** • **Speed reducer design** • **Preventive maintenance program** • **Food grade lubricant / grease**	
		Clogging on cooling coil → Growth of undesirable micro organisms	**B**	• **Cleaning program**	
2.4 Crystals separations	Separation of liquid phase from crystals	**Leak of lubricant in spin drier→ Undesirable substances**	**C**	• **Machine design** • **Food grade lubricant / grease**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
		Filter/sieve degradation in spin drier→ Chip of foreign body	**P**	• **Filter/sieve design** • **Preventive maintenance program**	
		Clogging up of spin drier → Growth of undesirable micro organisms	**B**	• **Cleaning program**	
		Clogging up of belt filter → Growth of undesirable micro organisms	**B**	• **Cleaning program**	
		Breakage of bucket lifting → Foreign body	**P**	• **Preventive maintenance program** • **Machine design**	
2.5 Drying	Getting the final product in compliance with the dry matter requirements	**Deterioration of outside air system filtration → Contamination with dust and/or filtering media**	**P**	• **Filtration system design** • **Preventive maintenance program**	
	Dryer	**Fire extinguishment system set off → Contamination by extinguishment product**	**C**	• **Food grade extinguishment product**	
		Loss of screw or part of equipment → Foreign body contamination	**P**	• **Machine design** • **Preventive maintenance program**	
		Crack in heating/cooling system → Steam/not drinking water contamination	**C**	• **Preventive maintenance program**	
		Lubricant leak in conveyor helix→ Undesirable substances	**C**	• **Machine design** • **Food grade lubricant/grease**	
		Boring of sieve → Chip of sieve	**P**	• **Preventive maintenance program**	
	Conveyor ***Sieve***	**Lubricant leak in crusher → Undesirable substances**	**C**	• **Machine design** • **Food grade lubricant/grease**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
3. Packaging	Packaging of the products in bags, boxes, drums, bigbags, IBC's etc.	**Contamination via the packaging process**	**CBP**	**-Packaging via dedicated production lines and packaging machines** **-Cleaning& inspection procedures** **-Usage on new and/or clean packaging materials**	
	Identify the products with the right label identification according to the applicable legislation and to be able to track & trace the products	**Wrong labelling & identification of the product could lead to wrong usage or unable to do a complete recall in case it would be necessary**	**CBP**	**-Labelling procedures** **-Check on batch identification system**	
4. Storage	Storage and keeping of feed additives	**Exposure to rain and/or damp conditions.** **Spoilage due to condensation and mould growth.** **Cross contamination with other feed materials.** **Contamination with other non-feed materials such as chemicals, fertilizers.** **Deterioration of the product due to poor stock rotation.** **Products for different species and medicated and unmedicated feeds not adequately segregated.**	**CBP**	**-Training and education of employees** **-Weatherproof storage facilities.** **- Effective segregation of different materials particularly when stored on floors.** **- Cleanout procedures between different types of products** **- Separate storage areas for feed and non-feed materials.** **- Proper stock rotation.** **- Effective consolidation and sheeting of clamped forages.**	
5. Shipment of packed goods or in bulk	Packed goods			**- Contractual agreements with transporters** **- Inspection before loading /dedicated transport** **- Use only certified and registered transporters according the requirements**	
	Bulk shipment			**- Contractual agreements with transporters** **- Inspection before loading /dedicated transport** **- Info about previous load(s) and request for cleaning certificates** **- Use only certified and registered transporters according the requirements**	

Standard Mining process for manufacturing of feed additives



Risk Assessment

- **Mining Processes**

Production characteristics

Mining is the extraction of valuable minerals or other geological materials from the earth. Mineral processing (or mineral dressing) is mainly based in various mechanical means of crushing, grinding, and washing that enable the separation (extractive metallurgy) of valuable metals or minerals from their gangue (waste material).

HACCP Analysis

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
BASIC ISSUES PRERREQUISITE PROGRAM (PRP) – see also Annex 2					
Incoming materials: • **Raw materials**	Purchase & sourcing of raw materials	**Presence of foreign objects like : glass, metal parts, ropes, scoops, synthetic materials, (small) stones, tools, internal liners of equipment, insulation materials, wood, jewellery from operators.**	**P**	• **Raw material specification and receiving inspection** • **Suitable process design and downstream filtration steps**	
		Presence of undesirable substances, e.g. heavy metals, pesticides, as described in Directive 2002/32/EC and its amendments.	**C**	• **Raw material specification and receiving inspection.** • **Supplier information, e.g. certificates, conformance statements, or contractual agreements** • **Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
		Presence of micro-organisms or virus.	**B**	• **Raw material specification and receiving inspection.** • **Supplier information, e.g. certificates, conformance statements, or contractual agreements** • **Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization, heating.**	
• **Indirect materials**	Purchase of indirect materials, e.g. lubricants, cleaning agents	**Presence of toxic substances may result in contaminated products**	**C**	• **Ensure suitable supplier documentation**	
• **Water**	Water may be supplied from communities or from wells, and used as process ingredient and cleaning	**Water pipes and reservoirs may constitute to** ▪ **growth of microbes, and** ▪ **dissolution of substances.** **In certain cases, purification systems may be established due to product quality.**	**BC**	• **When an ingredient, use potable water or a quality suitable for feeding animals** • **Prevent storage at temperatures which support growth of microbes** • **Monitor official control of potable water or the alternative water source** • **Separate non-potable water systems from potable water systems**	
• **Packaging material**	Purchase, Sourcing , Use and possible re-use of packaging	**Contamination via packaging containers or materials or parts of it.** ***Specific considerations:*** • **Special units like drying bags may present a contamination risk**	**CBP**	• **Measures to avoid contamination of empty containers, bags, lids, ect.** • **Packaging design and materials shall provide adequate protection for products to minimize product contamination during use** • **Minimize damage during handling** • **Accommodate proper labelling** • **Re-saleable packaging (also internal usage) shall be suitable durable, easy to clean and, where necessary, disinfect** • **Measures to prevent Silica gel drying bags or closing straps to contaminate the product**	
Maintenance	Maintenance work may conflict with on-going processes	**Possible contamination of equipment after maintenance**	**CP**	• **Documented cleaning after maintenance** • **Ensure that excess of lubricants are prevented from entering the process equipment**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
Cleaning	Cleaning of product contact surfaces and the production environment	**Possible contamination if equipment is not cleaned to an acceptable level.** **Possible residues of cleaning agents. The environment may cause cross contamination.** **Wet cleaning of equipment used for dry products may support growth of microbes.**	**C** **B**	• **Ensure adequate cleaning programs of equipment** • **Ensure cleaning is documented** • **Control carry-over** • **Ensure an adequate level of environmental hygiene (rooms, floors, the outside of equipment)** • **Prevent condensate from entering process equipment**	
Sampling operations		**Dirty sampling tool → Foreign body** **Glass sampling tool → Chip of glass**	**P**	• **Cleaning of sampling tool** • **Storage of sampling tool** • **Hands washing** • **Glass policy**	
Storage ▪ **Packed products and materials**	Storage of containers and bags	**Storage areas are sensitive to pest infestation, foreign objects and dirt in general. Degradation or microbial growth if temperature is not controlled in an adequate manner.**	**PCB**	▪ **Prevent pests from coming into the buildings / rooms by having closed doors / gates and screened windows when opened** ▪ **Prevent cross-contamination when containers / bags are damaged** ▪ **Adequate control of temperature (ambient, cold, freezer)**	
▪ **Bulk**	Storage on floor or silos of raw materials; products are probably not relevant for this topic	**Floor storage is sensitive to pest infestation, foreign objects and dirt from handling fork-lifts.** **Degradation or microbial growth if temperature is not controlled in an adequate manner.**	**PCB**	▪ **Prevent pests from coming into the building / room by having closed doors / gates.** ▪ **Adequate control on handling the raw material** ▪ **Adequate control of temperature (ambient or cold)**	
Pest control	Pest control	**Possible contamination if pests infest rooms or buildings or if pesticide are used**	**BC**	▪ **Prevent pests from coming into the buildings by having closed doors / gates and screened windows when opened** ▪ **Good hygiene practices** ▪ **Good sanitation, inspection of incoming materials and effective monitoring** ▪ **Ensure correct use of pesticides**	

