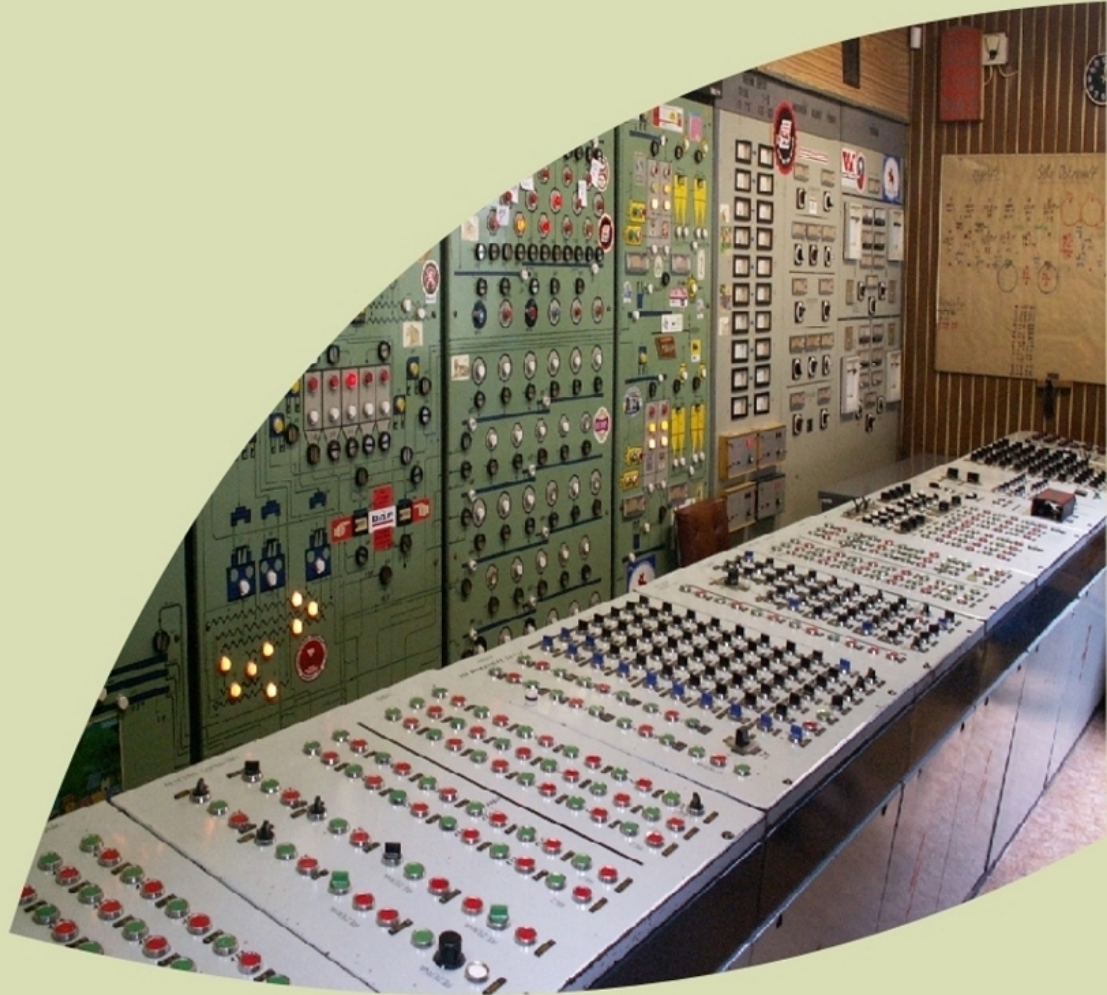




MINISTRY OF AGRICULTURE



BOHEMIAN-MORAVIAN UNION OF
ORGANIZATIONS FOR AGRICULTURE
SUPPLY AND PURCHASE



CODEX OF PRINCIPLES

of good practices and HACCP for the production,
storage and transport of additives, premixtures
and feed for food producing animals

2007



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ORGANIZATIONS FOR AGRICULTURE
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**of good practices and HACCP for the production,
storage and transport of additives,
premixtures and feed for food producing animals**

**Ministry of Agriculture
PRAGUE
October 2007**

The Codex of principles of good practices for post-harvesting treatment of crops, legumes and oilseeds, storage and transportation of feed, additives and premixtures, HACCP, production of premixtures and compound feed for food producing animals has been prepared in cooperation with the Ministry of Agriculture in conformity with the legal regulations in force in the Czech Republic and the European Communities. The Codex contains basic procedures each producer, supplier or carrier of additives, premixtures and feed can adopt and adapt to its own conditions and circumstances.

The Codex can be used both by producers putting feed into circulation as well as producers not putting feed into circulation but producing compound feed using premixtures for their own consumption.

The Codex replaces the Principles of Good Manufacturing and Hygienic Practice for Feed Producers issued in November 2003. The Codex was prepared by the Bohemian – Moravian Union of Organisations for Agriculture Supply and Purchase in co-operation with a team of experts and discussed with the Ministry of Agriculture. The Codex was created and published thanks to funds provided by the Ministry of Agriculture.

Authors' team leader:

Ing. Jiří Zedník, CSc.

Team of authors:

Ing. Jarmila Fischerová
Ing. Tomáš Pilát
Ing. Jiří Zedník, CSc.

Lectors:

Ing. Milan Koucký, CSc.
Prof. Ing. Zdeněk Mudřík, CSc.
Ing. Juraj Saksún
Ing. Marek Kumprecht

Responsible representative:

Ing. Zdeněk Kubiska

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SECTION - A

**Introduction, summary of legislation,
general definitions and terms**

1 Introduction

The Codex of good practices includes procedures for the post-harvesting treatment of crops, legumes and oilseeds, which are the main component of compound feed, to the principles of good storage and transport up to good production practice for premixtures and compound feed, including implementation of the Hazard Analysis and Critical Control Points (HACCP). In this way, the producers of premixtures and compound feed as well as carriers have available good practice principles they can use while creating their own procedures. Pursuant to Regulation (EP and EC) No 183/2005 laying down requirements for feed hygiene, the national instructions process and the wider feed branch with the understanding that these instructions should be consulted by representatives of the involved parties (e.g. Agrarian chamber, supervision body). However, it should be emphasized that feed business operators may use the principles contained herein on a voluntary basis; e.g. by adopting thereof completely or the sections necessary only depending on their conditions. They are however required to ensure the obligations for feed business operators listed in Annex II of Regulation (EC) No 183/2005.

