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THE CODE OF GOOD MANUFACTURING AND HYGIENE PRACTICE

FOR THE MANUFACTURERS OF PREMIXTURES AND COMPOUND FEEDINGSTUFFS CONTAINING PREMIXTURES OR COMPLEMENTARY FEEDINGSTUFFS FOR FARM ANIMAL NUTRITION

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This code was elaborated by the Bohemian-Moravian Association of Agricultural Supply and Purchasing Organisations in cooperation with a group of experts, and discussed with the CR Ministry of Agriculture.

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1.00.0 General Principles

The objective of good manufacturing practice codes is to provide manufacturers of premixtures, feedingstuffs containing premixtures and/or complementary feedingstuffs with a basis to produce and implement their own procedures of good manufacturing practice. This is required in a proposal of Regulation No. 2003/0071 of the European Parliament and of the Council of 14 April 2003, laying down requirements for feed hygiene, which is expected to be publicised the beginning of 2004. The Regulation will become legally binding for the Czech Republic after the EU accession.

The purpose of good manufacturing practice in the manufacture of premixtures and feedingstuffs is to produce premixtures and feedingstuffs in compliance with legal requirements and while adhering to procedures laid down in the Regulation. The manufacturers of premixtures and feedingstuffs containing the defined groups or types of additives must receive an approval from appropriate authorities.

1.10.1 The aim is to assure the monitoring of safety of feedingstuffs and premixtures at each stage of production in order to eliminate any negative effects on feed and food safety or the environment.

1.20.0 The principles apply to each manufacturer of premixtures and feedingstuffs containing additives and premixtures intended to be put into circulation or be used in feeding farm animals utilized in the manufacturing of food to be put into circulation. Requirements applying to the manufacturers vary between types or groups of additives used; the manufacturers are divided into the following categories:

1.20.1 Premix manufacturers using additives of the following groups: growth promoters, anticoccidials, chemotherapeuticals, vitamins A, D and chemically defined substances with similar effects.

1.20.2 Premix manufacturers using other additives and chemically defined substances with similar effects.

1.20.3 Feed manufacturers using additives and premixtures of the groups of growth promoters, anticoccidials and chemotherapeuticals for the manufacture.

1.20.4 Feed manufacturers using complementary feedingstuffs containing additives of the groups of growth promoters, anticoccidials and chemotherapeuticals for the manufacture.

1.21.0 According to good manufacturing practice the manufacturer is obliged to develop procedures aimed at achieving good manufacturing practice goals. These procedures should be based on results of HACCP studies.

1.21.1 HACCP studies are based on verifications of manufacturing technologies and procedures performed by the manufacturer usually before starting the manufacture of products with the same production procedures; or always before starting the manufacture of products requiring changes in production procedures; or if changes of manufacturing equipment have been performed which would significantly influence quality and safety of products, e.g. the use of different weighing systems, mixers, etc.

1.21.2 The manufacturer must check that the defined procedures are adhered to by the staff at all production stages. Results of checks must be critically appraised and documented by authorized personnel. They must be carried out at intervals no longer than one year.

1.21.3 The manufacturer must not declare as his own the products that were not manufactured in an approved operation in compliance with defined production

procedures, using approved manufacturing equipment. As a supplier, he is allowed to put products of other manufacturers into circulation, listing them in the product label, providing that these manufacturers are registered, their operations approved for a given type of production and their manufacture complies with good manufacturing principles.

1.30.0 Definitions and Terms

For the purpose of the Code the following terms are defined:
"**Feed materials"** - means various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in animal feeding either as such or in compound feedingstuffs;
"Feed ingredients" – means feedingstuffs intended for use in animal feeding either directly or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures;
"Compound feedingstuffs" – means mixtures of feed ingredients, whether or not containing additives, for oral animal feeding in the form of complete feedingstuffs or supplementary feedingstuffs;
"Complete feedingstuffs" – means mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration;
"Complementary/supplementary feedingstuffs" – means mixtures of feedingstuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if they are used in combination with other feedingstuffs;
"Daily ration" – means an average total amount of feed, converted to 12% moisture content, required by an animal of a given species, age and performance to satisfy all requirements;
"Additives" – means substances or preparations used in the manufacture of compound feedingstuffs or in animal nutrition in order to:

- affect favourably the characteristics of feed materials or of compound feedingstuffs or of animal products; or
- satisfy the nutritional needs of animals or improve animal production, in particular by affecting the gastro-intestinal flora or the digestibility of feedingstuffs; or
- introduce nutrition elements conducive to attaining particular nutritional objectives or to meeting the specific nutritional needs of animals at a particular time; or
- prevent or reduce the harmful effects caused by animal excretions; or
- improve animal environment.

"Premixtures" – means mixtures of additives or mixtures of one or more additives with substances used as carriers, or with the addition of amino acids, intended for the manufacture of feedingstuffs;
"Undesirable substances" – means substances or products which are present on the surface or inside products intended for animal nutrition, and which can pose a risk to animal and/or human health or the environment, or can exert undesirable effects on animal production, with the exception of pathogenic agents;
"**Banned substances or products"** – means substances or products which, by reason of their nature, affect adversely animal health or safety of animal origin

feed ingredients or foodstuffs, and must not be used in the manufacture of feedingstuffs or in animal nutrition;
"Withdrawal period" – means a minimum period of time between the receipt of feed containing an additive for which the period has been defined to the slaughter of an animal it was fed to or to the beginning of manufacture of animal origin products intended for human consumption.
"Conditionally usable feed materials, additives or premixtures" – means feed materials, additives or premixtures which do not comply with requirements laid down in the EU or Czech Republic legal regulations, and are not capable of being used for the original purpose, providing that health safety or these feed materials, additives or premixtures is not compromised.
"Deteriorated feed materials, additives or premixtures" – means feed materials, additives or premixes unfit for use in animal feeding.
"Farm animals" - means animals commonly reared by humans for farming purposes or fed to be used in human nutrition; or fur animals.
"Pets" – means animals kept by humans, without being used as farm animals;
"**Protein feed"** – means feed ingredients processed by a special technology, containing direct or indirect protein sources;
"Special nutrition purpose" – means nutrition aimed at meeting special nutritive-physiological requirements of a given category of farm animals or pets which can suffer from temporary or permanent impairment of digestion, nutrient absorption or metabolism, and which must be given feed corresponding with their health status.
"Putting into circulation" – means the keeping and storage of feed materials or additives or premixes with a view to selling them, offering them for sale or transferring them in any other way, for payment or free of charge.
"Biological testing" – means the determination of efficiency of feedingstuffs or additives under accurately defined conditions set in relevant regulations;
"**Manufacture type"** – means the scope of manufacture, i.e. of feed materials, additives, premixtures, compound feeds containing additives or premixtures or supplementary feedingstuffs;
"**Sample withdrawal"** – means the withdrawal of samples of feed materials, additives, premixtures and undesirable substances to be checked by appropriate authorities using a procedure laid down in the relevant decree, with the exception of pesticide residues and microorganisms (hereinafter referred to as "sampling").
"**Manufacturing plant"**– means the production unit involved in the manufacture or processing of feed materials, additives or premixtures;
"Minimum storage life" – means a date until which feed materials, additives or premixtures maintain their properties determining the quality, under given storage conditions;
"Supplier" – means an individual or legal physical person who keeps, handles and puts into circulation feed materials, additives or premixtures;
"Distributor" – means an individual or legal physical person who mediates the putting into circulation of feed materials, additives or premixtures.
"Handling" – means the keeping of feed materials, additives or premixtures including performance of changes of packaging, labelling or other treatments which do not change composition or quality of products;
"Batch" – means amounts of feed materials, additives or premixtures with uniform external composition, labelling and localisation;
"Cross-contamination" – means the occurrence of two or more types of

additives, undesirable substances or banned substances or products which exert contradictory or mutually inhibiting effects, undesirable or toxic effects, and their levels in feed exceed determinability limits or tolerances
”**Professional surveillance” –** means the supervision, inspections, verifications, monitoring, sampling and analyses performed by professional surveillance authorities.
“Manufacturer” means an individual or legal person who manufactures or processes feed materials, additives or premixtures, and as supplier is keeping his products before putting the into circulation or performs the putting into circulation activities; persons running running mobile feed mills are included.
“Primary agricultural production” – means farm animal rearing, field crop growing and harvesting, production of milk, eggs and slaughter animals.
“Production stage” – any phase of production, storage, transport, delivery, distribution, sale or import of feedingstuffs.
“Importer” –a legal or individual person who imports feed materials, additives or premixtures from third countries.
“Traceability” – a detection of origin of feedingstuffs or substances which are or could be processed into feed, at any stage of production, processing and delivery.
“Hazard” – a probability of adverse effects on health and seriousness of these affects as a consequence of the risk occurrence.
“Hazard analysis” – a process of collecting and evaluating information on different types of risk to health safety of feedingstuffs, premixtures or foodstuffs, and conditions enabling the presence of these risks in feed, with this information being required as basis for making decisions on the risk significance for feed and premix safety and on their allocation in the critical point system plan.
“HACCP (Hazard Analysis Critical Control Point)” –a systematic approach to the identification and assessment of hazards associated with all stages of manufacture of feed materials, additives and premixtures, the definition of for their and the identification of critical control points.
“**Critical Control Point”** – a point, step or procedure where control is possible and failure cannot subsequently be corrected. At a critical control point a danger to the safety of the feedingstuff can be prevented, eliminated or reduced to an acceptable level.
“Critical limit” – a limiting level of characteristic feature the exceeding of which causes feed material or premixture to be regarded as cross-contaminated, non-homogenous, non-complying with specification of characteristic features affecting its use, and therefore it can be designated as conditionally useable or deteriorated feed material or premixture.
“Partial sample” – a mass proportion of one batch received by one scoop of a probe.
“Pooled sample” – total mass or all partial samples withdrawn from one batch of feed material, additive or premixture.
“Final sample” – a sample created by homogenization and reduction of the pooled sample.
“**Sample for testing”** – a representative part of final sample treated according to a defined procedure-
“Determinability limit” – the lowest level of characteristic feature to be determined at which statistically acceptable correctness and accuracy is achieved.