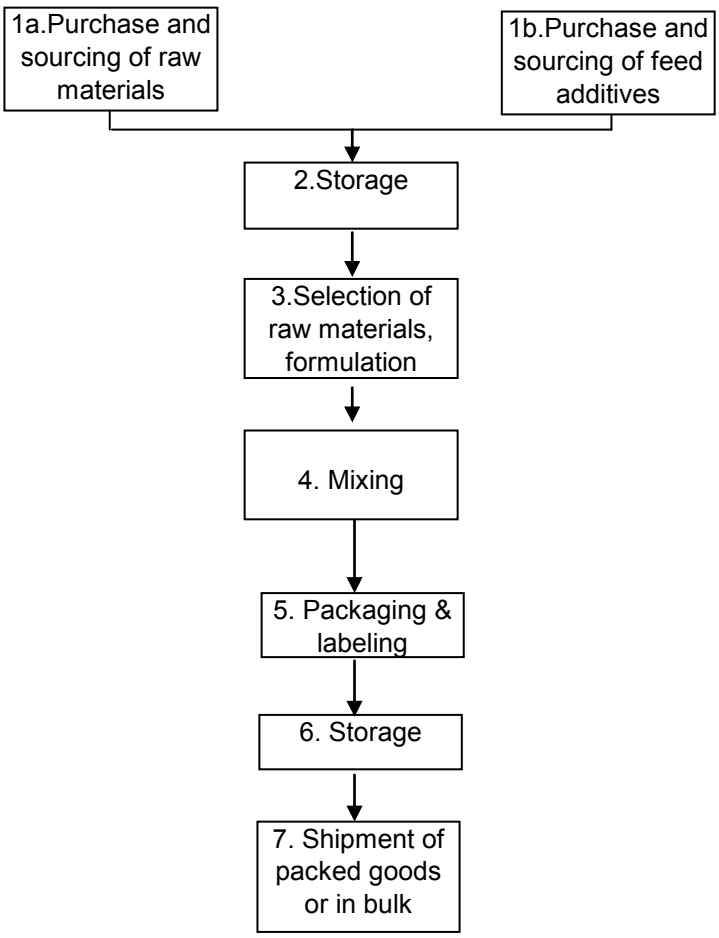
Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
Transportation (see also Annex 4) ▪ **Incoming**	Bulk transport of incoming ingredients	**Possible contamination from previous loads**	**CBP**	▪ **Contractual agreements with suppliers** ▪ **Dedicated tank transport** ▪ **Ask for cleaning certificates and previous loads before unloading** ▪ **Use only certified and registered transporters according the requirements**	
Transportation (see also Annex 4) ▪ **Outgoing**	Bulk transport of outgoing products as well as packed products	**Possible contamination from previous loads**	**CBP**	**Bulk:** ▪ **Contractual agreements with transporters** ▪ **Inspection before loading /dedicated transport** ▪ **Require and investigate cleaning certificates before loading** ▪ **Use only certified and registered transporters according the requirements** **Packed products:** ▪ **Contractual agreements with transporters** ▪ **Inspection of truck before loading**	
PROCESS STEPS					
1. Research in mining areas	Research in mining areas	**Natural contamination of the ore with heavy metals, dioxins**	**C**	• **Following processes to reduce the level of undesirable substances to an acceptable level** • **Compliance of the final product with legislation on undesirable substances**	
2. Extraction	Removal of rocks of diverse hardness and toughness from earth	**Oils, antifreezes and greases spilled during the process by heavy machinery (bulldozers, drills, explosives and trucks).**	**CP**	• **Good hygienic practices** • **Regular inspection of machinery, maintenance programme**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
		Contamination with foreign materials from machinery and operators like: glass, metal parts, ropes, scoops, synthetic materials, tools, internal liners of equipment, insulation materials, wood, jewellery from operators.			
3. Beneficiation	Operations to separate and concentrate the mineral values from waste through different physical and chemical techniques. This is typically performed by employing various crushing, grinding and froth flotation techniques	**Formation of contaminants and toxics due to inappropriate chemical reactions, high temperatures, residues of solvent, processing reagents…** **Contamination with foreign materials from equipment and operators like: oils, greases, glass, metal parts, ropes, scoops, synthetic materials, tools, internal liners of equipment, insulation materials, wood, jewellery from operators.**	**CP**	• **Written and standardized protocols, good laboratory practices** • **The downstream process removes the by-products to an acceptable level** • **Good hygienic practices** • **Regular inspection and calibration of the equipment**	
4. Mineral Processing	Operations to destroy the physical structure of the mineral and modify its chemical composition into a more useful chemical form. Include techniques such as smelting, electrolytic refining and acid attack or digestion (most are indistinguishable from chemical and refining plants)	**Formation of contaminants and toxics due to inappropriate chemical reactions, high temperatures, residues of solvent, processing reagents…** **Contamination with foreign materials from equipment and operators like: glass, metal parts, ropes, scoops, synthetic materials, tools, internal liners of equipment, insulation materials, wood, jewellery from operators.**	**CP**	• **Written and standardized protocols, good laboratory practices** • **The downstream process removes the by-products to an acceptable level** • **Good hygienic practices** • **Regular inspection and calibration of the equipment**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
5. Mixing Process		**Cross contamination** **Incorrect dosage** **Non-uniform distribution of ingredients**	**CP**	• **Cleanliness of the mixer** • **Written maintenance schedules 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, or only use dedicated mixing** • **Adequate dosing system** • **Use of food grade oils and detergents** • **Regularly test mixer efficiency**	
6. Packaging & Labelling	Packaging of the products in bags, boxes, drums, bigbags, IBC's etc.	**Contamination via the packaging process**	**CBP**	• **Packaging via dedicated production lines and packaging machines** • **Cleaning & inspection procedures** • **Usage on new and/or clean packaging materials**	
	Identify the products with the right label identification according to the applicable legislation and to be able to track & trace the products in cases it is necessary	**Wrong labelling & identification of the product could lead to wrong usage or unable to do a complete recall in case it would be necessary**	**CBP**	• **Labelling procedures** • **Check on batch identification system**	
7. Storage	Storage and keeping of feed additives	**Exposure to rain and/or damp conditions.** **Spoilage due to condensation and mould growth.** **Cross contamination with other feed materials.** **Contamination with other non-feed materials such as chemicals, fertilizers.**	**CBP**	• **Training and education of employees** • **Weatherproof storage facilities.** • **Effective segregation of different materials particularly when stored on floors.** • **Cleanout procedures between different types of products** • **Separate storage areas for feed and non-feed materials.** • **Proper stock rotation.** • **Effective consolidation and sheeting of clamped forages.**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
		Deterioration of the product due to poor stock rotation. **Products for different species and medicated and unmedicated feeds not adequately segregated.**			
8. Shipment of packed goods or in bulk	Packed goods			• **Contractual agreements with transporters** • **Inspection before loading /dedicated transport** • **Use only certified and registered transporters according the requirements**	
	Bulk shipment			• **Contractual agreements with transporters** • **Inspection before loading /dedicated transport** • **Info about previous load(s) and request for cleaning certificates** • **Use only certified and registered transporters according the requirements**	

Standard process for manufacturing premixtures



Risk Assessment

- **Production of Premixtures**

Production characteristics

The typical production process consists of a dry blending of certain micronutrients like minerals, vitamins etc. with suitable carriers in multi purpose equipment.