The basis of the Codex is the basic directive of the European food law, which is Regulation (EP and EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Requirements of this basic directive relate both to food and feed. One of the most important obligations of the feed business operator is the primary responsibility for the safety of the feed produced by the operator. The good manufacturing practice procedures create a system of self-control contributing to affirmation displayed to the producer and customer that the feed produced is of proper quality and safe for the food chain. The self-control system meets the obligations given in Regulation (EP and EC) No 178/2002 by ensuring the traceability of all feed produced, delivered and used.

The content of the Codex is based on the requirements given in Regulation (EP and EC) No 183/2005 and other legal directives of the EC and the Czech Republic related to feed. One of the basic obligations of the feed business operator is the consumption and use of feed only from those businesses that are either registered or approved according to Regulation (EP and EC) No 183/2005/EC.

The good manufacturing practices have been developed and implemented at all production levels ranging from primary farming production through processing up to food production. Development of the manufacturing practices supported by the EC and the member countries can be seen in all EU member states. The good manufacturing practice is also included in the Codex Alimentarius developed within FAO, a UN-based organization. Let's name some good manufacturing practices: Eurogap, Qualität und Sicherheit für Lebensmittel implemented in Germany and Austria, and GMP+ in the Netherlands. Each of these practices includes the good feed business practice. The European Feed Manufacturer's Federation (FEFAC) has developed a guide to good practice for the industrial compound feed and premixtures manufacturing, the EFMC. The Association of Agricultural Supply and Purchasing Organisations of Bohemia and Moravia, which joins businesses producing about 70% of the compound feed in the Czech Republic and is a FEFAC member, took charge of the task in developing a similar guide for compound feed and premixtures producers in co-operation with the Ministry of Agriculture. The guide stems from the same principles and obligations of similar guides developed abroad. The Codex of good manufacturing practices and HACCP replaces the Principles of Good Manufacturing and Hygienic Practice for Feed Producers issued late in 2003. In the sense of Article 21 of Regulation (EP and

EC) No 183/2005, the Codex will be submitted to the European Commission to be published in the Commission's registration system and made available to the member states. The Codex, available also in English, will also be published on the website of the Association of Agricultural Supply and Purchasing Organisations of Bohemia and Moravia www.cmsozzn.cz .

2 Summary of the feed legislation

The feed legislation of the Czech Republic has been formed by legal requirements in force in the Czech Republic for feed called "**national directives**" in EU documents as well as other regulations of the European Parliament and of the Council called "**directly applicable regulations of the European Communities**". For the Czech Republic, the national directive is the Feed Act No. 91/1996 Coll. as amended, including two executive decrees.

Whereas the national legislation must transpose all applicable directives or regulations of the Council and the EC Commission from the field of feed laws, the regulations of the European Parliament and of the Council apply directly as superior directives without any national modifications permitted. Prior to our accession to the EU, this was not the case and therefore, there are still some provisions of older regulations of the EC in the Feed Act including the executive decrees thereto, and such provisions would not apply directly but indirectly through law and decrees.

Effective from 1 January 2008, the overlap of the above-mentioned legal provisions is removed. In 2007, the Chamber of Deputies of the Parliament of the Czech Republic followed by the Senate of the Parliament of the Czech Republic discussed and the president approved the **amendment to the Feed Act**. The amendment was published in the Collection of Laws, chapter 69 (pages 2503 - 2514) as **Act No. 214** dated 18 July 2007 **amending Feed Act No. 91/1996 Coll.** as amended.

Now, the law contains all obligations and requirements for feed business operators resulting from the EC directives or EC decisions and those required by the member state. The references to the regulations indicated in the amendment are given by numerical links to foot notes unless the relevant law directive is quoted as a part of the provision. Duplicates were removed but users should have available and know related regulations of the EC in addition to the national directives.

Similarly to the Feed Act amendment, a new executive decree is available in order to execute the Feed Act. It will replace existing decree No. 451/2000 Coll. as amended.

Some changes should be noted **for the amendment of Act No. 214/2007 Coll.** Particularly in conformity with regulation of the European Parliament and of the Council (EC) No. 183/2005 laying down requirements for feed hygiene, the amendment modifies the procedure for submission of applications by feed business operators for approval or registration of operations, including documents to be submitted. The requirements contained in the amendment of the Feed Act published by Act No. 553/2005 Coll. are specified here in more detail. They apply to feed business operators of which operations have neither been approved nor registered yet or where a change subjected to the approval or registration procedure has taken place.

The amendment newly specifies the sanctions with a new classification of offences and administrative tort of legal entities and natural entities – businesses, in order to ensure legal assurance. Merits of cases were maximally and unambiguously specified and they also apply to the breach of obligations specified by relevant directly applicable directives of the European Communities.

It should be noted that the Act does not contain many definitions of mandatory basic terms and what certain requirements apply to but they are defined in relevant regulations.

The Act contains only those terms which are the subject of the transposed directives. This is also one of the reasons why users should have the relevant regulations of the EC available.

2.1 National legal feed directives:

Feed Act No. 91/1996 Coll., as amended by Act No. 244/2000 Coll., Act No. 147/2002 Coll., Act No. 320/2002 Coll., Act No. 21/2004 Coll., Act No. 444/2005 Coll., Act No. 553/2005 Coll., and Act No. 214/2007 Coll.

Decree No. 451/2000 Coll., executing the Feed Act, as amended, which will be replaced by a new executive decree in relation to the Feed Act amendment No. 214/2007 Coll.

Decree No. 124/2001 Coll., laying down the requirements for sampling and laboratory testing principles for foods, additives and premixtures including maintaining the samples, as amended.

The following legal directives of the EC were transposed to the national legal directives:

Article 16 Council directive 70/524/EEC of 23 November 1970 on additives in feed, as amended.

First Commission directive 76/371/EEC of 1 March 1976 establishing Community sampling methods for competent feed control.

Council directive 79/373/EEC of 2 April 1979 on the marketing of compound feed, as amended.

Commission Directive 80/511/EEC of 2 May 1980, authorising, in certain cases, the marketing of compound feed in unsealed packages or containers, as amended by Directive 98/67/EC.