"Correctness of method" – a tightness of conformity between a mean value calculated from a large number of test results and an acceptable reference value.
"Repeatability" – a value assumed to be lower than or equal to the absolute difference between two results of tests received under identical repeatability conditions, with 95% probability.
"Repeatability conditions" – conditions under which the results of independent tests can be obtained with the same method, material, in the same laboratory, by the same person using the same equipment in a short period of time.
"Reproducibility" – a value assumed to be lower than or equal to the absolute difference between two results of tests received under identical reproducibility conditions., with 95% probability.
"Reproducibility conditions" - conditions under which the results of independent tests can be obtained with the same method, material, in the same laboratory, by the same person using the same equipment.
"Homogeneity of additive distribution throughout a batch" – an admissible dispersion of values of the additive under observation found in a predetermined number of partial samples withdrawn from the batch.
"Working accuracy" – the ability of mixing equipment to mix a specified amount of indicator into the batch to achieve homogenous distribution after a set period of time.

2.00.0 Critical Points in the Production

The aim of the HACCP (Hazard Analysis Critical Control Point) system is to prevent, identify and assess potential hazards to animal health which may affect the human food chain, before such hazards arise. The objective of the system is not to become a substitute for other activities included in the continual implementation of good manufacturing and hygienic practice requirements.

HACCP technique is based on a systematic approach to the control of feedingstuffs, additives and premixtures, production process, product handling, in-plant environment and personnel, enabling to prevent potential hazards which may affect animal health, food quality or the environment. HACCP introduces the methods of monitoring and control at all stages of feed production that assure the efficiency of control system.

2.10.0 Principles of the Critical Control Point System

2.10.1 The HACCP technique implementation is based on the description of feed materials, additives and premixtures to be processed, preparatory procedures, individual stages of production, and finished products, confirming the presence of potential risks to animal health, food quality or the environment. This technique implies a continual examination of management and control procedures at each production stage, from the receipt of feed materials, additives or premixes to unloading finished products, for their ability to prevent the occurrence of the above-mentioned hazards.

2.10.2 Critical control points in particular procedures and operations must be identified by means of HACCP analysis at those locations where potential presence of risks can be expected, and these reduced or eliminated.

2.10.3 Characteristics and critical limits must be defined for each critical point. The characteristics chosen must be directly relating to the identification of hazards presenting a risk to animal health, food quality or the environment.

2.10.4 Methods and intervals of critical point checks must be defined in respect of situations that enable to clearly identify if a course of production process

complies with the one prescribed.

2.10.5 It is necessary to establish a documentation consisting in keeping records on critical control points including values of the characteristics monitored and descriptions of corrective actions taken.

2.10.6 If the critical limits are exceeded, detailed procedures to remove the causes must be employed and documented as part of corrective actions.

2.10.7 At least once a year a complete check of reliability of manufacturing equipment and procedures must be carried out.

2.10.8 The manufacturer must appoint a suitably qualified person to lead HACCP technique implementation. He will also lead a team who have the skills to evaluate the variety of hazards at all stages of the production process, including engineering, manufacturing operations, feed ingredients, effects on animal nutrition thereof and quality assurance.

2.20.0 The Identification of Hazards that Must Be Prevented

In the manufacture of premixtures and feedingstuffs containing additives, premixtures or complementary feedingstuffs the following situations are regarded as hazards:

2.20.1 The inclusion of feed materials and additives that are not permitted for the use in animal nutrition such as:

- feed ingredients, protein feeds or additives, a suitability of which for animal nutrition has not been confirmed,
- feed ingredients, protein feeds or feed additives showing levels of undesirable substances exceeding critical limits.

2.20.2 The exceeding of specified limit levels of additives in feedingstuffs or departure from declared levels of additives in premixtures due to:

- the incorrect functioning of scales working in automatic regime, with unacceptable deviations in doses of ingredients, particularly when weighing additives or premixtures, in all scales or in some scales;
- the use of manual scale with an insufficient working accuracy in respect of the doses of ingredients specified, producing errors greater than permitted deviations, particularly when weighing additives or premixtures;
- the use of scales in contradiction with the current metrological rules, i.e. the scales are not regularly checked or show alterations in working accuracy and are still used for ingredient weighing;
- The losses during the production process due to insufficient aspiration of manufacturing equipment or non-compliance with instructions for the application of additives into compound feedingstuffs or premixtures.

2.20.3 Non-homogenous distribution of additives in premixtures or compound feedingstuffs is caused mainly by:

- the incorrect functioning of mixers (damaged mixing elements or leaks), or an insufficient mixing time with respect to a product being worked (effects of ingredient structure, addition of liquids throughout the mixing time),
- the addition of insufficient doses of additives or premixtures into batches, with differences between amounts added into different batches exceeding an acceptable range of values measured in partial samples,
- an unsuitable construction of conveying lines or storage bins for finished products (conveying lines or storage bins can cause segregation of particles from premixtures or feedingstuffs)

2.20.4 Cross-contamination between finished products, caused mainly by:

- non-compliance with production procedures, i.e. no checks or cleaning of manufacturing equipment after the manufacture of premixtures or feedingstuffs containing hazardous additives are performed, or the additives or ingredients are used that have not been permitted in a given operation;
- an incorrect prescribed sequence of different products in the production process that does not assure that cross-contamination is avoided (decontamination programme); or a proper sequence is not followed (e.g. random insertion of product processing);
- the use of unsuitable and unverified manufacturing equipment that due to its construction or operation can cause cross-contamination,
- No consistent on-receipt examination for content of undesirable substances in incoming materials intended for use in the manufacture of feedingstuffs such as premixes, or examination of other components whether containing undesirable or banned substances is carried out.

2.21.0 Development and Implementation of Critical Control Point System

The development and subsequent implementation of the system of critical control points in the production proceeds from the assumption that **a manufacturing plant meets general requirements laid down in the current Feedingstuffs Regulations and has both material and organizational prerequisites for the manufacture of high quality and safe premixtures and feedingstuffs.** Without meeting these requirements it is impossible to develop and implement a functional system of critical control points.

The manufacturer is required to have:

- suitable manufacturing equipment, processing areas and stores; there must be a written schedule for maintenance of equipment and processing areas;
- written production procedures and storage rules in place;
- a written system of quality control;
- a programme for staff training and continual education including the explanation of all tasks in the production which they may be required to perform, production management, hygienic principles complying with good manufacturing practice, etc.
- defined hygienic conditions of production including methods and frequency of manufacturing equipment and processing areas cleaning, disinfection, insect and rodent extermination, methods of collection and disposal of waste from the storage and production,
- a prescribed method of dealing with complaints and product recall procedures including product modification or disposal
- a system in place for keeping records on manufacturing operations, complaint registration, including data archiving for a set period of time.

2.21.1 A system of critical control points should be developed by a team of employees or external experts with a sufficient level of knowledge on:

- technologies and manufacturing equipment for premixtures and feedingstuffs production,
- quality of feed ingredients, protein feeds, additives and premixes,
- animal nutrition issues and response of animals to additives or undesirable substances that may be contained in feed,
- the impact of feed materials and additives on quality and safety of animal origin products intended for human food production,

- the verification of quality of compound feedingstuffs, additives and premixtures.
- The team must be lead by the person responsible for control and monitoring of critical control point system.

While developing the system, the team must try to obtain the following information:

1) specifications of manufacturing operations including:

- types of manufacturing equipment and suitability for the premixture or compound feedingstuff manufacture,
- capacity of manufacturing equipment
- group characteristics of finished products,
- groups of feed ingredients, protein feeds, additives and premixes to be processed, including their properties, expected locations of critical points in the production process and reasons why these points should be regarded as critical.

2) the description of products or groups of products that may pose similar risks (contain the same groups of hazardous additives, or due to feed ingredients used they will probably show the levels of undesirable substances exceeding limits) which must include:

- the name of product or group of products with similar properties, e.g. products containing growth promoters and anticoccidials or products containing anticoccidials only, or products which contain no hazardous additives but may contain undesirable substances at levels exceeding limits, or products posing no risks,
- the description of product (group of products) use including proper and safe use rules,
- basic physical and chemical properties of product or group of products (requirements for further processing, e.g. pelleting or expansion including maximum temperatures during and after the processing, before loading, structure of finished products, dry matter content, preservatives, etc.),
- information on packaging and delivery of product (group of products)
- additional information on products to be provided by the manufacturer to customers,
- feed ingredients, protein feeds, additives, premixes used in the manufacture and chemical, physical or microbiological properties thereof, packaging, storage, labelling

3) The labelling of product usually reflects product purpose; labels must provide information on safe ways of product use. For products with a higher probability of risk occurrence due to customer's mistake, ways of avoiding the mistake should be pointed out, e.g. by highlighting the risks or describing safe ways of a product delivery to a customer, etc. in the label.

4) There must be a production process scheme or written plan describing each process stage, from the receipt of ingredients to delivery of finished products. The scheme or written plan of production process must clearly specify the tasks to be performed by personnel at each process stage. The scheme or plan must by followed by a diagram of manufacturing equipment outlay, including the description of positions and expected critical points.

5) The process scheme or plan must be tested under practical operation conditions, without unnecessary delays in the process, with the products

being chosen that do not present any risks, etc.

6) Hazard analysis must be carried out; premixtures and feedingstuffs manufacturers must check for:

- the presence of banned feed ingredients, protein feeds, or additives and premixes containing these;
- the presence of feed ingredients, protein feeds, additives or premixtures with levels of undesirable substances exceeding limits or contaminated with banned substances
- the exceeding of limits for levels of additives in premixtures or compound feedingstuffs
- non-homogenous products in terms of additive contents,
- cross-contamination.

2.21.2 The hazard analysis is focused on the assessment of

1) the effect of feed ingredients, protein feeds, additives and premixtures on compound feedingstuffs or premixtures; the following questions are to be answered:
   a) Which feed ingredients, protein feeds, additives or premixtures are used for the manufacture and what prescribed amounts should be included in the product?
   b) Do toxicological properties of feed ingredients, protein feeds, additives and premixtures show potential toxicological properties?
   c)Can feed ingredients used negatively influence the quality of animal origin products intended for foodstuff production?
   d) Are there any pathogens or facultative pathogens present in feed ingredients, protein feeds, additives or premixtures?
   e) Are there undesirable or banned substances at levels exceeding limits in feed ingredients, protein feeds, additives or premixtures?
   f) Are there any harmful impurities at levels exceeding limits in feed ingredients?
   g) Can any additional substances included in feed ingredients, some protein feeds and additives be potentially harmful to animal health or adversely influence animal product quality, or utilization of additives or nutrients from feed ingredients and some protein feeds?
   h) Have any additives with preservative effects been used at higher levels in the production of feed ingredients or protein feeds, and how the preservative levels will be reflected in finished products?
   i) What the technological procedures feed ingredients or protein feeds have gone through and whether these procedures could have affected their utilization for animal feed production?
2) The effects of processing on feedingstuffs and premixtures; the following questions are to be answered:
   a) Can during the production process occur uncontrollable mixing of feed ingredients, protein feeds, additives or premixtures due to unsuitable conveying lines, insufficient aspiration, non-compliance with prescribed procedures at the ingredient receipt, or containers with construction unsuitable for a given type of feed ingredient of protein feed?
   b) Can there be any uncontrollable departures from specified dosage of individual ingredients?
   c) Can there be any uncontrollable changes in the production process length (shortening of one batch production cycle, mainly due to shortening the

ingredient mixing time)?

d) Can cross-contamination of the product with unauthorized feed ingredients or additives occur?

e) Can there be losses in additives, hazardous ones in particular, during the production process, and at which production stages, and do these losses cause carry over and cross-contamiantion?

f) The effects of pelleting or extrusion temperatures on some additives (admissible temperatures for different additives such as vitamins, microorganisms, enzymes)

g) The effects of preservatives used on stability of additives in feeds.