HACCP Analysis

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
BASIC ISSUES PRERREQUISITE PROGRAM (PRP) – see also Annex 2					
Incoming materials: • **Raw materials and feed additives**	Purchase & sourcing of raw materials	**Presence of foreign objects like : glass, metal parts, ropes, scoops, synthetic materials, (small) stones, tools, internal liners of equipment, insulation materials, wood, jewellery from operators.**	**P**	• **Raw material specification and receiving inspection** • **Suitable process design and downstream filtration steps**	
		Presence of undesirable substances, e.g. heavy metals, pesticides, as described in Directive 2002/32/EC and its amendments.	**C**	• **Raw material specification and receiving inspection.** • **Supplier information, e.g. certificates, conformance statements, or contractual agreements** • **Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
		Presence of micro-organisms or virus.	**B**	• **Raw material specification and receiving inspection.** • **Supplier information, e.g. certificates, conformance statements, or contractual agreements** • **Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization, heating.**	
• **Indirect materials**	Purchase of indirect materials, e.g. lubricants, cleaning agents	**Presence of toxic substances may result in contaminated products**	**C**	• **Ensure suitable supplier documentation**	
• **Water**	Water may be supplied from communities or from wells, and used as process ingredient and cleaning	**Water pipes and reservoirs may constitute to** ▪ **growth of microbes, and** ▪ **dissolution of substances.** **In certain cases, purification systems may be established due to product quality.**	**BC**	• **When an ingredient, use potable water or a quality suitable for feeding animals** • **Prevent storage at temperatures which support growth of microbes** • **Monitor official control of potable water or the alternative water source** • **Separate non-potable water systems from potable water systems**	
• **Packaging material**	Purchase, Sourcing , Use and possible re-use of packaging	**Contamination via packaging containers or materials or parts of it.** ***Specific considerations:*** • **Special units like drying bags may present a contamination risk**	**CBP**	• **Measures to avoid contamination of empty containers, bags, lids, ect.** • **Packaging design and materials shall provide adequate protection for products to minimize product contamination during use** • **Minimize damage during handling** • **Accommodate proper labelling** • **Re-saleable packaging (also internal usage) shall be suitable durable, easy to clean and, where necessary, disinfect** • **Measures to prevent Silica gel drying bags or closing straps to contaminate the product**	
Maintenance	Maintenance work may conflict with on-going processes	**Possible contamination of equipment after maintenance**	**CP**	• **Documented cleaning after maintenance** • **Ensure that excess of lubricants are prevented from entering the process equipment**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
Cleaning	Cleaning of product contact surfaces and the production environment	**Possible contamination if equipment is not cleaned to an acceptable level.** **Possible residues of cleaning agents. The environment may cause cross contamination.** **Wet cleaning of equipment used for dry products may support growth of microbes.**	**C** **B**	• **Ensure adequate cleaning programs of equipment** • **Ensure cleaning is documented** • **Control carry-over** • **Ensure an adequate level of environmental hygiene (rooms, floors, the outside of equipment)** • **Prevent condensate from entering process equipment**	
Sampling operations		**Dirty sampling tool → Foreign body** **Glass sampling tool → Chip of glass**	**P**	• **Cleaning of sampling tool** • **Storage of sampling tool** • **Hands washing** • **Glass policy**	
Storage ▪ **Packed products and materials**	Storage of containers and bags	**Storage areas are sensitive to pest infestation, foreign objects and dirt in general. Degradation or microbial growth if temperature is not controlled in an adequate manner.**	**PCB**	▪ **Prevent pests from coming into the buildings / rooms by having closed doors / gates and screened windows when opened** ▪ **Prevent cross-contamination when containers / bags are damaged** ▪ **Adequate control of temperature (ambient, cold, freezer)**	
▪ **Bulk**	Storage on floor or silos of raw materials; products are probably not relevant for this topic	**Floor storage is sensitive to pest infestation, foreign objects and dirt from handling fork-lifts.** **Degradation or microbial growth if temperature is not controlled in an adequate manner.**	**PCB**	▪ **Prevent pests from coming into the building / room by having closed doors / gates.** ▪ **Adequate control on handling the raw material** ▪ **Adequate control of temperature (ambient or cold)**	
Pest control	Pest control	**Possible contamination if pests infest rooms or buildings or if pesticide are used**	**BC**	▪ **Prevent pests from coming into the buildings by having closed doors / gates and screened windows when opened** ▪ **Good hygiene practices** ▪ **Good sanitation, inspection of incoming materials and effective monitoring** ▪ **Ensure correct use of pesticides**	

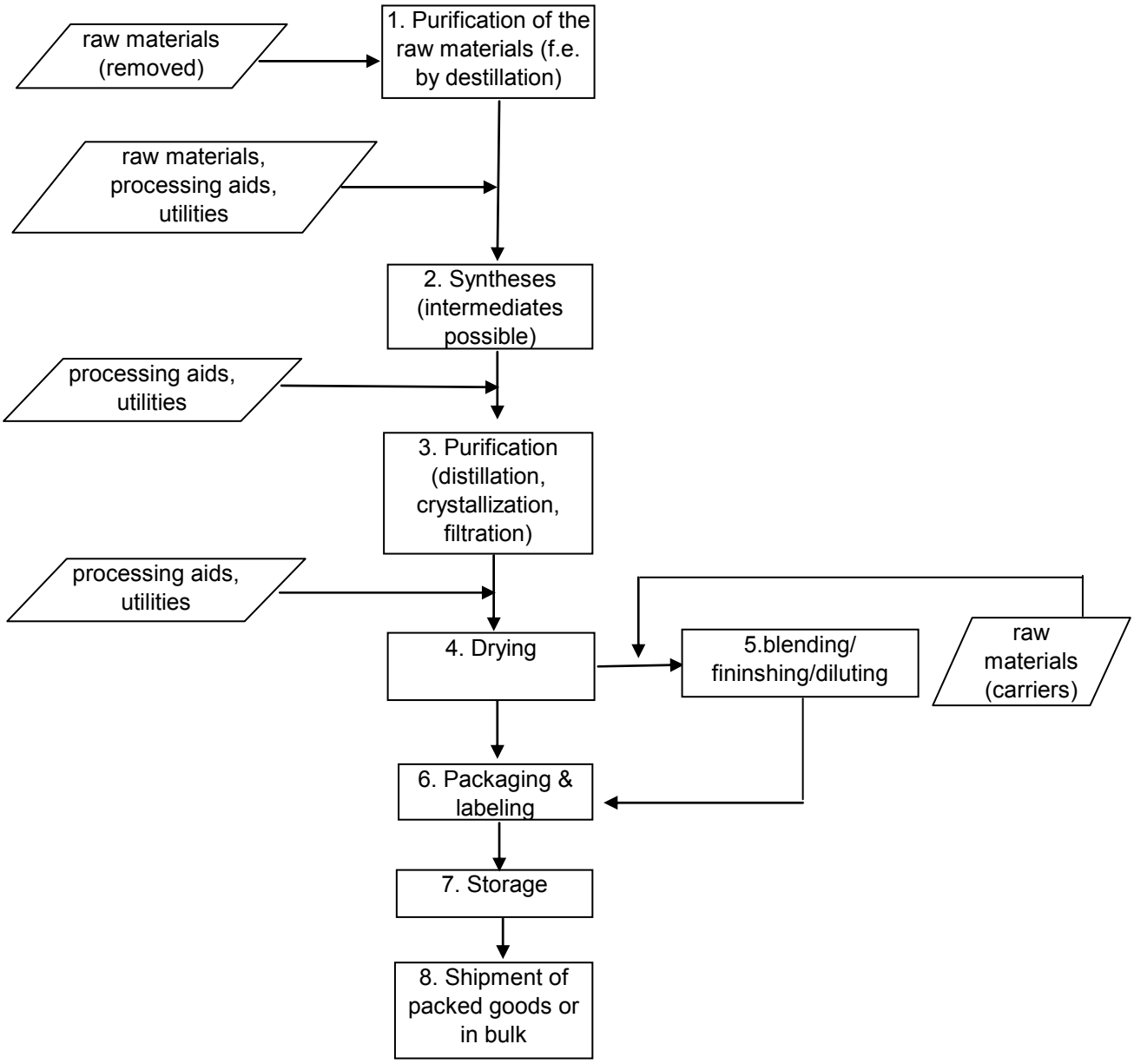
Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
Transportation (see also Annex 4) ▪ **Incoming**	Bulk transport of incoming ingredients	**Possible contamination from previous loads**	**CBP**	▪ **Contractual agreements with suppliers** ▪ **Dedicated tank transport** ▪ **Ask for cleaning certificates and previous loads before unloading** ▪ **Use only certified and registered transporters according the requirements**	
Transportation (see also Annex 4) ▪ **Outgoing**	Bulk transport of outgoing products as well as packed products	**Possible contamination from previous loads**	**CBP**	**Bulk:** ▪ **Contractual agreements with transporters** ▪ **Inspection before loading /dedicated transport** ▪ **Require and investigate cleaning certificates before loading** ▪ **Use only certified and registered transporters according the requirements** **Packed products:** ▪ **Contractual agreements with transporters** ▪ **Inspection of truck before loading**	
PROCESS STEPS					
2. Storage	Storage and keeping of ingredients and raw materials	**Exposure to rain and/or damp conditions.** **Spoilage due to condensation and mould growth.** **Cross contamination with other feed materials.** **Contamination with other non-feed materials such as chemicals, fertilizers.**	**CBP**	• **Training and education of employees** • **Weatherproof storage facilities.** • **Effective segregation of different materials particularly when stored on floors.** • **Cleanout procedures between different types of products** • **Separate storage areas for feed and non-feed materials.** • **Proper stock rotation.** • **Effective consolidation and sheeting of clamped forages.**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
		Deterioration of the product due to poor stock rotation **Products for different species and medicated and unmedicated feeds not adequately segregated.**			
3.Selection of raw materials, formulation	Selection of raw Materials for processing	**Selection of incorrect ingredient or incorrect**	**C**	• **Clear labelling** • **Verification check of ingredients**	
	Formulation	**Poor performance/ill health due to unsuitable premix design or formulation**	**C**	• **Feed formulations produced or checked by qualified nutritionists**	
4.Mixing (see also annex 6)	Mixing of additives with other additives, carriers	**Contamination from oils or cleaning agents,** **Foreign body contamination at addition points** **Incorrect addition/dosage of ingredients** **Inappropriate mixing, non-uniform distribution of ingredients** **Presence of residues due to cross-contamination**	**CBP**	• **Only use dedicated mixing or have a verified cleaning procedures** • **Use of food grade oils and detergents** • **Regularly test mixer efficiency** • **Good house keeping, jewellery policy etc** • **Sieve, metal detector** • **Preventive measures to control cross-contamination**	
5. Packaging and labelling	Packaging of the products in bags, boxes, drums, bigbags, IBC's etc.	**Contamination via the packaging process**	**CBP**	• **Packaging via dedicated production lines and packaging machines** • **Cleaning & inspection procedures** • **Usage of new packaging materials**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
	Identify the products with the right label identification according to the applicable legislation and to be able to track & trace the products in cases it is necessary	**Wrong labelling & identification of the product could lead to wrong usage or unable to do a complete recall in case it would be necessary**	**C**	• **Labelling procedures** • **Check on batch identification system**	
6. Storage	Storage and keeping of premixtures	**Exposure to rain and/or damp conditions.** **Spoilage due to condensation and mould growth.** **Cross contamination with other feed materials.** **Contamination with other non-feed materials such as chemicals, fertilizers.** **Deterioration of the product due to poor stock rotation.** **Products for different species and medicated and unmedicated feeds not adequately segregated.**	**CBP**	• **Training and education of employees** • **Weatherproof storage facilities.** • **Effective segregation of different materials particularly when stored on floors.** • **Cleanout procedures between different types of products** • **Separate storage areas for feed and non-feed materials.** • **Proper stock rotation.** • **Effective consolidation and sheeting of clamped forages.**	
7. Shipment of packed goods or in bulk	Shipment of packed goods	**Contamination of stock that was stored in good condition by: damaged packaging at the point of loading or during shipment**	**CBP**	• **Contractual agreements with transporters** • **Inspection before loading /dedicated transport** • **Use only certified and registered transporters according the requirements** • **Notification of any problems during transport**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
	Shipment of Bulk	**Contamination from:** **oils or cleaning agents,** **if the transporter is not dedicated to one product**	**CBC**	• **Contractual agreements with transporters** • **Inspection before loading /dedicated transport** • **Info about previous load(s) and request for cleaning certificates** • **Use only certified and registered transporters according the requirements**	