Commission Directive 82/475/EEC of 23 June 1982, laying down the categories of ingredients which may be used for the purposes of labelling compound feed for pet animals, as amended.

Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition, as amended.

Council Directive 83/228/EEC of 18 April 1983 fixing of guidelines for the assessment of certain products used in animal nutrition.

Commission Decision 85/382/EEC of 10 July 1985 prohibiting the use of protein products obtained from *Candida* yeast cultivated on alkalines in feed.

Commission Directive 86/174/EEC of 9 April 1986 fixing the method of calculation for the energy value of compound feed for poultry.

Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition, as amended by the Commission Directive 2001/79/EC.

Council Directive 93/74/EEC of 13 September 1993 on feed for special nutritional purposes.

Commission Directive 94 /39/EC of 25 July 1999 establishing a list of special uses of animal feed stuff for particular nutritional purposes, as amended.

Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC, and 93/74/EEC and repealing Directive 77/101/EEC, as amended.

Article 6 of the Commission Directive 98/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and

arrangements for approving and registration of certain establishments and suppliers operating in the animal feed sector.

Council Directive 2002/32 EC of 7 May 2002 on undesirable substances in animal feed, as amended.

Commission Directive 2003/126/EC of 23 December 2003 on the analytical method for the determination of constituents of animal origin for the official feed control.

Commission Decision 2004/217/EC of 1 March 2004 adopting the list of feed materials whose circulation or use for animal nutrition purposes is prohibited.

First Commission Directive 71/250/EEC of 15 June 1971 establishing the analytical methods of the Community for official feed controls, as amended.

Second Commission Directive 71/393/EEC of 18 November 1971 establishing the analytical methods of the Community for official feed controls, as amended.

Third Commission Directive 72/199/EEC of 27 April 1972 establishing the analytical methods of the Community for official feed controls, as amended.

Fourth Commission Directive 73/46/EEC establishing Community analytical methods for sampling for competent feed control, as amended.

Seventh Commission Directive 76/372/EEC of 1 March 1976 establishing the analytical methods of the Community for official feed controls, as amended.

Eighth Commission Directive 78/633/EEC of 15 June 1978 establishing the analytical methods of the Community for official feed controls, as amended.

Ninth Commission Directive 81/715/EEC of 31 July 1981 establishing the analytical methods of the Community for official feed controls, as amended.

Tenth Commission Directive 84/425/EEC of 25 July 1984 establishing the analytical methods of the Community for official feed controls, as amended.

Eleventh Commission Directive 93/70/EEC of 28 July 1993 establishing the analytical methods of the Community for official feed controls, as amended.

Twelfth Commission Directive 93/117/EEC of 17 December 1993 establishing the analytical methods of the Community for official feed controls, as amended.

Commission Directive 98/64/EC of 3 September 1998 establishing the analytical methods of the Community for the determination of aminoacids, crude oils and fats, and olaquinox in feed, as amended.

Commission Directive 1999/27/EC of 20 April 1999 establishing the analytical methods of the Community for the determination of amprolium, diclazuril and carbadox in feed, as amended.

Commission Directive 1999/76/EC of 23 July 1999 establishing the analytical methods of the Community for the determination of lasalocid sodium in feed.

Commission Directive 2000/45/EC of 6 July 2000 establishing the analytical methods of the Community for the determination of vitamin A, vitamin E and tryptophane in feed.

Commission Directive 2002/70/EC of 26 July 2006 establishing requirements for the testing of the presence of dioxins and polychlorinated biphenyls (PCBs) of the dioxin type in animal , as amended.

Commission Directive 2005/6/EC of 26 January 2005 amending Directive 71/250/EEC as regards reporting and interpretation of the analytical results required under Directive 2002/32/EC.

Legal and technical directives apply to the feed area in addition to the above-mentioned legal directives of the Czech Republic, particularly:

Act No. 307/2000 Coll., on agricultural warehouse certificates and public agricultural warehouses.

Decree No. 403/2000 Coll., listing the farming commodities for which agricultural warehouse certificates may be issued and conditions for operation of the public agricultural warehouses.

Further applicable technical directives if not in contradiction with the EU and Czech Republic law:

ČSN 46 1100 – Food cereals

ČSN 46 1200 – Cereals – part 1 to 10

ČSN 46 1300 – Legumes – part 1 to 5

ČSN 46 2300 – Oilseeds – part 1 to 7

2.2 Directly applicable regulations of the European Communities:

Regulation of the EO and the Council (EEC) No. 2377/90 of 26 June 1990, laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal substances in food of the animal origin, as amended.

Regulation of the EP and the Council (EEC) No. 999/2001 of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, as amended.

Regulation of the EP and the Council (EEC) No. 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended.

Regulation of the EP and the Council (EEC) No. 1774/2002 of 3 October 2002 laying down hygiene rules concerning the animal by-products that are not intended for human consumption, as amended.

Regulation of the EP and the Council (EEC) No. 1829/2003 of 22 September 2003 on genetically modified food and feed, as amended.

Regulation of the EP and the Council (EEC) No. 1830/2003 of 22 September 2003, on traceability and labelling of genetically modified organisms and traceability of food and feed produced from genetically modified organisms and on the amendment of the Directive 2001/18/EC, as amended.

Regulation of the EP and the Council (EEC) No. 1831/2003 of 22 September 2003, on additives in animal nutrition, as amended.

Regulation of the EP and the Council (EEC) No. 882/2004 of 29 April 2004, on official controls performed to ensure the verification of compliance with the feed and food law, the rules of the animal health and animal welfare, as amended.

Regulation of the EP and the Council (EEC) No. 183/2005 of 12 January 2005 laying down the requirements for feed hygiene.

2.3 Recommended legal regulations of the European Communities:

Commission Recommendation 2006/88/EC of 6 February 2006 on the reduction of the presence of dioxins, furans and PCBs in feed and food.

Commission Recommendation 2006/583/ES of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products.

Commission Recommendation 2006/576/EC of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products for animal feed.

3 General terms and definitions

In respect to feed legislation, the following shall apply:

Feed - various products of plant or animal origin, 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 directly as such or after processing or in compound feed.

Feed material - feed for direct feeding of animals in original or treated condition or feed intended for production of compound feed or as a carrier for production of premixes.

Specified protein feed - feed material representing either direct or indirect protein sources, produced using a special technological procedure.