3) The effects relating to putting premixtures and compound feedingstuffs into circulation; the following points are to be examined:

a) whether the way of packaging and labelling prevents the product from being mixed with other products, from cross-contamination, incorrect designation,.

b) the way of product transport; whether means of transport used, particularly for bulk transport are clean and have been entirely emptied.

c) possibilities of confusion of different feedingstuffs when handling bulk material at the customers site (if it is possible to mix the delivered feed with another one),

d) whether it is necessary to provide more information to customers on some types of premixtures or compound feedingstuffs (particularly on premixtures or compound feedingstuffs containing hazardous additives),

e) other failures that may occur at the customers.

2.21.3 Hazard Analysis

A hazard means a degree of probability of risk manifestation and seriousness of consequences of risks present in premixtures or compound feedingstuffs. It is important to carry out the hazard analysis when preparing and implementing a system of critical control points, particularly when preparing materials for the identification of critical control points. During the system operation it is part of critical control point system verification procedures.

The hazard analysis follows after a danger analysis which summarizes all risks to animal health, animal product quality and the environment relating to finished products, ingredients used and production processes. During the hazard analysis a degree of probability is judged, to which an identified hazard can be manifested (a frequency of manifestation of a given hazard is analysed) and at the same time consequences of manifestation of the hazard are assessed.

The objective of hazard analysis is to prepare a basis for a decision-making process consisting in the identification of critical control points. For instance, the hazard analysis will allow the manufacturer to:

- make up a sequence of products, feed ingredients, protein feeds, additives and premixes to be processed according to probability of hazard occurrence,
- make up an order of production stages according to probability of hazard occurrence and decide, depending on a hazard seriousness, whether there will be a critical point or only a control point identified in that particular process stage,
- define the urgency of manufacturing equipment reconstruction.

2.21.4 Qualitative Hazard Analysis

In order to identify a degree of hazard occurrence probability, a qualitative hazard

analysis must be carried out, examining biological, physical and chemical risks feed ingredients, protein feeds, additives and finished products may pose to premixtures and feedingstuff manufacturers. A degree of hazard probability is usually designated with capitals, with A meaning the highest hazard probability and other characters designating lower hazard probabilities.

2.22.0 Qualitative Hazard Analysis for Premix Manufacturers

2.22.1 Product characteristics from the biological hazard viewpoint

A) Special groups of products to be used in feedingstuffs intended for the consumption by risk groups of animals. These are usually products containing hazardous additives or limit levels of additives which are intended for a given species and category only.
B) Products which may cause cross-contamination and carry over during the production process or packaging.
C) Products containing unstable additives which during the production or putting into circulation process affect quality of finished products.
D) Products which are likely to be handled in a dilettante way when being put into circulation or used, which could lead to compromising heath safety of feed.

2.22.2 Product characteristics from chemical and physical hazard viewpoint

A) Special groups of products containing hazardous additives or above limit levels of additives that can pose a risk to animal health if present in a product intended for another animal category, can endanger human health.
B) Premixtures containing unstable additives that can affect their quality and utilization for the feed manufacture, or can affect their structure.
C) Production procedures that do not include operations to would eliminate a possibility of addition of inaccurate ingredient doses, additives in particular, in the batch, or cross-contamination, or enable to skip some prescribed process steps or to shorten the production cycle at the expense of mixing time, for example.
D) The occurrence of excessive levels of undesirable substances in premixtures that may affect their utilization.
E) If premixtures are likely to be exposed to dilettante handling when being stored at the manufacturing plant e.g. incorrect or incomplete labelling, alterations of quality parameters due to unsuitable storage conditions, damage of packages during the storage, etc.
F) It is impossible for a consumer (feed manufacturer) to detect and remove some undesirable substances at levels exceeding limits or banned substances or non-permitted additives in the premixture.

2.23.0 Qualitative Hazard Analysis for Feedingstuff Manufacturers

2.23.1 Product characteristics from the biological hazard viewpoint

A) Special groups of products intended for feeding to risk groups of animals. These are usually products containing hazardous additives, or not being allowed in feeds for those animals they may cause do harm to, or feed ingredients that cannot be fed to these animals such as all feedingstuffs for young animals containing hazardous substances.
B) Products which may cause cross-contamination during the production process, loading, transport and delivery (products manufactured after batches containing hazardous additives).
C) Products of unstable composition, quality of which can change during the production, loading, transport or delivery, e.g. products with great

differences between particle size of individual components, with no physical treatment to protect their stability or no inclusion of feed ingredients with agglomerating effect, products containing thermically unstable additives such as some vitamins, microorganisms or enzymes.

D) Products likely to be exposed to dilettante handling during the transport or putting into circulation resulting in compromised health safety.

2.23.2 Product characteristics from chemical and physical hazard viewpoint

A) A special group of products that are intended for feeding to risk groups of animals and contain hazardous additives or additives for which the lowest or highest permitted levels in feed have been defined. These are mainly feeds for young animals.

B) Products unstable due to their physical and chemical properties and prone to particle segregation causing non-homogeneity of additives during the production process and storage, e.g. mixtures of ground ingredients with pressed ingredients and premixtures, or an increased share of abrasion in pelleted or extruded feed during the storage, loading, transport and delivery.

C) Production process does not include operations that would eliminate failures such as the addition of inaccurate doses of additives or premixtures in particular, cross-contamination, departures from prescribed production procedures, or uncontrollable shortening of production cycle, e.g. of mixing time, etc.

D) In selected groups of products limit levels of undesirable substances may be exceeded due to feed ingredients, protein feeds or premixtures used. For instance, calcium carbonate contains increased levels of arsenic and the use of higher doses for poultry feed can lead to exceeding the limits in finished products.

E) Quality of some products or product groups is very likely to be compromised during the storage, e.g. in case of storing non-cooled pellets/extrudate or products with a higher moisture content.

F) The customer can by no means detect the presence of banned or undesirable substances, or excessive levels of hazardous substances in products, or cross-contamination, and therefore is unable to remove these defects.

2.32.3 Classification of hazards relating to the products analysed according to points 2.22.1 and 2 or 2.23.1 and 2

Products or ingredients designated with letters A to F according to potential risks they may present are usually classified into 6 categories, with a highest number category (VI) comprising the highest risk products and ingredients.

The categories include products designated as follows:

Analysed product	Category	Hazard characteristics according to letters A – F
Premixes and feedingstuffs for young animals containing hazardous additives (x)	VI	The characteristics A and B to F apply to premixtures and feedingstuffs of this category.
Premixtures and feedingstuffs (x)	V	All characteristics B to F apply to premixtures and feedingstuffs of this category.
Premixtures and feedingstuffs (x)	IV	4 of the total 5 characteristics B to F apply to premixtures and feedingstuffs of this category.
Premixtures and feedingstuffs (x)	III	3 of the 5 characteristics B to F apply to premixtures and feedingstuffs of this category.
Premixtures and feedingstuffs (x)	II	2 of the 5 characteristics B to F apply to premixtures and feedingstuffs of this category.
Premixtures and feedingstuffs (x)	I	1 of the 5 characteristics B to F applies to premixtures and feedingstuffs of this category.
Premixtures and feedingstuffs (x)	0	none of the characteristics A to F applies to premixtures and feedingstuffs of this category.

2.23.4 The classification of products or product groups according to the characteristics A to F is usually presented as a table; moreover, different products, product groups or ingredients can be designated either (+) if they can be classified according to a given characteristic, or (-) if not. The hazard analysis follows after the danger analysis and precedes to the identification of critical points.

2.24.0 Quantitative Hazard Analysis

is associated with each stage of production process, however, it can be also applied to finished products or ingredients. The analysis results in a numerical presentation of a hazard importance. The hazard importance includes probability of a hazard manifestation and its seriousness.

One of general quantitative methods of hazard analysis, the Failure Modes and Effect Analysis (FMEA) procedure, which is an analysis of potential failures and consequences thereof, can be used as an aid for the implementation and operation of critical point systems.

The above-mentioned procedure is based on the assumption that failures of individual operations or ingredient defects are known, therefore it is possible to evaluate failure causes in a given operation with regard to manufacturing equipment, and consequences of the failure both for subsequent process operations and the production system as a whole. FMEA investigates the impact of defects or failures of different sections of the system, it does not solve problems arising from combined failures of different system sections, however. During the implementation and operation of critical point systems the FMEA procedure can be used for calculation of risk magnitude and consequences at different stages of production process.

FMEA comprises all elements of hazard analysis, from the definition of a

range of action, identification of types of potential failures, assessment of seriousness of failure consequences, application of procedures to rectify possible consequences, identification of causes, determination of probability of failure occurrence (failure frequency) and hazard probability calculation, to corrective actions to take to minimise the risk.

When implementing a critical control point system, the following FMEA procedures are to be carried out:

a) analysis of consequences,
b) analysis of failure occurrence frequency,
c) assessment of detection reliability,
d) risk quantification.

Any risks identified at any stage of production process are ascribed values of characteristics under observation (indices). The magnitude of each characteristic (index) is expressed with figures 1 - 10. Risk magnitude "R" is calculated as a product of the following three characteristics (indices) monitored: risk category "K", frequency of danger manifestation "C", and detection reliability "S".

2.24.1 Hazard categories

show seriousness of consequences of a manifested risk.

An example of categorization and ascribed values:

Seriousness	Ascribed Value
Deaths of animals or health impairments resulting in deaths (serious consequences for the consumer) serious consequences for the manufacturer, e.g. high fines, authorization reversal or production permit withdrawal, criminal prosecution for damages caused by the product	10
Negative impact on quality of animal origin products or even product damage (in a mass scale) due to the feed used	8
Mass disease in animals resulting in no deaths but decreased performance	5
Individual cases of impaired quality of animal origin products or diseases in animals	3
No danger present	1

A degree of seriousness and values ascribed can be adjusted according to production type and conditions.