Standard Chemical process for manufacturing of feed additives



Risk Assessment

- **Chemical Processes**

Production characteristics

The typical production process consists of a chemical reaction of organic and/or inorganic raw materials under defined conditions whereby organic and/or inorganic processing aids, steam, water, air and gas could be inserted into the process. After the synthesis the final product is purified by e.g. distillation/crystallisation/filtration and dried.

HACCP Analysis

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
BASIC ISSUES PRERREQUISITE PROGRAM (PRP) – see also Annex 2					
Incoming materials: • **Raw materials**	Purchase & sourcing of raw materials	**Presence of foreign objects like : glass, metal parts, ropes, scoops, synthetic materials, (small) stones, tools, internal liners of equipment, insulation materials, wood, jewellery from operators.**	**P**	• **Raw material specification and receiving inspection** • **Suitable process design and downstream filtration steps**	
		Presence of undesirable substances, e.g. heavy metals, pesticides, as described in Directive 2002/32/EC and its amendments.	**C**	• **Raw material specification and receiving inspection.** • **Supplier information, e.g. certificates, conformance statements, or contractual agreements** • **Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
		Presence of micro-organisms or virus.	**B**	• **Raw material specification and receiving inspection.** • **Supplier information, e.g. certificates, conformance statements, or contractual agreements** • **Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization, heating.**	
	Purchase & sourcing of raw materials used in the downstream purification steps	**Raw materials used in the downstream purification steps, certain contaminants are considered when establishing the raw material specification, e.g. pathogenic micro-organisms, virus.**	**B**	• **Raw material specification and receiving inspection.** • **Contractual agreements**	
	Purchase & sourcing of raw materials used in the chemical synthesis	**Raw materials used in the synthetic process steps.**	**B**	• **None**	
• **Indirect materials**	Purchase of indirect materials, e.g. lubricants, cleaning agents	**Presence of toxic substances may result in contaminated products**	**C**	• **Ensure suitable supplier documentation**	
• **Water**	Water may be supplied from communities or from wells, and used as process ingredient and cleaning	**Water pipes and reservoirs may constitute to** ▪ **growth of microbes, and** ▪ **dissolution of substances.** **In certain cases, purification systems may be established due to product quality.**	**BC**	• **When an ingredient, use potable water or a quality suitable for feeding animals** • **Prevent storage at temperatures which support growth of microbes** • **Monitor official control of potable water or the alternative water source** • **Separate non-potable water systems from potable water systems**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
• **Packaging material**	Purchase, Sourcing , Use and possible re-use of packaging	**Contamination via packaging containers or materials or parts of it.** ***Specific considerations:*** • **Special units like drying bags may present a contamination risk**	**CBP**	• **Measures to avoid contamination of empty containers, bags, lids, ect.** • **Packaging design and materials shall provide adequate protection for products to minimize product contamination during use** • **Minimize damage during handling** • **Accommodate proper labelling** • **Re-saleable packaging (also internal usage) shall be suitable durable, easy to clean and, where necessary, disinfect** • **Measures to prevent Silica gel drying bags or closing straps to contaminate the product**	
Maintenance	Maintenance work may conflict with on-going processes	**Possible contamination of equipment after maintenance**	**CP**	• **Documented cleaning after maintenance** • **Ensure that excess of lubricants are prevented from entering the process equipment**	
Cleaning	Cleaning of product contact surfaces and the production environment	**Possible contamination if equipment is not cleaned to an acceptable level.** **Possible residues of cleaning agents. The environment may cause cross contamination.** **Wet cleaning of equipment used for dry products may support growth of microbes.**	**C** **B**	• **Ensure adequate cleaning programs of equipment** • **Ensure cleaning is documented** • **Control carry-over** • **Ensure an adequate level of environmental hygiene (rooms, floors, the outside of equipment)** • **Prevent condensate from entering process equipment**	
Sampling operations		**Dirty sampling tool → Foreign body** **Glass sampling tool → Chip of glass**	**P**	• **Cleaning of sampling tool** • **Storage of sampling tool** • **Hands washing** • **Glass policy**	
Transportation (see also Annex 4) • **Incoming**	Bulk transport of incoming ingredients	**Possible contamination from previous loads**	**CBP**	▪ **Contractual agreements with suppliers** ▪ **Dedicated tank transport** ▪ **Ask for cleaning certificates and previous loads before unloading** ▪ **Use only certified and registered transporters according the requirements**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
Transportation (see also Annex 4) ▪ **Outgoing**	Bulk transport of outgoing products as well as packed products	**Possible contamination from previous loads**	**CBP**	**Bulk:** ▪ **Contractual agreements with transporters** ▪ **Inspection before loading /dedicated transport** ▪ **Require and investigate cleaning certificates before loading** ▪ **Use only certified and registered transporters according the requirements** **Packed products:** ▪ **Contractual agreements with transporters** ▪ **Inspection of truck before loading**	
PROCESS STEPS					
1. Purification of raw materials	Distillation separates chemicals by the difference in how easily they vaporize. The two major types of classical distillation include continuous distillation and batch distillation.	**Contamination of the raw materials in case of incomplete distillation**	**C**	• **Check the temperature**	