Compound feed – mixture of feed materials with or without addition of additives, intended as complete or complementary feed for animal feeding.

Complete feed – mixture of feed which composition covers daily feeding dose.

Complementary feed - mixture of feed with a high content of specific nutrients covering the daily feeding dose after mixing with other feed.

Mineral feed - complementary feed consisting mainly of minerals containing more than 40% of ash.

Molasses feed - complete or complementary feed containing at least 14% of all sugars in dry substance expressed as saccharose and where molasses is, among others, used for production.

Lactose compound feed - mixture served dry or in liquid after dilution by the relevant liquid volume, intended for the feeding of young animals as a complement or as a substitute for post-colostral milk or for feeding of calves for food production.

Product for animal feeding feed material, premixture, additive, feed and all other products used for feed or for animal feeding.

Additive - a substance, micro-organism or preparation, other than feed and premixture, intentionally added to the feed or water to meet one of the following functions in particular:

- a) positive effect on the feed properties;
- b) positive effect on properties of animal products;
- c) positive effect on colouring of decorative fishes and birds;
- d) satisfy nutrient requirements of animals;
- e) positive effects on the consequences of animal production on the environment;
- f) positive effect on animal production, efficiency or welfare of animals, particularly a positive effect on the gastrointestinal tract or digestibility of feed; or
- g) coccidiostatic or histomonostatic effect.

Premixture – mixture of additives or mixture of one or more additives with the feed materials or water used as carriers, not intended for direct animal feeding;

Carrier - feed material or water used for production of the premixtures they are used in

Protective period - minimum time to elapse from termination of animal feed containing a certain additive for which the period is determined to animal slaughter or the beginning of animal product production designed for human consumption to avoid the presence of residues of additives in volumes exceeding maximum limits set by a special legal regulation¹⁾ and the Community regulations;

Best before - period for which the feed, additive or premixture stored under determined storage conditions retains the properties defining its qualities;

Daily feeding dose - average total amount of feed calculated to 12% moisture content that an animal of its kind, age category and utility needs to ensure its nutrient needs;

Undesired substance - a substance or a product present on the surface or inside the products designed for animal feed, posing a potential hazard to the animal, human health or the environment or with potential negative effect on animal production, except for pathogenic factors;

Prohibited substance or prohibited product - a substance or product of which essence negatively influences the health condition of the animal or safety of raw materials or food of animal origin, not permitted for use during feed production or animal feeding.

Conditionally usable feed, additive or premixture - feed, additive or premixture not conforming to any of the requirements defined by law or legal directives issued based thereof or the Community regulations, and which cannot be used for the original purpose provided that safety of said product is retained for such feed, additives or premixture.

Degraded feed, additive or premixture - feed, additive or premixture not qualified for animal feed.

Farm animal - an animal bred by humans for economic purposes or bred for the purposes of human nutrition, and fur-bearing animals.

Pet animal - an animal bred in a stud, bred by humans and not intended for consumption, not a farm animal except for fur-bearing animals.

Special purpose nutrition - provision of specific nutritional-physiological requirements of a certain category of farm or pet animal, of which digestion, ingestion or metabolism may be temporarily or permanently disrupted and which may have a positive effect from the feed corresponding to its state.

Special nutrition feed ("diet feed") - feed of which specific composition or production method significantly differs from other feed and is designed for special nutritional-physiological purposes; it is not a vet. preparation or medicament.

Biological testing - determination of the efficiency and safety of feed or additives.

Sampling - taking of samples for official control of feed, additives, premixtures and undesired substances by a procedure defined in a decree, except for residues of pesticides and micro-organisms.

Partial sampling - a weight portion of one part obtained by one scoop of a sampling tool.

Summary sample - total weight of all partial samples taken from one part of feed, additive or premixture.

Final sample - a sample created following homogenization and potential reduction from a summary sample.

Test sample - a representative part of the final sample treated in a specified way.

Determination limit - the lowest concentration of a determined feature where statistically acceptable correctness and accuracy is obtained.

Method correctness - closeness of concordance between average values obtained from many test results and accepted reference value.

Repeatability - value assumed to be lower or equal to the absolute value of the difference between two test results obtained under the repeatability conditions with 95% probability.

Repeatability conditions - the conditions under which independent test results are obtained using the same method, identical material, in an identical laboratory, by an identical lab operator with the use of identical equipment within a short time frame.

Reproducibility - value assumed to be lower or equal to the absolute value of the difference between two test results obtained under reproducibility conditions with 95% probability.

Reproducibility conditions - the conditions under which independent test results are obtained using the same method, identical material, in different laboratories, by different lab operators using different equipment.

Measurement uncertainty - a parameter associated to a measurement result, characterising the variance of values that may be legitimately associated with the measured quantity.

Part - amount of feed, additive or premixture expressing uniformity by its outer arrangement, labelling and local deposition.

Cross contamination

a) presence of two or more additives, undesired substances or the presence of prohibited substances or products of mutually opposite or inhibitive effects, unwanted or toxic effects;

b) presence of an undesirable or prohibited substance in feed or the presence of additives not used for the given animal type and category.

Placing on the market – holding, storage, sale of feed, additive or premixture for the purpose of sale, including offering for sale or any other form of transfer to the third person, whether free of charge or not.

Producer - a legal or natural entity producing or processing feed, additives or premixtures, holding them as a vendor prior to marketing or marketing them; a producer is also an entity operating a mobile feed production plant.

Vendor - a legal or natural entity holding feed, additive substance or premixture, manipulating or marketing them.

Distributor - a legal or natural entity intermediating the distribution of feed, additives or premixtures on the market without being the holder of the products.

Importer - a legal or natural entity importing feed, additives or premixtures from the third countries.

EU member state - also countries of the European Economic Area and Switzerland ("member state").

Third country - a country that is not a member state.

Farming primary production - breeding of farm animals, growing of crop plants including harvesting, milk or egg production and the production of slaughter animals; also includes animal hunting, fishing and picking of freely growing products.

Stage of production, processing and distribution - means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacturing, storage, transport, distribution, sale and supply of feed products.

Feed business - means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed products including any producer producing, processing or storing feed for feeding to animals on his own holding.

Feed business operator - a natural or legal entity responsible for conformity to the requirements of food laws within the feed business it manages.

Operation - any unit of a feed business.