2.24.2 Frequency (probability) of hazard manifestation

It can be judged according to a number of proven defective products with regard to seriousness of defects expressed as percentage of defective products in total number of products examined, or according to frequency of defects expressed as a number of defective products in a time unit (e.g. one year)

Examples of a risk manifestation frequency:

- very high frequency (more than 50% cases) value ascribed: 10
- high frequency (35 to 50% cases) 8
- medium frequency (20 to 35% cases) 5
- low frequency (10 to 20% cases) 3
- very low frequency (less than 10% cases) 1

2.24.3 Detection reliability (control measures)

is usually determined by a method of production process control, i.e. whether it is controlled manually with appropriate control elements (control measures are part of production process and can be checked) or automatically with control elements being part of control programme that can be checked both during the production process and reversely.
Examples of detection reliability

- the production process is equipped with a minimum number of control element or it is impossible to find control elements (process is not under control)	Value ascribed : 10
- the production process is 50% under control	Value ascribed: 5
- the production process is under full control, e.g. completely automatized, or regulation elements are under full control, personnel and the checking they carry out are demonstrably controllable	Value ascribed: 1

Quantitative risk analysis is expressed as a sum of K+C+S.
Under premix manufacture conditions the quantitative risk analysis procedure according to FMEA can be considered as an aid only, a more efficient tool for the critical point system identification only is the qualitative risk analysis providing that it has been formulated by trained and skilled staff.

2.25.0 The Identification of Critical Points

The identification of critical points is based on knowledge of manufacturing equipment, production process and description of extreme situations that may occur. For the critical point identification a decision-making diagram presented bellow can be used. In practice the whole production process must be gradually examined and considerations taken which production stages or operations might cause hazards, and which risks to health safety of premixtures or feedingstuffs can be prevented through monitoring and corrective actions.

If there are the control are points identified in the production process and corrective measures taken to be performed by personnel operating these points to decrease a hazard occurrence probability, it is unfounded to identify these points as critical.

2.25.1 Decision-making diagram

is a tool for the identification of critical points. When using the diagram, an identified hazard is followed gradually through each stage of production process, from the beginning to delivery, and questions in the diagram are answered in a given order until reaching the "stop"; than the next identified danger in another process stage is switched to.

2.25.2 An example of assessment of additives, feed ingredients, protein feeds received in the production process according to the decision-making diagram (1st production stage):

Question 1 **– Have any precautionary measures against the identified risks been taken?**

No – define, how and where the risks can be controlled (sensoric examination against specifications, check that a receipt bin has been emptied, check

transport routes chosen, check a receipt container). If any departure from specification is found, material cannot be received.

Yes – the precautionary measures have been taken, proceed to Question 2.

Question 2 **– Is this operation specifically designed to eliminate hazards or reduce them to an acceptable level?**

No – proceed to Question 3 (at this step there is still hazard present therefore this is not a critical point).

Yes – this is a critical point.

Question 3 **– Can cross-contamination occur or can the hazard be increased to an unacceptable level?**

No – it is not a critical point

Yes – proceed to Question 4 (on-receipt cross-contamination may occur).

Question 4 – **Will the measures taken eliminate the risk in the following step or will they reduce the risk to an acceptable level?**

No – it is a critical point

Yes – it is not a critical point (only if the measures are observed).

2.26.0 Determination of Characteristics and Values of Critical Limits for Each Critical Point

When determining characteristics to be examined in critical points we should focus mainly on hazardous additives or other additives, or selected undesirable substances or animal protein because these are predominant factors affecting the rise of risk. Their critical limits and tolerances are set in Feedingstuffs Regulations. In the protocol of critical point control, values measured, permitted limits and tolerances are listed, in case of cross-contamination, levels measured and maximum permitted levels which are not yet regarded as cross-contamination (determinability limits and relevant tolerances) are listed.

2.26.1 Definition of monitoring system of a situation under control at critical points

In the monitoring all critical points must be included in order to enable to objectively judge a characteristic under observation (additive, undesirable substance, banned substance) at all process stages thereby confirming the finding (the reason are potential mistakes at sampling and testing).

The control system must be defined for each critical point in an appropriate way to:

a) enable the monitoring to detect every threat to controlled situation in critical points and based on the data measured carry out timely corrections of production process preventing the exceeding of critical limits,
b) enable to correct the production process according to results of control, even in case of only adverse trends towards exceeding critical limits being shown,
c) Results of control must be assessed by a trained employee appointed by the manufacturer and capable of carrying out corrective actions.
d) Protocols on the control of critical points must be confirmed by competent persons, discussed and corrective actions taken in time

2.26.2 Definition of corrective actions

In the main, corrective actions include actions relating to defect product manipulation (product recalls, reworks, disposals) and actions to take to bring critical points under control. Corrective actions are listed in protocols and separately, as part of documentation on critical points, archived for a set period of time.

2.26.3 Definition of verification procedures

The efficiency of monitoring (control plan) of critical points is to be examined by prescribed verification procedures carried out at predetermined interval. As a rule this is included in the manufacturer's control plans.

The verification function of a system usually includes:

- the examination of system and records,
- the examination of critical points that they are in a controlled state,
- the monitoring of development of tested characteristics at critical points,
- the judgement of monitoring (plan) function according to results of control by means of other testing methods independent of testing methods used in the control,
- dealing with complaints.

2.26.4 Documentation of critical points

The manufacturer must designate a suitably qualified person as having responsibility for the documentation. The documentation must be archived for a certain period of time specified in Feedingstuffs Regulations, or, if not legally specified, decided by the manufacturer.

The documentation includes the following items:

- plans of the system of critical control points,
- records on the system development (records on product specifications, hazard analysis including control measures, identified critical points, critical limits, monitoring procedures (control)),
- records on the system operation (protocols on critical point checks, results of testing, records on verification procedures, records on dealing with products in an uncontrolled state),
- production procedures, formulations used (specifications for the manufacture) when the checking of critical points took place,
- emergency rules defining procedures to be used in case of power failure, etc.,
- job description for competent production stuff involved in the critical control point system,
- testing methods which will be used for checking the critical points
- staff training methods and records on the production, storage and quality control.

The above-mentioned documentation can be replaced by production procedures, quality control plan, storage and organizational rules providing that these documents deal with the above-mentioned issues.

3.00.0 Processing Areas and Equipment

Provisions on manufacturing equipment apply to manufacturers of premixtures, compound feedingstuffs with premixtures or complementary feedingstuffs.

Processing areas are usually plotted in a view outlay plan with description of purpose of production facilities. Manufacturing equipment is documented in a precise and complete technological diagram with descriptions of each machine position in order to enable a clear assessment of each part and stage of production process.

As a rule, production facilities and equipment must be suitably placed, designed and maintained to meet requirements for processing and manufacturing of all types of feedingstuff or premixture, or groups of selected types of feedingstuff or premixture.

3.00.1 When designing a new production plant or preparing reconstruction of an old

feedingstuffs or premixtures production plant, it is necessary to consider the following points:

- entire emptying of conveying lines, including storage and dosage bins an other manufacturing equipment, in particular items in which hazardous additives or premixes containing these are processed,
- suitable weighing equipment for ingredient addition must be chosen with regard to required batch weight. A scale must enable to weigh any specified amount without excessive deviations,
- working accuracy of mixers must correspond with types of production or ingredients, with additives in particular,
- separate storage of ingredients or final products must be possible; mixing between ingredients or final products must be prevented,
- there must be a separated aspiration of manufacturing equipment, with aspiration dust being always returned to a place where it was produced, for each production stage separately. If this cannot be assured, dust must be disposed of. It is inadmissible to mix together aspiration dust containing additives with dust from places where these additives have not been present.

3.00.2 These requirements are mainly aimed at:

- the elimination or substantial reduction of cross-contamination,
- the assurance of observation of limit levels of additives,
- the assurance of homogenous distribution of additives in premixture or compound feed batches.

3.10.0 The production areas, processing areas, stores and laboratories must be cleaned on a regular basis and waste accumulation must be prevented. A plan of tidying and cleaning of production areas and equipment must be produced by the manufacturer; the tidying and cleaning must take place at regular intervals and be suitable for a production type and operational safety. The plan for tidying and cleaning is usually part of manufacturing procedures. The plan also includes insect and rodent extermination from processing areas and equipment. Usually, mechanical cleaning of all production areas is carried out simultaneously with insect extermination.

There must be records kept on inspections and cleaning which must include information on measures to be taken in case an insufficient level of hygiene was found. The documentation also includes records on insect and rodent extermination that have been carried out including insecticides used and subsequent checks.

3.10.1 The processing areas must be effectively lit and ventilated. The buildings and processing areas must be protected from surface water and animal penetration. Only authorized personnel are allowed in the production areas. Other personnel are allowed in only if received a permit from the production manager to perform repairs or maintenance and their stay must be controlled by a designated employee. Authority supervision staff is allowed in the premises only if accompanied with the person responsible for the production or a designated person.

3.10.2 The construction and surface finish of floors must relate to the process. Floors in the mill and the surfaces of exterior access areas in close proximity to the mill must be maintained in a good state of repair in order that material cannot accumulate on uneven surfaces.

3.10.3 Walls and ceilings of production areas, including storage containers must be kept

in a clean condition to prevent the multiplication of pests and eliminate fire or explosion hazards.

3.10.4 The frequency of cleaning production areas and equipment must be suited to a production type and intensity.

3.10.5 In the production areas waste produced in the manufacturing process must not be accumulated for a longer period of time. Waste must be sorted according to its harmfulness and regularly removed from production areas, stored in places designed for this purpose and subsequently disposed. Records on waste disposal must be kept by a designated person. For this purpose a waste management plan must be formulated by the manufacturer which will be an annex to the code of practice.

3.10.6 When designing manufacturing operations and equipment, potential failures must be taken into account, and the design and construction must minimize the risk of the failure occurrence.

3.10.7 The design and layout of manufacturing equipment must enable to check that efficient cleaning and maintenance are carried out. The plan must not include equipment incapable of sensoric control and cleaning. For this purpose all storage areas for materials processed must have big enough *entrance holes* with sealable locks, and in places where frequent checks are necessary these holes must have instant closures. If, in spite of these measures, places incapable of being checked and cleaned are found, the manufacturer must try to minimize the risk in the framework of critical point system; if the risk cannot be minimized within the system, technical adjustments at these places must be performed.