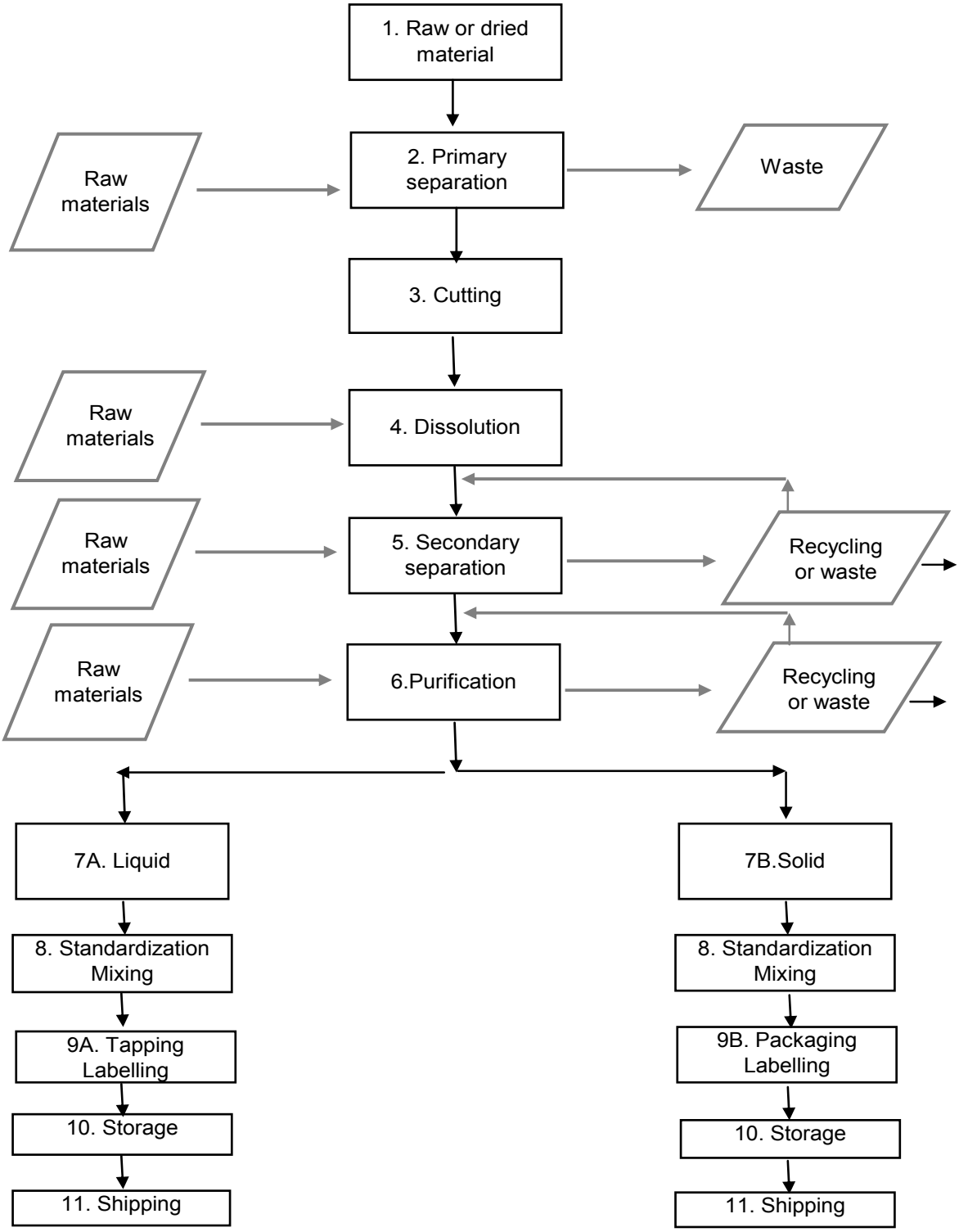
Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	remarks
2. Synthesis (intermediates possible)	More than one synthetic reaction is likely to take place. Probably the last reaction is where the "active molecule" is created and from this step onwards the feed hygiene requirements are followed.	**Besides the wanted substance some by-products are formed**	**C**	• **The downstream process removes the by-products to an acceptable level**	
3. Purification	Crystallization / recrystallization: Production of a purer sample of a substance by slow precipitation of crystals from a solution of the substance.	**Besides the wanted substance by-products precipitate**	**C**	• **Remove the by-products by elution**	
		Crack in cooling system → Contamination by not drinking water	**C/B**	• **Preventive maintenance program**	
		Leak of lubricant in speed reducer → Undesirable substances	**C**	• **Man hole protection (edge)** • **Speed reducer design** • **Preventive maintenance program** • **Food grade lubricant/grease**	
	Distillation: Distillation separates chemicals by the difference in how easily they vaporize.	**Contamination of the product in case of incomplete distillation**	**C**	• **Check the temperature**	
	Ion exchange.: A method of separating ions from a solution by reversibly binding them onto a resin that has charged sites on its surface. Ion exchangers are used to remove metal ions from (drinking) water.	**Microbial growth during the process**	**B**	• **Perform a regular regeneration of the resin**	
	Filtration via activated carbon which is a porous form of carbon that acts as a powerful adsorbent, used to decolorize liquids, recover solvents, and remove toxins from water and air.	**Reduced capacity of the activated carbon during the process**	**C**	• **Exchange or recycle the carbon in regular terms**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	remarks
4. Drying	General drying processes	**Occurrence of harmful substances during the process** **Contamination by drying aids such as additives** **Formation of dioxins, Nox and PAHs in case the burning process passes not optimal** **Contamination of the product if cyclone dust is returned in the process** **Formation of CO and soot in case of incomplete burning** **Contamination with fly ash from drying gases**	**CP**	• **Use of clean fuels** • **Check on fuel quality where applicable** • **Avoid use of pollute drying aids** • **Check of burners where applicable** • **Avoid carry back of dust or ash** • **Monitoring of CO levels where applicable** • **Check on soot forming where applicable** • **Flue gas cleaning before drying**	
5. Blending / Finishing / Diluting	Blending: Blending of small batches to a bigger batch or with the intention to homogenize the product	**Contamination in case the blending line is not clean or not dedicated to these products**	**CBP**	• **Cleaning and inspection procedure of the mixing line** • **Only use dedicated mixing**	
	Finishing:Homogenization, delumping, sieving	**Contamination in case the finishing line is not clean or not dedicated to these products**	**CBP**	• **Cleaning and inspection procedure of the finishing line** • **Only use dedicated finishing line**	
	Diluting: Blending the concentrated feed additive to a practical dilution, ready for use	**Contamination in case the mixing line is not clean or not dedicated to these products**	**CBP**	• **Cleaning and inspection procedure of the mixing** • **Only use dedicated mixing**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	remarks
6. Packaging & Labelling	Packaging of the products in bags, boxes, drums, bigbags, IBC's etc.	**Contamination via the packaging process**	**CBP**	• **Packaging via dedicated production lines and packaging machines** • **Cleaning & inspection procedures** • **Usage on new and/or clean packaging materials**	
	Identify the products with the right label identification according to the applicable legislation and to be able to track & trace the products in cases it is necessary	**Wrong labelling & identification of the product could lead to wrong usage or unable to do a complete recall in case it would be necessary**	**CBP**	• **Labelling procedures** • **Check on batch identification system**	
7. Storage	Storage and keeping of feed additives	**Exposure to rain and/or damp conditions.** **Spoilage due to condensation and mould growth.** **Cross contamination with other feed materials.** **Contamination with other non-feed materials such as chemicals, fertilizers.** **Deterioration of the product due to poor stock rotation.** **Products for different species and medicated and unmedicated feeds not adequately segregated.**	**CBP**	• **Training and education of employees** • **Weatherproof storage facilities.** • **Effective segregation of different materials particularly when stored on floors.** • **Cleanout procedures between different types of products** • **Separate storage areas for feed and non-feed materials.** • **Proper stock rotation.** • **Effective consolidation and sheeting of clamped forages.**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	remarks
8. Shipment of packed goods or in bulk	Packed goods	**Possible contamination with foreign materials, pests or other goods in case the packaging gets damaged**	**CBP**	• **Contractual agreements with transporters** • **Inspection before loading /dedicated transport** • **Use only certified and registered transporters according the requirements**	
	Bulk shipment	**Possible contamination by previous loads**	**CBP**	• **Contractual agreements with transporters** • **Inspection before loading /dedicated transport** • **Info about previous load(s) and request for cleaning certificates** • **Use only certified and registered transporters according the requirements**	