¹⁾ Act No. 166/1999 Coll., on vet care and on change to some related laws (veterinary law), as amended.

SECTION – B

GOOD PRACTICE PRINCIPLES

**for post-harvesting treatment of cereals,
legumes and oilseeds**

1 General provisions

1.1 Recommendation of good practice for the post-harvesting treatment of cereals, legumes and oilseeds

The good practice for the post-harvesting treatment of cereals, legumes and oilseeds is based on the Regulation of the EP and the Council No. 178/2002 laying down the general principles and requirements of the food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. The regulation mentioned above includes feed in its provisions, as well. Furthermore, it is based on the Regulation of the EP and the Council No. 183/2005/EC, laying down requirements for feed hygiene. The laws of the Czech Republic make links to these regulations.

1.2 Importance of the post-harvesting treatment of cereals, legumes and oilseeds

The post-harvesting treatment of cereals, legumes and oilseeds follows their harvesting and precedes their storage. At this moment, the grains are not eligible for storage usually because of increased moisture and admixtures and impurities. Should the post-harvesting treatment be done late or not at all, there is a danger of conditions developing for the growth of undesired micro-organisms, particularly mould, which can - through the development of toxins - change their applicability with respect to hygiene and the grains may become unusable for food as well as for animal nutrition purposes.

1.3 Goal of post-harvesting treatment

The goal of the post-harvesting treatment of cereals, legumes and oilseeds is separating grains from impurities and reducing grain moisture to conform to storage conditions and at the same time, to clear the differences in the impurities and moisture content occurring between lots or supplies of the same type of cereals, legumes and oilseeds. The reason for varying moisture levels is the varying impurities content, which have different physical properties when compared to the grains (higher hygroscopic levels, impaired free-flowing consistency due to reduced specific weight) as well as the content being non-uniformly distributed in the grain stock. During manipulation, they tend to separate and create clusters of increased moisture and therefore it is necessary to perform grain pre-cleaning before other post-harvesting treatments.

1.4 Good practice processing in relation to technology

The technology used for the post-harvesting treatment of cereals, legumes and oilseeds usually relates to the storage. An operator of the technological facility for the post-harvesting treatment creates the good practice for the post-harvesting treatment of cereals, legumes and oilseeds if the operator only produces and does not perform storage. Should the operator perform storage as well, he may decide on the suitability of any type of post-harvesting treatment based on the storage method and he usually assigns the good practice for the post-harvesting treatment to that for storage. When developing the good practice, the operator follows these principles and considers his technological facility.

1.5 Responsibility for acceptance, post-harvesting treatment and storage

The operator of the technological facility determines the person responsible for the acceptance, post-harvesting treatment and, if applicable, storage in its good practice. He defines the authorisations and responsibility of the person.

2 Terms and definitions for good practice for post-harvesting treatment of cereals, legumes and oilseeds

Natural grain or seed condition – means grains or seeds after harvesting, the quality of which does not conform to requirements stipulated in legal or technical directives for storage, use in food or for animal feed and which can be treated so that they meet these requirements.

Post-harvesting treatment – means treatment of grains or seeds in their natural condition to a quality suitable for storage and future use.

Moisture – means grain or seed weight reduction by drying under specified conditions.

Impurities – means all foreign substances, organic and inorganic, other than grains or seeds of tested types. Detailed specification of impurities by the use of cereals, legumes and oilseeds is given in applicable legal directives.

Hazardous impurities – means seeds and plant products containing toxic or health hazardous substances (alkaloids, glycosides, etc.) or causing organoleptic or technological product defects.

Admixtures – means grains or seeds of cereals, legumes or oilseeds of differing quality, lowering the overall value, and grains or seeds of a determined plant species in applicable legal and technical directives.

Supply (delivery) – means the volume of grains or seeds received or dispatched at the same time and included under an agreement or a transport bill. The supply may consist of one or more lots or parts of lots.

Lot – means the defined part of the supply where uniform properties for quality evaluation are expected.

Pre-cleaning – means the removal of macro impurities including natural condition grain and seed residues.

Drying – means the reduction of natural condition grain or seed moisture to that suitable for storage.

Active ventilation – means reduction of the temperature of the grains or seeds and the air between the grains or seeds through outer air treated/not treated by cooling to temperatures under 10° C, which is actively brought to this space using a suitable technological instrument of the store and removed from it.

Preservation – means the uniform addition of approved additives from the group of preserving agents in defined doses depending on grain or seed moisture to the stock of grains and seeds if they are intended for feed purposes.

Cleaning – means the removal of impurities and admixtures from grains and seeds following drying or active ventilation to a content lower than defined for use (food, feed).

Botanical (species) purity – means weight % of the declared grain or seed species after the removal of impurities, related to the weight of the test sample.

Combined sample – means a sample prepared from final samples of individual supplies or lots by their weight so that a relative and average representation is achieved. The combination condition is that individual supplies or lots have uniform characteristic features, e.g. similar moisture, admixtures and impurities content, without strange smells or disease attacks.

3 Requirements for devices used in post-harvesting treatment of cereals, legumes and oilseeds

The operator implements requirements defined by the device manufacturer including the requirements determined by good practice. The device should allow cleaning, control and must not influence the quality of natural grains or seeds negatively.

3.1 Requirements for the facility used for pre-cleaning of natural condition grains and seeds

For pre-cleaning purposes, simple flat vibration or round separators with suitable meshes for the removal of macro impurities are usually used. They usually sort the natural condition grains and seeds into two fractions. In addition to general device requirements, the output of the separator should conform to the traffic routes output and in case the drying or preservation follows the post-harvesting treatment, the drier or preservatives dosing device performance as well. The device must minimally damage grains or seeds and minimally influence their quality. It must be tight, i.e. to place fractions obtained into specified traffic routes, exhausted by aspiration to avoid dust release and to allow the operators to check its function.

3.2 Requirements for grains or seeds cleaner

For grains or seeds cleaning, multi-function separating devices are usually employed, so-called "combined separation" by dimensions and particle shapes (separation using multiple sieves of different mesh size or shape) and by aerodynamic properties (exhaust of light impurities by air from the grains or seeds flow). In addition to general device requirements, it must be equipped with:

- a) sieves of different mesh sizes or shapes depending on the cereals, legumes or oilseeds separated, and the operators should be able to check their function;
- b) continuous control of exhausted air, to be tight, i.e. to place separated fractions into the determined traffic routes while not lowering the quality of the separated grains and seeds;
- c) it must be closed and the dust releases should be removed by aspiration.