3.10.8 Manufacturing equipment must be regularly checked by personnel responsible at intervals corresponding with the nature of potential risks. The objective, method and frequency of checks are usually specified in the production process. If necessary, records are kept on checks performed in selected controlled places.

3.10.9 Manufacturing equipment must be designed so as to prevent cross-contamination. If cross-contamination cannot be eliminated by the design, the equipment must be always run a flushing batch through after the manufacture of premixtures or feedingstuffs containing hazardous substances. The waste must be disposed of.

3.10.10 The scales used must have suitable upper and lower limits of weighing range and working accuracy for the specified amounts of ingredients. It is inadmissible to use a scale which is not suitable for specified amounts of ingredients. The scale must be capable of recording actual amounts of ingredient or admissible deviations.

3.10.11 Scales and other measuring equipment used for ingredient dosage should be at least once a year calibrated by an authorized company. If these are specified measuring devices, they must be verified according to metrological rules at predetermined interval. A company must issue records on calibration or verification containing data required by current legislation. Scales showing deviations greater than tolerances in production process and regulations must not be used in the manufacture.

3.10.12 When necessary, the manufacturing operation must be monitored with devices capable of recording vital parameters of selected production section or record and announce failures of equipment.

3.10.13 Important manufacturing equipment must be checked at regular intervals and cleaned if necessary; records must be kept on results of checks and cleaning. This includes in particular the equipment for removal of all kinds of impurities

(particularly ferromagnetic impurities), weighbridges for ingredient dosage checked indirectly by means of test production; if deviations from specification greater than ± 1% occur, weighbridges must be adjusted and calibrated; mixers must be checked for tightness and possible leaks and condition of mixing elements examined. If leaks or damages to mixing elements are found, the mixing equipment cannot be used for the manufacture.

Only weighbridges meeting legal requirements and manufactured by an authorized company can be used in the production process. Mixers can be used for the premix and feedingstuff manufacture only if their working accuracy has been verified according to a type of production. Mixers used for the manufacture of premixtures and feedingstuffs with less than 0.2% premixes the must have a working accuracy of 1:100,000. In the manufacture of feedingstuffs with more than 0.2% premixtures working accuracy of 1:10,000 is required.

The above requirements relating to manufacturing equipment checks, determination of frequency of checking and documentation are usually specified in production procedures.

3.10.14 Methods of maintenance, including determination of frequency and specification of responsibilities are usually defined in the maintenance plan.

4.00.0 Personnel

The manufacturer must have sufficient staff possessing the specific skills and qualifications necessary for the manufacture of the above mentioned products. The manufacturer must create an organisational chart setting out the qualifications and experience (length of practice) necessary for certain positions and responsibilities. The organisational chart must be available to appropriate authorities for inspection. Staff powers and responsibilities relating to product quality and safety must be recorded as written job descriptions and signed. Any changes in the production process or relevant regulations must be clearly explained to all personnel involved. The manufacturer must provide staff with regular training covering manufacturing procedures, production control, quality control, relating records to maintain their levels of knowledge; the staff must confirm that they understand the scope of training.

4.00.1 The manufacturer specifies requirements for the production staff training and abilities according to tasks they will perform. The personnel responsible for production must meet requirements laid down in the relevant regulations. A permanent exemption of a person responsible for production from these requirements is inadmissible. Knowledge and skills of all production people must be increased by regular informing about production requirements, production control, quality control and safety. This training should be performed at least once a year and each time a change occurs. All new production employees must be explained all relevant regulations and this must be confirmed by their signatures, before they start working.

4.00.2 The organisational chart must clearly set out competencies at each level of management. In written job descriptions the powers and responsibilities for the production must be either clearly explained or briefly defined with references to relevant rules issued by the manufacturer (production procedures, storage rules, etc.). The manufacturer's rules must not lay down collective responsibilities or define no responsibilities (operational personnel are responsible for the production).

5.00.0 The Manufacture of Premixtures and Feedingstuffs

A detailed description of production process including control mechanisms is usually set out in the production procedures. At the leading position the person responsible for the production, e.g. production manager must be written, and his or her powers and responsibilities defined. In general, there are the following duties of the manufacturer that must be taken into account when formulating a production process.

5.00.1 Manufacturers of premixtures or feedingstuffs containing additives or premixtures, or complementary feedingstuffs must assure compliance of each production process stage with legal regulations and guidelines, which leads to the identification and control of critical points in the production process.

5.00.2 There must be technical or organisational measures taken to prevent or minimise cross-contamination and failures in the production. Throughout the production process there must be sufficient and appropriate means of control employed.

5.00.3 The monitoring must detect presence of banned feed ingredients, banned of undesirable substances and pathogens. A suitable control strategy must be established to minimize the risks.

5.00.4 Waste and material that cannot be sold must be isolated and identified. Any materials presenting risks listed in the section 5.00.3, hazardous additives or medicinal substances, or materials that can be contaminated with these substances, must be disposed of in a suitable way and must not be used as feed (usually incinerated as hazardous waste).

5.10.0 Production processes must be formulated to suit manufacturing equipment of a production line; if several production lines are in operation and each of them has different technical layout or produces different types of premixture or compound feed, or groups of premixtures of compound feeds, there must be an independent production process in place for each production line. Production processes must be suited not only to manufacturing equipment but also to types or groups of premixtures or compound feeds if produced in different ways. If this is the case, all the identified critical points in the production process must be checked and, if possible, an independent working procedure with identified critical points established for this part of production.

The production process is usually divided as follows:

a) the receipt of ingredients
b) a type of ingredient processing, if processed
c) the addition of ingredients, both in solid and liquid form
d) the mixing of ingredients into a batch,
e) the pelleting or extrusion of products, which is mostly considered as independent production procedure,
f) the storage, packaging, loading, transport and delivery of finished products,
g) the manufacturing technology aspiration,
h) the cleaning and insect extermination of manufacturing equipment and production areas, and rodent extermination if manufacturing equipment operators are authorized to perform it.

For each part of production process there must be a detailed description of personnel tasks, intervals and documentation of checks and documentation.

5.11.0 Premixture production procedures must include:

5.11.1 Tasks associated with the receipt of ingredients for the production:

- the receipt from the store of additives, feed ingredients of protein feeds

according to production specifications. At the receipt details on labels of packaged materials must be checked whether an ingredient has been released for the production or not and that packages are originally sealed and not damaged.

- If packages are damaged, the structure of material must be examined and if found unsatisfactory, the package is returned to the store.
- Before the receipt of bulk ingredients the person responsible must check how much a receipt container is already filled, if the right transport routes have been chosen, a receipt bin is empty and equipped with a grate.
- If bulk ingredients are delivered directly from the manufacturer, the person responsible must perform sensoric examination of ingredients received and withdraw a final sample from each batch.

5.11.2 In the premix manufacture the ingredient processing usually does not take place, right after the receipt of ingredients premixes are added into a batch. The addition process must include:

- check of scales to weigh additives by means of control weights. If scales show a greater deviation than admissible, they must not be used for ingredient dosage,
- a scale with weighing range corresponding with the required weight must be used for ingredient weighing,
- if the weighing is done manually, each ingredient must be separately weighed and then transferred into a collection bin and added to the mixer. Gradual weighing of ingredients into one bin is allowed providing that a prescribed sequence and amounts of ingredients are adhered to because it is difficult to withdraw an incorrect amount of ingredient from the mixer. Therefore ingredients to be added in higher amount must be weighed first and lower amount ingredients are usually weighed in the middle part of the weighing process,
- containers and other tools used for the weighing must be cleaned and residues removed prior to the weighing,
- if bulk materials are weighed with an automatic scale, an operator must make sure that s proper dosage container is used and regular checks of weighing fluency are carried out, and if the process is interrupted, he built up material must be removed,
- required and actual weights of ingredients must be recorded including deviations from the required weights, and stated whether these deviations are admissible or not,
- before putting the amounts weighed to the mixer, an operator must make sure that the mixer is empty, funnel is clean and equipped with a protective grate.

5.11.3 Mixing

Personnel responsible for the mixing process must:

- check that the mixer is tightly closed and does not leak, mixing elements are not damaged and the mixer is empty, both before the mixing process and after. If recesses of material are found in the mixer, it must be cleaned, particularly if hazardous additives were used in the preceding batch,
- check that the mixing time is correctly set and corresponds with the time for which the mixer was verified. The mixing time starts at the moment when the mixer is filled with all solid ingredients. Liquid ingredients can

be added only after two thirds of mixing time have elapsed,
- If the mixer is equipped with a container for finished product, personnel must make sure that it is emptied both before and after the mixing, and if recesses are found, the container must be cleaned. The container must also be cleaned each time a preceding batch contained hazardous additives.
- If a mixing unit is aspired, filters must be checked that they are clean.

5.11.4 Transport, packaging, storage, loading and delivery of finished products

5.11.5 If finished products are conveyed from the mixer to the packaging unit, the personnel responsible for this part of the process are assigned the following tasks:
- to make sure, before starting the manufacturing process, that the conveying line and closures are correctly set
- to check the functioning of conveying lines during the conveying process, e.g. that dampers (slides) are closed and do not let material out, or adjust dampers to let material fill the conveying line according to load,
- after finishing the material conveying, the line must be let running until empty.

5.11.6 Packaging of final products

Personnel responsible for this process part perform the following tasks:
- Before packaging they must check that a scale is functioning properly, is empty and clean; this is necessary if a preceding batch contained hazardous additives.
- If an automatic scale is used, they must set a required weight of bag contents, bag weight, according to manufacturing specifications,
- If not specified, they must choose a suitable type of package according to package weight.
- During the packaging process, if the automatic scale is not verified, the control weighing with a verified scale must be performed and the automatic scale reset accordingly.
- After the filling a package must be sealed and labelled. Labels must be checked that they include required details relating to the product contained in the package.
- Closed and labelled packages must be placed on pallets in numbers corresponding with pallet construction weight. When a pallet is fully loaded it is wrapped in foil if required due to a number of packages.
- If a plan of quality control requires personnel to withdraw a final sample from each batch, this must be carried out according to the procedure defined in the quality control plan. The sample is given the same label as the product and handed over to a person responsible for sample keeping.

5.11.7 The storage of finished products

Personnel responsible for this process part perform the following tasks:
- The way of placing products in the warehouse (locations set out in a plan, acceptable stacking of packages or pallets) is defined.
- What steps must be taken if a product is not allowed for delivery.
- Warehouse cleaning.

5.11.8 The loading of finished products

Personnel responsible for this process part perform the following tasks:
- A person must be appointed to issue finished products form the

warehouse.