Standard Extraction process for manufacturing of feed additives



Risk Assessment

- **Extraction Processes**

Production characteristics

Some thickening, colouring or flavouring additives may be produced from natural raw materials (botanic materials) by extraction methods, which mostly are executed either by aqueous solutions or by using organic solvents, or by a combination of both. The distinctive characteristics of such production methods are the combination of series of solution and precipitations steps, pH adjustments, in order to refine and isolate the required molecule. The down-stream process ends with a drying step, followed by grinding and sieving, unless the final product is liquid.

HACCP Analysis

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
BASIC ISSUES PRERREQUISITE PROGRAM (PRP) – see also Annex 2					
Incoming materials: • **Raw materials**	Purchase & sourcing of raw materials	**Presence of foreign objects like : glass, metal parts, ropes, scoops, synthetic materials, (small) stones, tools, internal liners of equipment, insulation materials, wood, jewellery from operators.**	**P**	• **Raw material specification and receiving inspection** • **Suitable process design and downstream filtration steps**	
		Presence of undesirable substances, e.g. heavy metals, pesticides, as described in Directive 2002/32/EC and its amendments.	**C**	• **Raw material specification and receiving inspection.** • **Supplier information, e.g. certificates, conformance statements, or contractual agreements** • **Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
		Presence of micro-organisms or virus.	**B**	• **Raw material specification and receiving inspection.** • **Supplier information, e.g. certificates, conformance statements, or contractual agreements** • **Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization, heating.**	
• **Indirect materials**	Purchase of indirect materials, e.g. lubricants, cleaning agents	**Presence of toxic substances may result in contaminated products**	**C**	• **Ensure suitable supplier documentation**	
• **Water**	Water may be supplied from communities or from wells, and used as process ingredient and cleaning	**Water pipes and reservoirs may constitute to** ▪ **growth of microbes, and** ▪ **dissolution of substances.** **In certain cases, purification systems may be established due to product quality.**	**BC**	• **When an ingredient, use potable water or a quality suitable for feeding animals** • **Prevent storage at temperatures which support growth of microbes** • **Monitor official control of potable water or the alternative water source** • **Separate non-potable water systems from potable water systems**	
• **Packaging material**	Purchase, Sourcing , Use and possible re-use of packaging	**Contamination via packaging containers or materials or parts of it.** ***Specific considerations:*** • **Special units like drying bags may present a contamination risk**	**CBP**	• **Measures to avoid contamination of empty containers, bags, lids, ect.** • **Packaging design and materials shall provide adequate protection for products to minimize product contamination during use** • **Minimize damage during handling** • **Accommodate proper labelling** • **Re-saleable packaging (also internal usage) shall be suitable durable, easy to clean and, where necessary, disinfect** • **Measures to prevent Silica gel drying bags or closing straps to contaminate the product**	
Maintenance	Maintenance work may conflict with on-going processes	**Possible contamination of equipment after maintenance**	**CP**	• **Documented cleaning after maintenance** • **Ensure that excess of lubricants are prevented from entering the process equipment**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
Cleaning	Cleaning of product contact surfaces and the production environment	**Possible contamination if equipment is not cleaned to an acceptable level.** **Possible residues of cleaning agents. The environment may cause cross contamination.** **Wet cleaning of equipment used for dry products may support growth of microbes.**	**C** **B**	• **Ensure adequate cleaning programs of equipment** • **Ensure cleaning is documented** • **Control carry-over** • **Ensure an adequate level of environmental hygiene (rooms, floors, the outside of equipment)** • **Prevent condensate from entering process equipment**	
Storage ▪ **Packed products and materials**	Storage of containers and bags	**Storage areas are sensitive to pest infestation, foreign objects and dirt in general. Degradation or microbial growth if temperature is not controlled in an adequate manner.**	**PCB**	▪ **Prevent pests from coming into the buildings / rooms by having closed doors / gates and screened windows when opened** ▪ **Prevent cross-contamination when containers / bags are damaged** ▪ **Adequate control of temperature (ambient, cold, freezer)**	
▪ **Bulk**	Storage on floor or silos of raw materials; products are probably not relevant for this topic	**Floor storage is sensitive to pest infestation, foreign objects and dirt from handling fork-lifts.** **Degradation or microbial growth if temperature is not controlled in an adequate manner.**	**PCB**	▪ **Prevent pests from coming into the building / room by having closed doors / gates.** ▪ **Adequate control on handling the raw material** ▪ **Adequate control of temperature (ambient or cold)**	
Pest control	Pest control	**Possible contamination if pests infest rooms or buildings or if pesticide are used**	**BC**	▪ **Prevent pests from coming into the buildings by having closed doors / gates and screened windows when opened** ▪ **Good hygiene practices** ▪ **Good sanitation, inspection of incoming materials and effective monitoring** ▪ **Ensure correct use of pesticides**	
Transportation (see also Annex 4) ▪ **Incoming**	Bulk transport of incoming ingredients	**Possible contamination from previous loads**	**CBP**	▪ **Contractual agreements with suppliers** ▪ **Dedicated tank transport** ▪ **Ask for cleaning certificates and previous loads before unloading** ▪ **Use only certified and registered transporters according the requirements**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
Transportation (see also Annex 4) ▪ **Outgoing**	Bulk transport of outgoing products as well as packed products	**Possible contamination from previous loads**	**CBP**	**Bulk:** ▪ **Contractual agreements with transporters** ▪ **Inspection before loading /dedicated transport** ▪ **Require and investigate cleaning certificates before loading** ▪ **Use only certified and registered transporters according the requirements** **Packed products:** ▪ **Contractual agreements with transporters** ▪ **Inspection of truck before loading**	
PROCESS STEPS					
1. Raw or dried material	Control of the botanical material (e.g. seaweed) which is used as input for the process	**Possible contamination with undesirable and unwanted substances as well as foreign objects**	**CB**	**Specification and testing in regards to parameters which are not removed during downstream process**	**Note**
2. Primary separation	To remove foreign material and process interfering substances	**The natural material may contain ions which influence on the downstream process but most likely not on feed safety**	**None**	**None**	
3. Cutting	Process step to achieve an acceptable particle size to support efficient dissolution	**None**	**None**	**None**	
4. Dissolution	Step to produce a solution	**None**	**None**	**None**	
5. Secondary separation	Precipitation and filtration to remove cell debris. This step may include precipitation in organic solvents	**None**	**None**	**None**	

Process steps	Process description	Hazard description	Cat.	Suggestion of control & preventive measures	Remarks
6. Purification	Purification may include a series of steps, e.g. removal of solvent, pH adjustment, ultra filtration, diafiltration, carbon filtration, chromatography	**Residues of solvents.** **Growth of microbes if process time is prolonged and temperature is in the microbial optimal range**	**CB**	**Controlled downstream**	
7A. Liquid	Continue to step 8	**None**	**None**	**None**	
7B. Solid	Several possible steps: ▪ Spray-drying ▪ Granulation and sieving ▪ Precipitation, drying, grinding and sieving	**Possible contamination from equipment**	**P**	**Metal-detector down-stream**	
8. Standardization & Mixing	Addition of substances in order to achieve the expected concentration or viscosity	**Possible contamination from added materials or from process.**	**PCB**	**Metal-detector or screen installed down-stream.** **Final product specification, including residues of organic solvents and microbial testing**	
9A. Tapping & Labelling	Tapping process is almost closed and covered	**Very little possibility of contamination with foreign objects**	**P**	**Sieves and/or strainers are installed to hold back foreign objects and the equipment is checked for possible content**	
9B. Packaging & Labelling	Packaging process is almost closed and covered	**Very little possibility of contamination with foreign objects**	**P**	**Sieves and/or metal detector are installed to hold back foreign objects**	
10. Storage	Storage in closed containers	**If needed, control of temperature to prevent microbial growth.** **It cannot be excluded that deterioration of products may introduce an unhealthy molecule**	**B** **C**	**See general section** **See general section**	
11. Shipping	Bulk transport of outgoing products as well as packed products	**Possible contamination from previous loads**	**CBP**	**See general section**	

Annex 12: GUIDANCE ON PRODUCT RECALL

Introduction

This section of the guidance outlines the elements of a product recall plan and the actions to take when unsafe feed additives and premixtures must be removed from the feed and/or food chain.