3.3 Requirements for grains or seeds dryer

Dryers are classified into naturally drying and artificially drying machines depending on the media used; there are also dryers using cold or hot air as the drying medium as well as smoke gase drying. When it comes to the method of removal of saturated drying media from the drier area, we distinguish between dryers with atmospheric air moisture removal (contact heating, dielectric or infrared heating), with atmospheric under pressure air moisture removal (vacuum drying), and with flowing air moisture removal. Most often, smoke gases combined with air are used as the medium and the moisture is removed by the flowing air. For this type of drying, pouring down dryers are used, they may be divided into sections (pre-drying, drying, cooling) and they usually have lateral input of the drying medium. In addition to general requirements, a dryer must be equipped with temperature sensors for determining the temperature of the drying medium and air temperature in the drying and cooling sections. The volume of the drying and cooling medium should be adjustable. The dryer must cool the grains or seeds to temperatures under 40° C. The medium used for air heating must not negatively influence the grain or seed quality, particularly by increasing the content of undesired substances (aromatic

hydrocarbons) over a specified limit. Combustion gases should be prevented from entering into the dried grains and seeds.

3.4 Requirements for active grains or seeds ventilator fan

The device is usually installed in the store for cereals, legumes and oilseeds as a part of the storage facility for short-term or long-term storing. The device should be designed so that the fan power conforms to the air exchange in the inter-grain space required. The pressure of forced in air should conform to the grain or seed pouring height in the storage at all points in which the air is brought in. The device should evenly distribute the air to the grain stock (particularly in case of airshed or floor stores) and at the same time, should remove air from the storage space above the stock. The store should be equipped with a stock temperature measurer in at least three layers (bottom, central and upper).

3.5 Requirements for the preserving agents application device

The device is usually installed in the stores intended for storing of preserved crops or legumes for animal feeding. The device must provide:

- a) equal dosing and distribution of the preserving agent into the grain stock;
- b) accurate setting of doses;
- c) should be made from stainless material;
- d) the output should conform to the output of traffic routes in the storage space and the output for the grain pre-cleaning device;
- e) must allow checking, cleaning and must not influence quality in a negative way.

3.6 Requirements for grains or seeds cooler

For this purpose of post-harvesting treatment, either a device for contact grain and seed cooling or a device using cooled air as a medium being analogous to active ventilation is used. It is usually a part of the store and its cooling output should conform to the storage capacity. The device should provide:

- a) quick cooling of grains or seeds stock to a temperature under 10° C
- b) such an air pressure and volume corresponding to volume of the filled, cooled storage space and height of the grains or seeds stock layer.

The device should allow checking, cleaning and must not influence quality in a negative way. A precondition is that the cooled storage space be equipped with temperature sensors.

4 Procedures of the post-harvesting treatment of cereals, legumes and oilseeds

In the course of the post-harvesting treatment, the operators will arrange the following:

- individual operations are controlled and performed in a way preventing risks with the potential to threaten the treated products and to eliminate or minimise these;
- the post-harvesting treatment products are protected against contamination or corruption.

The post-harvesting treatment procedures can be divided into three phases:

- a) receipt of cereals, legumes, oilseeds associated with sorting of lots or supplies of the same type by moisture level;

- b) the post-harvesting treatment (pre-cleaning, drying if needed, pre-storage cleaning);
- c) storing.

4.1 Receipt and sorting

Cereals, legumes and oilseeds are delivered for the post-harvesting treatment in bulk form in most cases. Upon receipt, the weight of individual lots is checked and partial samples are usually taken at the same time; the summary sample created is then treated to the final sample marked with type, vendor, delivery date and weight detected in conformity with the quality control plan. Should more lots be delivered from the same vendor on the same day and their quality does not substantially differ, a combined sample is taken from the final samples of individual lots. The combined sample is tested for the determined quality indicators according to the quality control plan. Should increased moisture level exceeding the limit specified for the selected storage method be discovered upon receipt, the lots are separated and the post-harvesting drying treatment is carried out on them. The person responsible for receipt, post-harvesting treatment and, if applicable, for storage will decide on the manner of separating these lots. This section of the good practice should clearly indicate the procedure for instances where the lot does not conform to the agreed quality e.g. due to higher moisture, impurity content, strange smells, the presence of live vermin, and how the lot will be separated from the others and what the post-harvesting treatment will be.

4.2 Storing of non-treated lots or supplies

Should lots or supplies of cereals, legumes or oilseeds be found to be non-conformant to the storage quality during the receipt inspection because of their moisture and impurity contents, they should be stored separately and then dried and cleaned. The stored weight of non-treated condition must not exceed the post-harvesting treatment capacity for the grain or seed type and moisture may be used as the determining factor. The period of temporary storing of cereals or legumes must not exceed 24 hours, e.g. if the cereal or legume grains are moisture sized over 17% or of oilseeds over 15%. Should the period be exceeded, the quality changes. Therefore, the receipt should be controlled to treat any problematic stocks by drying. Should the stock be equipped with effective active ventilation, which is able to keep the stock temperature under 25° C, the storage time can be prolonged up to 48 hours. The above does not apply in cases of preservation of crops and legumes. During the storage of non-treated stock, the operators check the temperature and it is recorded in an operation journal.

4.3 Pre-cleaning procedure

Pre-cleaning is always used when lots or supplies of cereals, legumes or oilseeds contain macro-impurities, right before drying or storing with active ventilation, provided that their moisture and temperature does not exceed 17% and 25° C respectively, or before preservation. The pre-cleaning occurs on flat vibration or round rotary separators usually fitted with one sieve with the exhaust permanently turned on to remove grain or seed dust. Cleaning is directly used instead of pre-cleaning in case there is storage with active ventilation or preservation. Prior to pre-cleaning, the operators check the discharge of the receipt container, the setup of the traffic routes, the function of the separator (condition and fitness of the sieve) and the space available for storage of the grains or seeds and for collection or storage of the pre-cleaning waste.