- The personnel must decide when the finished product can be loaded.
- The personnel must check labels and make sure that the right product is handled, packages are not damaged, and check numbers of packages loaded.
- If competent, the personnel must issue documents on product delivery.

5.11.9 Aspiration of manufacturing equipment and cleaning of production areas

This part must be covered in the production process description if not listed in other documents such as sanitation rules.

Personnel responsible for this process part perform the following tasks:

- They must decide which aspiration equipment must be regularly checked and cleaned, and define intervals of checking and cleaning.
- They must decide which production areas and manufacturing equipment must be cleaned, choose methods and intervals of cleaning if not defined in other parts of production process.
- If personnel are appointed to carry out insect and rodent extermination, they must define methods to be used, intervals and locations, and procedures to be carried out, and how baits must be disposed of after they become no more efficient.

5.11.10 Critical points in the production process

The manufacturer identifies critical points in the production process on the basis of system verification. In premix plants it is usually the site where products are filled into packages that is an important critical point. At this point a correct dosage of additives, homogenous distribution of additives throughout the batch and potential cross-contamination occurrence during the production process can be checked.

5.12.0 Production Procedures in the Feedingstuff Manufacture

The following rules apply to plants producing feedingstuffs containing additives and premixtures, or complementary feeds containing hazardous additives. Production process descriptions must in all their parts must specify the following tasks:

5.12.1 The personnel responsible for the receipt of ingredients must:

- check that there are no recesses in the receipt container, each time a new ingredient is to be placed in it,
- check that the receipt bin is empty and equipped with a protective grate,
- check that the right conveying line has been chosen,
- before putting an ingredient in the receipt bin, conveyed bulk material must be sensorically examined, results compared with declarations; material must also be checked for visible defects (presence of foreign objects, live pests or changed structure or colour),
- during the conveying process personnel must examine the functioning of conveying lines, that dampers are tightly closed and ingredient particles are not placed in other bins then destined,
- if personnel must withdraw samples from a received batch, this must be performed in compliance with the procedure description in the quality control plan and samples must be given the same labels as ingredients they were withdrawn from and handed over to a person responsible for sample keeping.

At the receipt of packaged ingredients personnel perform the following extra tasks:

- examination of packages received that a type of ingredient corresponds with specifications and the ingredient has been released for production.

5.12.2 With ingredient processing usually the following tasks are associated:

Before the start of processing:

- Suitable sieves must be placed into main grinders and into a grinder in a control line if installed, or, if drum grinders are used, the grinding slit must be adjusted to comply with the manufacturing specification or personnel knowledge.
- Conveying routes must be adjusted to transport of ingredients into containers above the grinders, and from the grinders to grinder containers or containers placed above the mixing unit.
- Magnetic impurity separators must be checked and cleaned if necessary.
- Aspiration equipment must be checked and cleaned if included in the processing line.

In the course of processing:

- Sensoric examination of particle size must be performed, using a sieve with appropriate hole size for a type of product.
- The functioning of ferromagnetic particle separators must be checked and cleaning performed if necessary.
- The functioning of conveying lines, particularly dampers must be checked that ground material is placed in the designated containers.

5.12.3 Tasks associated with ingredient addition

- Amounts of ingredients in dosage containers must be checked and if necessary, containers refilled during the production process.
- If the production specifications contain an ingredient which has not been listed in a scheme container filling in the control unit, operators must first check that the right container has been emptied and according to type of dosage unit decide whether a newly accepted ingredient will be placed in the container or not.
- If automatic dosage systems are used, operators must check how production specifications are described in the control computer, a sequence of produced batches which will be respected by decontamination programme and whether an ingredient will be dosed with a scale with corresponding weighing range. As next step the operators will decide on the order of ingredients added, with the highest dose ingredients being added at the beginning and the lowest dose ingredients in the middle of addition process; at the same time they must take into account specific gravity of ingredients (an ingredient with the lowest specific gravity must not be added last).
- If ingredients are added by hand, operators must check a scale using control weights for compliance with a defined tolerance of ± 1%, and if a scale shows a greater deviation, it must not be used any more.
- In the case of manual weighing ingredients must be sensorically examined during the weighing for differences between packages or presence of foreign particles.,
- Actual weights of ingredients must be recorded and compared with specifications whether there is not a greater than allowed deviation; if an automatic scale is used, a similar procedure must be employed.
- In the case of manual addition, hoppers must be cleaned between different products.

- If automatic scale systems are used, control batches are processed at pre-determined interval and extent. The actual ingredient amounts weighed for a given batch are compared with the batch weight using a verified scale. If repeatedly greater deviations than ± 1% are found, the calibration of the whole weighing system must be carried out.

5.12.4 Tasks associated with ingredient mixing

In this process part usually the following tasks for personnel are defined:

before the start of mixing:

- to check that a mixer whether it is empty, as well as adjacent containers above and under the mixer, the mixing elements are not damaged. Simultaneously, operators must check pneumatic connections if these have been installed,
- to check that a dust filter is clean, if not, clean or change it,
- to set a mixing time if it is not pre-set in the control system,
- to examine dampers and valves in the container above the mixing unit of in conveying routes,
- in rotating mixing units check position of a drum slit against mouths of conveying lines or container,
- if a mixing unit and following conveying lines include an automatic sampler, the operator must set a specified production weight in the control system according to which a number of withdrawn samples is determined,

during the mixing:

- to check that the mixer unit is tight and does not leak,
- to check that the mixer unit has been entirely emptied, including a container under the mixing unit,

after the mixing: if personnel is designated to prepare a sample from a batch, they must homogenize and reduce a pooled sample withdrawn by an automatic sampler and subsequently make a final sample that is immediately sealed and designated with a label listing type of product, production date and batch production weight.

5.12.5 Pelleting

The personnel responsible for the pelleting process must:

- check that both the main and compensatory containers above the pelleting press, screw conveyor to conditioner, conditioner, cooling column, cyclone and before loading container for pelleted material have been emptied,
- according to the production specifications place a pelleting press die and put a suitable sieve in the sorting sieve for pellets, set according to specification temperature for hydrothermal treatment,
- adjust conveying lines according to containers designated for the batch before and after the pelleting,
- if the pelleting line is automatically controlled, a required press performance, hydrothermal treatment temperature, and, if possible, pressure of rolls must be set,
- during the pelleting process they must check that a pre-set temperature of conditioning is maintained, examine cohesion of pellets, pellet temperature after cooling; according to temperatures measured they adjust frequency of cooling column emptying or press performance, check the function of cyclones and their air closures and the function of

sorting sieve,
- after the pelleting process they must make sure that all parts of pelleting line have been emptied and clean the pelleting press, screw conveyor and conditioner.

5.12.6 Transport, storage, packaging and delivery of finished products

The personnel responsible for this process part must:

Conveying:
- before starting the production, check the adjustment of conveying lines and containers into which products will be placed,
- during the production check the functioning of conveying lines, particularly tightness of dampers if they do net let material penetrate into other containers than specified,
- after the production process a period of time must be decided for which the conveying lime must be let running empty to carry material residues in a designated container,

Storage:
- storage containers for material intended for packaging or bulk delivery are usually strictly defined for products containing hazardous additives. Changes in container positions must be permitted by the responsible person and containers cleaned before changing positions,
- on a regular basis, usually after emptying a container, personnel remove dust form upper part of walls and ceiling and put it in a waste bin,

Packaging:
- check a scale and container, and clean it if necessary,
- set a scale according to specified weights of contents and package weight,
- choose a suitable type of package for a product if not specified,
- if a scale is not verified, perform random checks of package weight and adjust the scale accordingly,
- check a package designation that it corresponds with a type of packaged product and that details on a label are correct,
- remove packages damaged during packaging process of handling form storage and change them, including a designation,
- before closing a package perform a sensoric check of its contents colour and structure if consistent between packages. If changes are ascertained, packages are placed outside the loading area,

Final product loading:
- in case of bulk material delivery a person responsible must check whether a conveyor is empty,
- during conveyor filling personnel if authorized, must withdraw a sample from consignment using a procedure defined in the quality control plan and immediately seal the sample, designate it the same as product and hand it over to be stored; at the same time they examine the product for sensoric changes, if these are found, the loading must be stopped,
- if personnel are authorized, they can check packages for damages. If so, the packages must bee excluded form loading, their designations and numbers must be checked.

5.12.7 Production technology aspiration

The personnel responsible for this process part must:
- check the functioning of passive and active aspiration, including

frequency determination, in passive aspiration also dust bags must be shaken clean (usually after finishing production of batch containing hazardous substances),

- clean active aspiration if a substantial built up of dust particles has been found,
- adjust active aspiration automatic cleaning intervals according to production cycle length, a pre-determined intervals carry out maintenance of dust bag tissue or boxes with filtration tissue in active aspiration.

5.21.8 Cleaning of production areas and equipment, insect and rodent extermination

This part specifies methods and frequency of cleaning production areas and equipment and, if personnel are authorized, insect and rodent extermination. Cleaning procedures are specified also for equipment, cleaning procedures for which are not defined directly in different parts of the production process. Primarily the areas and equipment must be cleaned where additives or premixes of additives are handled and processed. A pre-determined frequency of cleaning should correspond with a number of products processed and also hygiene, safety and fire protection rules must be taken into account.

Insect extermination should always be carried out along with complete mechanic cleaning of production areas. Frequency depends on sensoric examination for warehouse pests or their development stages. After the insect extermination the building must be cleaned and aired. Rodent extermination is carried out in case of rodent occurrence or preventatively. Used baits and residues from insect extermination must be disposed of as harmful waste by incineration.

5.12.9 Critical points in the production process

The manufacturer must identify critical points in the production and ensure their control according to a plan.

In the production process of feedingstuffs containing additives and premixes of additives, hazardous additives in particular, critical points are usually allocated into a stage in which correct doses of additives or premixtures, homogenous distribution throughout a batch a cross contamination can be checked. For this reason it is suitable to place critical points for mash products into a stage of mixing and other critical points place into the loading stage. In both the critical points all the above-mentioned risks can be controlled and at the same time check that a preventative control is performed in the critical points identified for each stage of production process. In the production of pelleted or extruded feedingstuffs it is necessary to set an independent production procedure because these treatments increase a number of critical points, and next critical point is usually identified at a place where cooled but not yet sorted pelleted material (extrudate) can be controlled and thereby possible losses of additives due to the pelleting and cooling, or potential cross-contamination detected.