Its objective is to protect public health by informing authorities and consumers (when necessary) of the presence on the market of potentially hazardous feed additives and premixtures, and to facilitate a rapid identification and removal of these products from the production and distribution chain. The effectiveness and success of this plan relies on a fully functional traceability system that allows the identification and location of products within the feed and/or food chain.

Feed additives and premixtures business will also remove products from the market for reasons other than safety; these cases are not covered in this guidance.

In case silos are not emptied between deliveries or because of continuous production, the recall procedure should define how far back previous lots in that silo should be involved in the recall process or additional analyses should prove that certain lots are or are not involved in the crisis that triggered the recall.

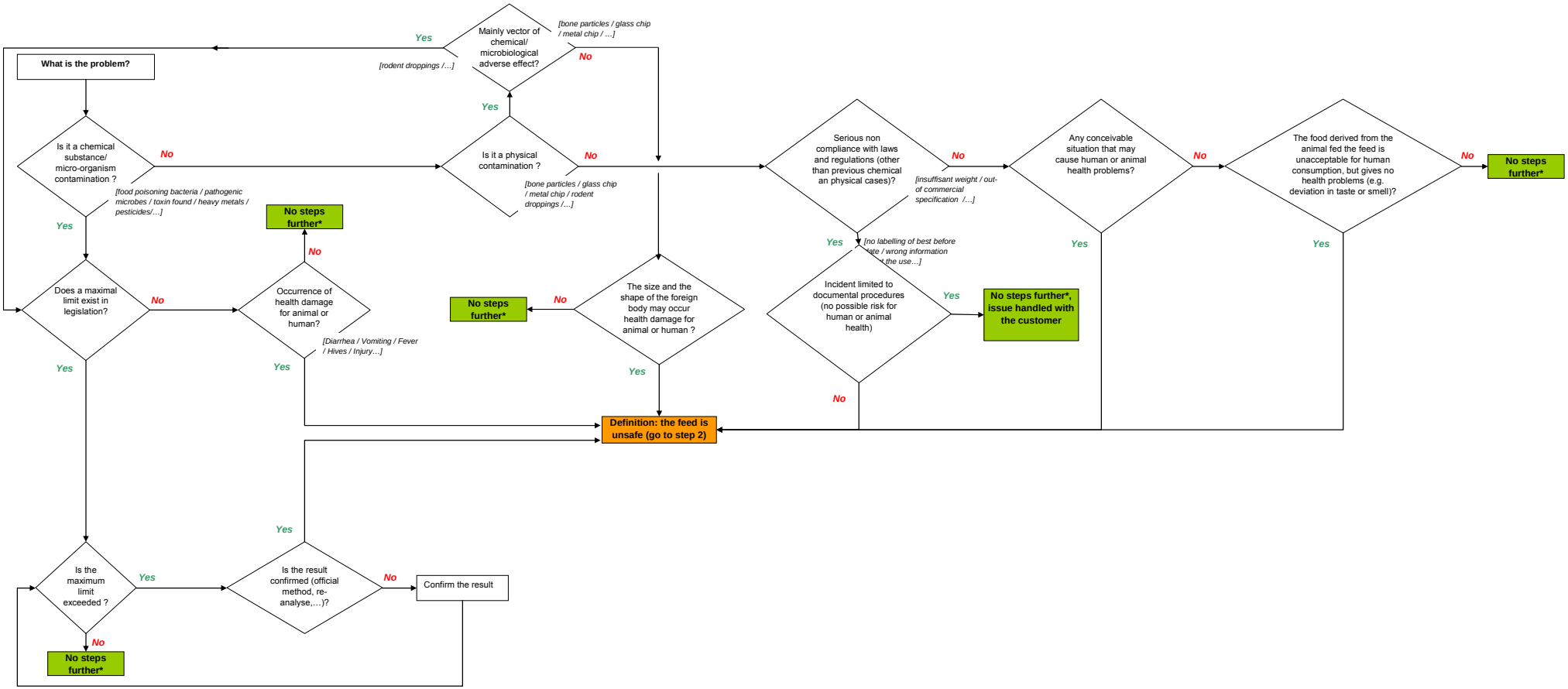
Regulatory framework: Regulation (EC) 178/2002 laying down the general principles and requirements of food law

Art. 15:

- Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.

- Feed shall be deemed to be unsafe for its intended use if it is considered to:
  - Have an adverse effect on human or animal health
  - Make the food derived from food-producing animals unsafe for human consumption

Step 1: Define whether the feed is unsafe



Step 2: Define the status of the product

The following definitions are relevant:

a. *The* defined amount of the product is no longer under control by the operator by either
- being held with a view to sale at distributors,
- being used by a customer,
- being held with a view to use at a customer, or
- being under transport and complete control is questionable

b. *The defined amount* is still under complete control by the operator by either
- having not left the operator's premises
- being under transport but complete control is manageable

Step 3: What to do

According to Art 20 of REGULATION (EC) No 178/2002, laying down the general principles and requirements of food law, it is the responsibility of the feed business operators to take the immediate and necessary actions in order to prevent a feed safety problem to spread.

Depending on the status of the product: a or b (step 2)

Follow the steps marked with **X** in the sequence up-down.

Steps marked with **--** do not need to be followed.

Status of the product:	*a*	*b*
Segregate existing stock	**X**	**X**
Initiate a recall process	**X**	--
Inform the competent authorities (Art 20)	**X**	**X**
Inform the competent authorities (Art 20) in case other Feed Business Operators could have potentially similar problems with their imported, produced, processed, manufactured or distributed feed.	**X**	**X**
Inform the competent authorities (Art 20) in case of problems with their produced, processed, manufactured feed, having not left the operator's premises or being under transport where complete control is manageable.	--	--

Inform FAMI-QS and your Certification Body	X	--
Cooperate with the competent authorities in respect of handling the critical feed safety situation, e.g. • Information on names of suppliers/customers • Destruction or reprocess of the batch/batches, lot/lots or consignments/consignments • Other information needed to support the Rapid Alert System	X	--
Conduct necessary corrective and preventive actions	X	X

Annex 13: TABLES OF REFERENCES OF THE GUIDE TO GOOD PRACTICE FOR FEED ADDITIVES AND PREMIXTURES OPERATORS REQUIREMENTS WITH THE CORRESPONDENT LEGAL TEXT

- **TABLE 1: Guide to Good Practice for Feed Additives and Premixtures Operators transferred to Regulatory Requirements**