4.4 Drying procedure

Prior to drying, the operator checks the discharge of the drier, sees whether the traffic routes are set correctly including the bin used for the dried grains or oilseeds. Should the cereals, legumes or oilseeds be macro-contaminated, the operator performs pre-cleaning before drying and sets the air temperature for drying in accordance to the grain or seed moisture. The temperature of the drying medium should not exceed 120° C (for seeds of cereals, legumes and malting barley 80° C), and temperature is reduced depending on the required temperature of inter-grain space in the pre-drying and drying section of the drier. The air temperature in the inter-grain space should not exceed 80° C (for seeds of cereals, malting barley, legumes and oilseeds max 60° C) and the grain temperature should not exceed 60° C for feed cereals, 45° C for food cereals and 35° C for legumes and oilseeds. Depending on cereals, legumes and oilseeds moisture, drying is either one-stage for moisture up to 18% or multi-stage for higher moisture. Depending on the design of the drier and the use of drying temperatures, one drier pass can remove max 4 to 5% of moisture when using a temperature mode not infringing on grain quality. The moisture limit for drying without quality infringement is 24% and 28% for legumes & cereals and corn respectively. Higher temperatures damage wheat gluten and germinative activity in general for seeds and malting barley. In the course of drying, the operators check the temperature of the drying medium, the temperature in the inter-grain space of the drier sections and the temperature in the inter-grain space in the cooler. Depending on the temperatures observed, the temperature is controlled by burner power and/or the drier charging or discharge speed. The operator keeps records on the inspection in the operation journal. Dried grains or seeds should not be immediately stored in an airshed storage without active ventilation or floor storage of the stock height over 1 m even though the temperature of the inter-grain space does not exceed 25° C in the drier. The reason is the temperature difference between the inter-grain space temperature and the inner grain or seed temperature, which is usually higher and is balanced within 48 hours of storing.

4.5 Active ventilation procedure

In case the cereals and legumes moisture does not exceed 17% (or better 16%), the operator will check the active ventilation (fan operation), discharge the silo bin, check the cleanliness of the air flows for the airshed storage including their horizontal deployment, and should the stock already be deposited in the airshed, the operator will check its temperature. In case the stock temperature exceeds 25° C, the silo bin or the storage space is not replenished and the received cereals, legumes or oilseeds are placed in another silo bin or the storage space. The operator will also check the installation of suitable sieves in the separator and adjust the air flow. At the same time, the transport routes will be set, the receiving container will be discharged and the operator will check the space for collection of the waste from cleaning. Then, cleaning and storing of grains or seeds starts; if their temperature is below 25° C, the grains are stored in a layer allowing the required number of air flows in the inter-grain space. For 17% moisture, up to 1,500 air flows in the inter-grain space are required within 24 hours. For this purpose, the power of the fan (air volume per time unit) and approximate volume of the inter-grain space should be available and the maximum permitted pouring height can be calculated from these values and the required number of air flow exchanges. The operator turns the active ventilation fans on provided that the surrounding air moisture does not exceed 75 %. The operator will check the stock crops or seeds temperature daily in three layers (bottom, central and upper), the moisture of the stocked

grain on an ongoing basis and outer air moisture as well. The operator keeps records of the temperature in the operation journal.

4.6 Preservation procedure

Preservation is performed only for cereals and legumes intended for feeding and those cleaned before preservation. Only additives from the group of authorised preserving agents available both in solid and liquid state are used for this purpose. The preserving agents are usually available in the form of a mixture of several additives with possible corrosive effects, they are caustics and they are volatile. Depending on composition, producers specify their dosing or dilution (applies to liquid products) as well as dangerous handling. Storing the preserved grain occurs in a selected storage space, which structurally conforms to the storage of preserved cereals and legumes. The space should not usually then be used for storing crops and legumes intended for food purposes. The cereals or legumes whose moisture does not exceed the moisture specified by the product producer and which are pre-cleaned can be used for preservation. Usually, the maximum permissible moisture is 30%. Prior to preservation, the operator must check the discharge of the receipt container, the setting of the transport routes, the emptiness and cleanliness of the storage space (or if it contains the same type of preserved cereals or legumes) and if the space used for storing waste from cleaning is full. Furthermore, the operator determines the grain moisture if not specified upon receipt and sets the dosing of the preservative depending on the grain moisture; if dilution is needed, dilution with water in the proportion specified by the producer will be done. Then, receipt of the products starts during which the operator checks the dosing device and adjusts the dosing for newly received lots depending on the moisture detected. Prior to spraying, the cereal and legume temperature should not exceed 25° C. The operator keeps data on the moisture checks, if applicable, the type of preservative, the set dosing and temperature in the operation journal.

4.7 Cold air active ventilation procedure

The procedure is identical to that for the active ventilation with the understanding that the air is cooled down to 3 to 5° C prior to blowing into the stock. Should cold air active ventilation be used, cereals and legumes of moisture up to 20% can be stored provided that they will be cooled down to max temperature 10° C during receipt or within 20 days thereafter at the latest and maintained at that temperature during the storage. In addition to the active ventilation tasks specified under 4.50, the operator should check the cooling device and monitor the cooling air temperature in addition to the stock temperature in three layers in the course of the active ventilation. The operator keeps records of the temperatures detected in the operation journal.

5 Quality control for cereals, legumes and oilseeds during the post-harvesting treatment

In addition to the control specified for individual operations, random inspections of the cleaning and drying quality are performed during the post-harvesting treatment according to the quality control plan. For this purpose, moisture tests, admixtures and impurity contents test, gluten quality and germinative activity for malting barley are conducted. Partial samples are taken during the post-harvesting treatment from the cereals or seeds prior to their storing. A summary and final sample is made from the partial samples. The

sample package is then closed and marked with the crop or seed type, sampling date, approximate weight it represents (if necessary), and the person who made and delivered the sample for tests confirms it with the signature. The frequency of the control and features tested is specified in the quality control plan. The tests should be conducted immediately as the operator arranges the post-harvesting treatment depending on the test results. The test results are included in the relevant records.

6 Maintaining records

In addition to keeping records on the post-harvesting treatment (temperature and moisture control), other related records are kept:

- a) records on weights received and issued by vendors;
- b) records on received lots or supplies marked by the vendor as they contain, are composed of or produced from genetically modified seeds (hereinafter "GM" only). The declaration of the vendor, whether the products are GM or not, serves as proof. If they are GM, their name and clear identification number is specified (e.g. "produced of GM soybean MON-04032-6");
- c) records on the test results of the final and combined samples from the received and issued lots and supplies and from the controls during the post-harvesting treatment;
- d) records on the use of preserving agents, their type and consumption, including preservatives stock (storage space) where they have been used;
- e) records on the use of decontamination products, including the name of the decontaminator, the decontamination type and quantity used, including indication of the storage space where it was used as well as the results of the residues presence analysis;
- f) records on the presence of vermin in the area for the post-harvesting treatment or adjacent storage facility (it is usually a part of the operation journal).