6.00.0 Quality Control

Manufacturers of premixtures and feedingstuffs containing additives, premixes or complementary feedingstuffs containing hazardous additives must formulate a written quality control plan as part of safety system. One of conditions is that the manufacturer must own or contract a laboratory which will analyse ingredients and finished products. The laboratory must have suitable equipment and trained staff who will check that defined characteristic are adhered to and

guarantee that ingredients and products tested in the laboratory correspond both with values declared and are fit for feeding to a given animal species and category.

A qualified person must be designated as having responsibility for quality control.

6.10.0 Powers and Responsibilities of a Qualified Person

Powers

- a power to check all personnel involved in the quality control system that they fill their duties,
- a power to suggest and discuss corrective actions assigned at quality control and critical point control and check that they are implemented,
- a power to determine parameters that will be tested in ingredients used and finished products including determination of testing intervals,
- a power to determine sampling places, sampling procedures for quality control purposes,
- a power to decide on testing methods for determined characteristics,
- a power to inspect laboratories involved in the quality control system and safety assurance system for ingredients and products,
- a power to determine characteristics that will be tested in recalled products,
- a power to determine method of defect removal in defective products,
- a power to present proposals of critical control point system verification and proposals of changes in the quality control plan.

Responsibilities:

A qualified person is responsible for:

- the control of adherence to the quality control plan,
- the control of adherence to the system of product verification at critical points
- the keeping and retaining of records defined by the quality control plan and system of critical point verification for a period of time defined by the regulations,
- amendments to the quality control plan and critical point verification system
- factual correctness of test results of the in-plant laboratory and documents on the quality control of ingredients and products including document of critical point control,
- the adherence to regulations relating to quality control,
- if sampling and testing is not carried out in compliance with the regulations, this person is responsible for verification of manufacturer's rules and adherence to them.

6.20.0 Requirements to Personnel of In-Plant or Contractual Laboratory

In-plant or contractual laboratory must have suitably qualified personnel who will test characteristics defined in the quality control plan or critical point control system. Therefore personnel must know and master methods of testing the determined characteristics. The personnel level of knowledge must be systematically deepened and tested by a demonstrable method, e.g. by means of attestation or ring tests.

6.30.0 Requirements to Equipment of In-Plant or Contractual Laboratory

Equipment of laboratories must be suitable for methods determined in the quality

control plan and must guarantee quantitative determinations of characteristics corresponding with determined repeatability and reproducibility for the testing method used. Devices must be well maintained and regularly checked by the person responsible. Defective devices must not be used for the testing. The functioning of devices must be kept continual records on and if required, it must be calibrated by an authorized person.

6.40.0 Quality Control Plan Must Contain the Following Items:

- the explanation of abbreviations used and definitions of terms, particularly a definition of the term "batch" for different ingredients and finished products,
- the determination of sampling methods, sampling tools and sampling points within the quality control plan,
- the determination of minimum sample weight, method of sample packaging, sealing, labelling and keeping including identification of locations where samples will be kept and for how long, and personnel responsible for sample keeping,
- the determination of a sample disposal method including documentation and personnel responsible for disposals,
- the determination of sample testing methods,
- the determination of characteristics that will be tested in contractual laboratories and ways of checking results of these laboratories,
- the determination of characteristics that will be tested in contractual laboratories and ways of checking results from these laboratories,
- the determination of ways of record keeping on quality control and length of time of archiving, personnel responsible for archiving,
- the determination of procedures of product verification in case of product recall (sampling methods, characteristics tested, dealing with defects),
- which defects of ingredients and products will be considered as removable and which will be reason for ingredient or product disposal,
- powers and responsibilities of qualified persons responsible for quality assurance.

Beside the above points the quality control plan may include also critical control system clearly identifying critical points, determining frequency of checking, characteristics to be tested at critical points, sampling methods to be used at critical points, methods of assessment of results from critical points and people who must be informed about the results and who will decide on corrective actions to be taken and check their implementation.

7.00.0 Storage and Transport of Ingredients and Products

In general, the following requirements can be defined for the storage and transport:

7.00.1 Finished products must be stored separately and it is inadmissible to keep them in the same store as ingredients to be processed.

7.00.2 Finished products must not be put into used packages.

7.00.3 Ingredients and finished products must be stored and transported in suitable packages or stored in appropriately designed silos constructed, adjusted and maintained in order to ensure good storage conditions. Only personnel appointed by the manufacturer is allowed in stores or competent public authorities accompanied with staff members designated by the manufacturer.

7.00.4 Ingredients and finished products to be transported must be easily identifiable in order to avoid exchange, cross-contamination or deterioration.

7.00.5 Packages and equipment used in the transport, storage, handling and weighing must be kept in clean condition. The manufacturer must introduce a cleaning programme for this purpose or include the cleaning programme in the production procedures and storage rules formulated. The method of cleaning defined in the programme must ensure a reduction of occurrence of disinfection means traces to a minimum level.

7.00.6 In stores suitable temperature must be maintained depending on ingredients and products stored. Stores must be dry and well ventilated.

7.00.7 In the stores the occurrence of warehouse pests must be monitored and if some ingredients of products are infested, the material must be separated from other material stored and decontaminated.

7.00.8 The storage personnel tasks are usually determined by the storage or silo rules. The rules must be suited to a plant and be based on the warehouse and adjacent production areas construction and other documentation such as manufacturing procedures and quality control plan.

7.00.9 Storage or silo rules usually define:

a) the person responsible for observation of the rules, his/her powers and responsibilities.
b) On-receipt check of ingredients (delivery documents- delivery note are checked against ingredient designation, weight of ingredients delivered, sensoric examination of visible defects, presence of pests, packages of damages, package labels).
c) If personnel are designated to withdraw samples for delivered batches, they must withdraw, pack, label samples and hand them over to the person responsible.
d) Before the receipt of bulk components personnel must check that ingredients are to be stored at a clean place and protected from mixing with other ingredients, ingredients must be deposited in the reserved store at reserved place to be stored according to a plan. If ingredients are stored in silos or container s the personnel must check how full a silo or container is.
e) At the receipt of bulk components in silos or containers personnel must make sure that conveying lines are functioning properly and material is not placed into other containers than specified and must remove foreign objects from the receipt bin.
f) During the storage personnel must check stored material (measure temperature, check for the occurrence of pests) and according to the storage time he must move material to avoid excessive packing. When moving material, its quality must be sensorically checked.
g) If necessary, treatments of ingredients before and during the storage must be performed such as removal of impurities.
h) The issue of ingredients from the store is carried out in compliance with manufacturing specifications.
i) Rests of non-processed ingredients, premixes or protein feeds in particular must be placed back to the store at a designated locating, and check that packages are identically labelled. The residual material must be weighed, too.
j) If ingredients are received with labels stating that they show higher moisture contents, these must not be stored for a long period of time and must be either returned to a supplier or quickly processed.

k) Ingredients showing hygroscopic properties must be stored in dry warehouses in airtight packages; the packages must be placed on mats.

7.10.0 Storage of Feed Ingredients, Protein Feeds, Additives and Premixes

The above-mentioned ingredients must always be stored separately from finished products.

7.10.1 An independent separated area must be reserved for the storage of feed ingredients containing animal protein. Bulk feed ingredients containing animal protein must be accepted in the store and unloaded from the store via an independent transport route which must not be used for other ingredients.

7.10.2 Additives or premixes must be stored in a separate area; additives must be separated from premixes in the storage area depending on:

a) type and date of receipt,
b) examination results (deferred from production, examined, release for production),
c) damaged or rejected filled packages which will either be returned to a supplier or disposed of.

It is useful if storage facilities can be locked because some additives or premixes containing these additives may be dangerous. It is inadmissible to use additives and premixes for production which are first filled in damaged packages, than placed into non-original packages, or products in packages with incomplete information on the label or unlabelled. In this case defective packages must be returned to the supplier or the whole consignment can be returned.

7.10.3 Storage conditions must comply with fire safety characteristics of ingredients, which must be available to the person responsible for storage.

7.20.0 Storage of Finished Products

Storage rules must include personnel tasks and storage instructions if not specified in production procedures. General rules and duties Appling to the storage are listed in the section 7.00.0.

7.21.0 Storage of premixtures

Personnel responsible for premix storage must ensure that

a) premixes are stored separately according to type and date of production,
b) only premixes released for delivery are loaded,
c) They must check premix labels, number of packages and total weight of product to be delivered.
d) If premixes are stored for a longer period of time, contents of packages must be checked that have not got hard or do not show altered temperatures.
e) Stores must be cleaned and material residues placed outside the stores into special packages as harmful waste intended for disposal.

7.22.0 Storage of Feedingstuffs Containing Additives or Premixes or Complementary Feeds Containing Hazardous Additives

During the storage of feedingstuffs it is necessary that the personnel responsible fill the following tasks:

a) ensure the storage of feedingstuffs containing animal protein in an independent area separated form other feedingstuffs,
b) ensure the storage of feedingstuffs containing hazardous substances in the areas reserved,
c) check that storage areas are clean, as well as containers before the filling and after the emptying,

d) carry out checks of conveyors for bulk feed transport that they are empty before being filled and require their cleaning according to cleaning programme,
e) check packages for damages; damaged packages must be returned to be repacked,
f) check product labels if complying with type of product loaded and containing the required details,
g) check a number of packages loaded and if necessary, check the weight of the vehicle after subtracting weight of load form total weight,
h) issue required documents on loading; if a bulk product is to be delivered, the documents must be supplemented with the product designation if not included in the document,
i) keep the storage for feedingstuffs in clean condition and check for the occurrence of storage pests; residues after storage cleaning must be placed in a separate area into reserved packages and disposed of by incineration,
j) depending on the store construction, animals must be prevented from penetration into the store,
k) the store must be cleaned and insect extermination performed at predetermined interval,
l) baits for rodents must be regularly replaced; used baits and impurities after the insect extermination cleaning must be disposed of by incineration.

8.00.0 Record Keeping by the Manufacturer

All the manufacturers must keep records containing relevant information on ingredients and finished products by reason of traceability for the production to final destination. The manufacturer must appoint persons as having responsibility for the record keeping and retaining, specify their duties and powers. During retaining the records the manufacturer must observe legal regulations on record keeping and archiving relating to feedingstuffs, additives and premixtures. The manufacturer must define the method of record keeping (in writing or in electronic form).

8.10.0 Documentation Relating to Production and Critical Control Points

Both the premix and feedingstuff manufacturers must have a system of documentation to define and ensure the control of critical points in the production process and to formulate and implement the quality control plan. They must collect results of relevant controls and evaluate them. This documentation must be archived for a period of time set in feedingstuff regulations in order to be able to trace each product batch that has been put into circulation and ensure responsibility in case complaints occur.