Guide Sections		**Regulatory references**		
#	**Section**	**Reg. 178/2002/EC**	**Reg. 183/2005/EC**	**Reg. 1831/2003/EC**
1.	**Scope**	Art.15 Art. 17	Art 1, Approval of establishments Art. 20 Art. 22 Art. 2 Art. 5,6 Art. 23	Art.1 Art. 3 Art. 17
2.	Terms and definitions	Mentioned in the Guide		
3.	**Management Systems**			
3.1	General requirements	Art. 17 Art. 4	Art. 4,1 Art. 5,4 Annex II: Quality Control	Art. 5 Art. 7
3.2	Management Principles	Art. 5 Art. 6	Art. 6 + 7	Art. 7
3.3	General Documentation Requirements	Art. 6	Art. 7 Annex II, Quality Control (3) Art. 5,3 Annex II: Production (2)	./. Art. 7
4.	**Management Responsibility**			
4.1	4.1 Management Commitment	Art. 17	Art. 4 Art. 5	./.
4.2	Quality and safety policy	Art. 6 Art. 15 Art. 17	Art. 4 Art. 5	./.
4.3.	Responsibility, authority and communication	Art. 17	Art. 6 Art. 7 Annex II: Production (1) Annex II: Quality Control (1)	./.
4.4	Management representative	./.	./.	./.
4.5	Management review	./.	./.	./.
5.	**Resource management**			
5.1	Provision of resources	./.	Annex II: Facilities and equipment Annex II: Personnel Annex II: Production Annex II: Quality Control	./.
5.2	Human resources	./.	Annex II: Personnel	./.
5.3	Infrastructure	./.	Annex II: Facilities and equipment Annex II: Production	./.
5.4	Work environment	./.	Annex II: Facilities and equipment	./.
6.	**Product realisation**			
6.1	Product requirements			

Guide Sections		Regulatory references		
#	Section	Reg. 178/2002/EC	Reg. 183/2005/EC	Reg. 1831/2003/EC
6.1.1	Determination of requirements related to the product	Art. 17	Art. 5	Art. 3
6.1.2	Compliance of the product to the requirements	Art. 15 Art.12	Art. 5 Annex II: Quality Control Art. 25	Art. 3
6.1.3	Customer communication	./.	./.	./.
6.2	HACCP program	Art. 6	Art.6 Art.7	./.
6.3	Design and development			
6.3.1	Development of new production processes	Art. 6 Art. 15	./.	./.
6.3.2	Change control	Art. 15	Art. 6 (3) Annex II Personnel	./.
6.4	Handling of incoming materials			
6.4.1	Sourcing of incoming materials	Art. 18 Art. 11 Art 24	Annex II: Production Annex II: Quality Control Art. 23	./.
6.4.2	Verification of incoming materials	Art. 18	Art. 1 Annex II: Quality Control Annex II: Record-Keeping	./.
6.5	Production of finished goods			
6.5.1	Quality control and production	./.	Annex II: Production Annex II: Quality control; Annex II: Storage and Transport; Annex II: Record-Keeping Annex II: Record-Keeping Annex II: Storage and Transport	Art. 16
6.5.2	Verification of processes for production	./.	Art. 6 (2f); (3)	./.
6.5.3	Identification and traceability	Art. 18	Art.1, b Annex II, Quality Control Annex II, Record-Keeping Annex II: Production	./.
6.5.4	Preservation of products	./.	./.	./.
6.6	Transport	Art. 4 Art. 17 Art. 18 Art. 20	Annex II: Production; Annex II: Storage and Transport	./.
6.7	Control of monitoring and measuring devices	./.	Annex II: Production	./.
6.8	Cleaning	./.	Art. 6,2(a)	./.
6.9	Pest control	./.	Annex II: Facilities and Equipment Art. 6,2(a)	./.
7.	**System review**			
7.1	General Review	Art. 17	./.	./.
7.2	Internal audits	Art. 17	./.	./.
8.	**Control of non-conforming products**			
8.1	General requirements	Art. 20	Annex II: Quality Control	./.
8.2	Complaint handling system	./.	Annex II: Complaint and Product Recall	./.
8.3	Recall - Withdrawal	Art. 15	Annex II Complaints and Product	./.

Guide Sections		Regulatory references		
#	Section	Reg. 178/2002/EC	Reg. 183/2005/EC	Reg. 1831/2003/EC
		Art. 20 Art.20,3 Art. 50	Recall Art. 29	
9.	**Statistical techniques**	./.	./.	./.

- **TABLE 2: Regulatory requirements transferred to the Guide to Good Practice for Feed Additives and Premixtures Operators**

Regulatory references: *Headings and first column*

Guide sections: *Cells*

#	Reg. 178/2002/EC	Reg. 183/2005/EC	Reg. 1831/2003/EC
1	./.	1: Scope 6.4.2: Product Realisation 6.5: Product Realisation	1: Scope
2	./.	1: Scope	2 : Terms and Definitions
3	2 : Terms and Definitions	2 : Terms and Definitions	1: Scope 6.1.1: Product Realisation 6.1.2: Product Realisation
4	3.1: Management System 6.6 : Product Realisation	3.1: Management System 4.1: Management Responsibility 4.2: Management Responsibility	./.
5	3.2: Management System	1: Scope 3.1: Management System 3.3: Management System 4.1: Management Responsibility 4.2: Management Responsibility 6.1.1: Product Realisation 6.1.2: Product Realisation	3.1: Management System
6	3.2: Management System 3.3: Management System 4.2: Management Responsibility 6.2: Product Realisation 6.3.1: Product Realisation	3.2: Management System 3.3: Management System 4.3: Management Responsibility 6.2: Product Realisation 6.3.2: Product Realisation 6.5: Product Realisation 6.8 : Product Realisation 6.9: Product Realisation	./.
7	./.	3.2: Management System 4.3: Management Responsibility 6.2: Product Realisation	3.1: Management System 3.2: Management System 3.3: Management System
8	./.	./.	./.
9	./.	./.	./.
10	./.	./.	./.
11	6.4.1: Product Realisation	./.	./.
12	6.1.2: Product Realisation	./.	./.
13	./.	./.	./.
14	./.	./.	./.

#	Reg. 178/2002/EC	Reg. 183/2005/EC	Reg. 1831/2003/EC
15	1: Scope 4.2: Management Responsibility 6.1.2: Product Realisation 6.3.1: Product Realisation 6.3.2: Product Realisation 8.3: Control of Non-Conforming products	./.	./.
16	./.	./.	6.5: Product Realisation
17	1: Scope 3.1: Management System 4.1: Management Responsibility 4.2: Management Responsibility 4.3: Management Responsibility 6.1.1: Product Realisation 6.6 : Product Realisation 7.1: System review 7.2: System review	./.	1: Scope
18	6.4.1: Product Realisation 6.4.2: Product Realisation 6.5: Product Realisation 6.6 : Product Realisation	./.	./.
19	./.	./.	./.
20	6.6 : Product Realisation 8.1: Control of Non-Conforming products 8.1: Control of Non-Conforming products 8.3: Control of Non-Conforming products 8.3: Control of Non-Conforming products	1: Scope	./.
21	./.	./.	./.
22	./.	1: Scope	./.
23	./.	1: Scope 6.4.1: Product Realisation	./.
24	6.4.1: Product Realisation	./.	./.
25	./.	6.1.2: Product Realisation	./.
26	./.	./.	./.
27	./.	./.	./.
28	./.	./.	./.
29	./.	8.3: Control of Non-Conforming products	./.
30	./.	./.	./.
31	./.	./.	./.
32	./.	./.	./.
33	./.	./.	./.
50	8.3: Control of Non-Conforming products	./.	./.
Annex			
Facilities and equipment	./.	5.1: Resource Management 5.3: Resource Management 5.4: Resource Management 6.9: Product Realisation	./.
Personnel	./.	5.1: Resource Management 5.2: Resource Management 6.3.2: Product Realisation	./.
Production	./.	3.3: Management System 4.3: Management Responsibility 5.1: Resource Management 5.3: Resource Management	./.

#	Reg. 178/2002/EC	Reg. 183/2005/EC	Reg. 1831/2003/EC
		6.4.1: Product Realisation 6.5: Product Realisation 6.6 : Product Realisation 6.7 : Product Realisation	
Quality control	./.	3.3: Management System 4.3: Management Responsibility 5.1: Resource Management 6.1.2: Product Realisation 6.4.1: Product Realisation 6.4.2: Product Realisation 6.5: Product Realisation 8.1: Control of Non-Conforming products	./.
Storage and Transport	./.	6.5: Product Realisation 6.6 : Product Realisation	./.
Record-Keeping	./.	6.4.2: Product Realisation 6.5: Product Realisation	./.
Complaints and Product Recall	./.	8.2: Control of Non-Conforming products 8.3: Control of Non-Conforming products 8.3: Control of Non-Conforming products	./.