The documentation must contain:

a) manufacturing specifications for each product including optimizing calculations used for specification and date of production (production protocol, optimization outcome),
b) weights of different products manufactured,
c) personal names and addresses of individual persons or business names and addresses of manufacturing company, supplier of premix importer and premix customer,
d) personal names and addresses of individual persons or business names and addresses of the customer's company buying feedingstuffs

containing additives and premixtures,

e) documentation must be kept specified in relating instructions (production procedures, quality control plan, storage rules, complaint rules.

8.10.1 Documentation that Must be Kept to Ensure Traceability in Premix Manufacturers

Beside the documentation specified in the section 8.10.0 the manufacturer must keep documentation on:

a) names and addresses of manufacturers of additives or their suppliers,
b) origin and amounts of additives used for different types of premixture including production date and batch number,
c) date of premix production, batch number
d) names and addresses of compound feedingstuff manufacturers or suppliers who were delivered premixes with stated delivery date, type and designation of premix, weight of delivered premix and batch number.

8.10.2 Documentation that Must be Kept to Ensure Traceability in Manufacturers of Feedingstuffs Containing Additives and Premixtures

Beside the documentation specified in the section 8.10.0 the manufacturer must keep documentation on:

a) names and addresses of manufacturers of additives, premixtures and their suppliers,
b) date of additive production, batch number, type and weight of additive or premixture used for the batch production,
c) type and weight of complete or complementary feedingstuffs manufactured with production dates and batch numbers,
d) the record keeping on deliveries of feedingstuffs containing additives or premixtures, which must include name and address of customer, production and delivery dates, type and weight of product delivered.

9.00.0 Complaints and Product Recalls

The manufacturer should produce complaint rules for this purpose setting out conditions and procedures for processing complaints and product recalls. The manufacturer must explain the complaint rules to customers, usually at signing contracts or must show the complaint rules to the customer if he asks for it. The complaint rules must comply with the provisions of Commercial Code and current feedingstuffs regulations.

9.10.0 The complaint rules usually describes:

a) how deliveries of premixtures or compound feedingstuffs are carried out,
b) delivery conditions,
c) responsibilities for product quality,
d) product delivery documentation,
e) duties of the customer at product receipt (identification of visible defects and their assessment), and duties to announce these defects,
f) responsibility of the seller for defects,
g) requirements the buyer is entitled to have when receives defective goods, e.g.:
   - replacement with perfect product,
   - if product of lower weight than declared was delivered, correct weight must be delivered immediately,
   - price reduction,
   - withdrawal form purchase contract, etc.
h) reimbursement of cost incurred due to insufficient accomplishment

i) how complaints due to other product defects will be dealt with; or product recalls, e.g.:
- if a customer provides technical support at product recall,
- by when a perfect product will be delivered after the product recall,
- at which place samples will be withdrawn form the recalled products, by whom, and who will check their quality,
- if losses incur, documents the customer must submit, and in which case he will be responsible for the loss.

9.20.0 The manufacturer must keep records on:

- complaints; a date of receiving a complaint and person appointed to deal with it must be recorded,
- product recalls; it must be recorded which product was rejected, date of production and delivery, weight at delivery and weight at recall, which characteristics are to be tested, results of rejected product quality control re-assessment, conclusions stating whether the product will be reworked or disposed of.

10.01.0 A Survey of Feed Legislation of the Czech Republic and Principal Relations to the EU Feed Legislation

Feed Legislation of the Czech Republic:

Act no. 91/1996 Col., on feedigstuffs in wording of later regulations (amended by Act no. 244/2000 Col. and Act no. 147/2002 Col., on Central Agricultural Control and Testing Institute in wording on Act no. 309/2002 Col.)

Decree no. 451/2000 Col., implementing Act on feedingstuffs in wording of later regulations (amended by Decrees no. 343/2001 Col., no. 472/2001 Col., 169/2002 Col., 544/2002 Col. And no. 284/2003 Col.)

Decree no. 124/2001 Col., laying down requirements to sample withdrawal and principles of laboratory testing methods of feed materials, additives and premixes and methods of sample retaining.

In accordance with the future development of feed legislation this chapter will be updated and supplemented with the Annex to the Code of Good Manufacturing and Hygiene Practice.

In the feedingstuffs regulations of the Czech Republic the following EU legal regulations have been implemented:

Council Directive 70/524/EEC of 23 November 1970 on additives in feeds in the wording of later amendments.

Council Directive 96/51/EEC of 23 July 1996, amending Council Directive 70/524/EEC on additives in feeds in the wording of later amendments.

Council Directive 87/153/EEC of 16 February 1987, laying down the main principles for evaluation of additives used in animal nutrition, in the wording of Commission Directive 2001/79/EC of 17 September 2001.

Council Directive 79/373/EEC of 2 April 1979 on placing compound feedingstuffs on the market, in the wording of later amendments.

Council Directive 80/511/EEC of 2 May 1980, permitting, in certain cases, to place on the market compound feedingstuffs in non-sealed packages or containers, in the wording of later regulations.

Commission Directive 82/475/EHS of 23 June 1982, defining groups of ingredients which can be used for the identification of compound feedingstuffs for domestic animals, in the wording of later regulations.

Commission Directive 86/174/EEC of 9 April 1986, specifying the method of energy content calculation in compound feedingstuffs for poultry.

Commission Directive 91/357/EEC of 13 June 1991, defining groups of ingredients which can be used for the identification of compound feedingstuffs for other than domestic animals, in the wording of later amendments..

Commission Decision 91/516/EEC of 9 September 1991, laying down a list of ingredients, the use of which in compound feedingstuffs is banned, and subsequent Decisions 92/508/EEC, 95/274/EC, 97/582/EC, 1999/420/EC and 2000/285/EC.

Commission Decision 85/382/EEC of 10 July 1985, imposing a ban on the use of protein in feed produced by the yeasts of Candida genus cultivated on n- alcanes,

Council Directive 96/25/EC of 29 April 1996 on circulation of feed ingredients, amended by Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and cancelled by Directive 77/101/EEC, in the wording of later amendments.

Council Directive 1999/29/EC from 22 April 1999 on undesirable substances and products in animal nutrition, in the wording of Council Directive 2001/102/EC of 27 November 2001, amended by Directive 1999/29/EC.

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in feedingstuffs.

Council Directive 93/74/EEC of 13 September 1993 o feedingstuffs intended for special nutrition purposes, in the wording of later amendments.

Commission Directive 94/39/EC of 25 July 1994, laying down the list of feedingstuffs intended for special nutrition purposes, in the wording of later amendments and supplements.

Council Directive 82/471/EEC of 30 June 1982 on certain products use in animal nutrition, in the wording of later amendments.

Council Directive 83/228/EEC of 18 April 1983, laying down main principles for assessment of certain products used in animal nutrition.

Council Directive 95/53/EC of 25 October 1995, laying down principles of organization of authority controls in animal nutrition sector, in the wording of later amendments.

Directive 2001/46/EC of the European Parliament and of the Council 2001/46/ES of 23 July 2001, amending Council Directive 95/53/EC, laying down the principles of organization of authority controls in animal nutrition sector and Council Directives 70/524/EEC, 96/25/EC and 1999/29/EC on animal nutrition.

Commission Directive 98/68/EC of 10 September 1998, specifying a template of document listed in Article 9, Section 1 of Council Directive 95/53/EC and certain rules for the control of feedingstuffs imported from their countries at their accession in the EU.

Council Directive 95/69/EC of 22 December 1995, laying down conditions and procedures for approval and registration of some manufacturing operations and suppliers in the feed industry, amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC, in the wording of later amendments.

Commission Directive 98/51/ES of 9 July laying down some implementation regulations for Council Directive 95/69/EC, laying down conditions and procedures for approval and registration of some manufacturing operations and suppliers in the feed industry.

Council Directive 70/373/EEC of 20 July 1970 on introduction of EC methods of sample withdrawal and analytical methods for official feedingstuff control, in the wording of later amendments.

First Commission Directive 71/250/EHS of 15 June 1971, laying down analytical methods of EC for official control of feedingstuffs, in the wording of later amendments.

Second Commission Directive 71/393/EHS of 18 November 1971, laying down EC analytical methods for official control of feedingstuffs, in the wording of later amendments.

Third Commission Directive 72/199/EEC of 27April 1972, laying down EC analytical methods for feedingstuff official control, in the wording of later amendments.

Fourth Commission Directive 73/46/EEC, laying down EC analytical methods for feedingstuff official control, in the wording of alter amendments.

First Commission Directive 76/371/EEC of 1 March 1976, laying down EC sampling methods for feedingstuff official control.

Seventh Commission Directive 76/372/EEC from 1 March 1976, laying down EC analytical methods for official control of feedingstuffs, in the wording of alter amendments.

Eighth Commission Directive 78/633/EEC of 15 June 1978, laying down EC analytical methods for official control of feedingstuffs, in the wording of later regulations.

Ninth Commission Directive 81/715/EEC of 31 July 1981, laying down EC analytical methods for official control of feedingstuffs.

Tenth Commission Directive 84/425/EEC of 25 July 1984, laying down EC analytical methods for official control of feedingstuffs.

Eleventh Commission Directive 93/70/EEC of 28 July 1993, laying down EC analytical methods for official control of feedingstuffs.

Twelfth Commission Directive 93/117/EEC of 17 December 1993, laying down EC analytical methods for official control of feedingstuffs.

Commission Directive 98/64/EC of 3 September 1998, laying down EC analytical methods for determination of amino acids, crude oils and fat and olaquindox in feedingstuffs, amending Directive 71/393/EEC.

Commission Directive 98/88/EC of 13 November 1998, laying down general principles of microscope identification and evaluation of animal origin components for official control of feedingstuffs.

Committee Directive 1999/27/EC of 20 April 1999, laying down EC analytical methods for determination of amprolium, diclazuril and carbadox in feedingstuffs, amending Directives 71/250/EEC, 73/46/EEC and cancelling Directive 74/203/EEC.

Commission Directive 1999/76/EC of 23 July 1999, laying down EC analytical methods for determination of sodium lasalocide in feedingstuffs.

Commission Directive 1999/79/EC of 27 July 1999, amending third Commission Directive 72/199/EEC of 27 April 1972, laying down EC analytical methods for official control of feedingstuffs.

Commission Directive 2000/45/EC of 6 July 2000, laying down EC analytical methods for determination of vitamin A, vitamin E and tryptophan in feedingstuffs.

Commission Directive 2002/70/EC of 26 July 2002, laying down requirements to determination of dioxine and polychlorinated biphenyles levels in feedingstuffs.