7 Cleaning and decontamination of the operation areas and post-harvesting treatment facilities including related stores

The operator specifies in its good practice what areas are to be cleaned and decontaminated, the method, the frequency of cleaning and how to dispose of the generated waste.

7.1 Cleaning of the post-harvesting treatment area, adjacent storage, technological facilities and decontamination during its preparation.

The technology, operation areas and adjacent storage should be free of residues, impurities and dust, removed adequately as permitted by the spatial design. At the same time, the technology is inspected and repaired, if needed. Lockable spaces should be decontaminated using approved products. A record is created in the operation journal on the preparation and decontamination and a document on decontamination is included in the records.

7.2 Cleaning of operation areas, adjacent storage and technology

The areas and adjacent stores should be cleaned daily and depending on climatic conditions the receipt area should be cleaned several times a day of dirt brought in on the

wheels of vehicles, and of dust. Cleaning of the technology should be done at every change to the post-harvesting cereal or seed type and in cases in which there is a dosing device for application of preservatives, the technology should be cleaned daily. A record is created in the operation journal on cleaning.

8 Collection, storage and disposal of waste from the post-harvesting treatment

The operator should develop a plan describing the collection and storage points of the waste (unless identical to the collection points). At the same time, the method of collection and storage will be defined. The collection point is usually close to the waste origin point. The point should be spatially separated from the other operation or storage areas to avoid mismatch or contamination. The waste is stored in a way preventing its dispersion; bags or containers are used in most cases. The waste created during cereals and seeds cleaning is stored loosely in dust chambers or suitable containers. The waste are all impurities created during the cereals or seeds cleaning, residues from cleaning of the operation areas, technology and storage, sweepings from cleaning of the operation areas and the storage facility.

8.1 Waste separation

Wastes generated during the post-harvesting treatment are classified by hazard into hazardous waste and other waste. Hazardous wastes are residues and impurities generated after cleaning of the decontaminated store or residues after cleaning of the dosing device for the preservatives. Non-hazardous waste is other waste.

8.2 Waste disposal

Only an authorised entity may dispose of waste. Other waste is usually composted or used for treatment as bio-fuels. Hazardous waste is disposed of depending on the hazard type and is usually incinerated in incinerators. A company conducting waste disposal should provide a document indicating the waste category, weight, date and method of disposal, unless the latter is specified in an agreement concluded with the post-harvesting treatment operator.

9 Related directives

- quality control plan;
- waste management plan, if the operator is obliged to compile the plan;
- the good practice for storage (storage rules), unless the post-harvesting treatment good practice is included therein.

SECTION – C

GOOD PRACTICE PRINCIPLES

**for storage of feed, additives and premixtures
(„Storage Rules“)**

1 General provisions

The principles are based on the obligations defined in the Regulation of the EP and the Council No. 178/2002 laying down the general principles and requirements of the food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety and Regulation of the EP and the Council No. 183/2005, laying down requirements for feed hygiene. Furthermore, from the Regulation of the EP and the Council (EEC) No. 882/2004 on official controls performed to ensure the verification of compliance with the feed and food legislation, animal health and animal welfare rules and the Regulation of the EP and the Council No. 852/2004 laying down the primary responsibility for food safety.

1.1 Good practices for storage of feed, additives and premixtures apply to producers who produce and stock

- feed (feed materials);
- premixtures;
- compound feed with additives, premixtures or complementary feed and to natural and legal entities storing feed (feed materials), compound feed, additives and premixtures.

1.2 Contractual storing

Should the storage be provided for other natural or legal entities (contractual storing), the good practice should define under which conditions it may be provided, e.g. according to the good practice for feed storage by a storage organisation or contractual conditions and in the latter, the contractual conditions should be attached to the good storing practice.

1.3 The operator will specify in the good storing practice

- a) store name or number and operation name where the store is located;
- b) types of feed (feed materials), additives and premixtures to be stored in individual stores;
- c) description of the store and the installed technology;
- d) the manner of storing of the feed (feed materials), additives and premixtures in individual stores;
- e) quality control upon receipt, during storage and dispatch;
- f) keeping receipt, storage (e.g. data on quality controls performed, stored materials temperatures, etc.) and dispatch records on the stocks;
- g) the method of managing complaints and recalling of defective feed, additives and premixtures;
- h) a person responsible for storing by individual stores (role of the person) and their authorisations and responsibilities.

2 Requirements for feed, additives and premixtures stores and their technologies

Depending on specific requirements for the stored materials, stores of silo, airshed, floor (multi-storey stores) and combined types are used. Furthermore, the stores can be divided by technology installed, which is usually related to the storage system, e.g. stores for dry

feed (moisture under 14%), stores with active ventilation, stores with the technology of stock cooling using cold air or stores adapted to storing chemically-preserved feed with installations of preservative application technologies intended for this purpose.

In this good practice section the storage operator specifies what store type it is, describes the technology with technology schemes for the silo stores and floor plans including individual positions for the airshed or the floor stores or for individual floors of the stores, including total capacity of the store. For better understanding, there are general storage requirements and requirements according to the manner of storing of the feed, additives and premixtures.

General requirements on stores

The stores should allow separated storing of different feed, additives and premixtures including their identification during the storing time. They should provide dry storage and retaining of stored feed, additives and premixtures in the quality required (limitation of temperature and moisture effects). They should also be designed to avoid mixing of individual types or contamination or deterioration. The areas for free storage should be arranged to minimize self-sorting and to avoid retaining of stored feed during discharge. The structural design of the stores should allow cleaning, bird and vermin access limitation, control of the stored feed during the storing period and disinfecting and deratizing of the stores. The stores should have areas reserved for storing waste generated during grains cleaning or waste originating from store cleaning, including sweepings, and should the waste be stored loosely, the storage area should be separated. The stores may be used solely for the material types for which they were originally designed and permitted for operation.

2.1 Requirements on the stores for feed

In addition to the general requirements, the feed stores should conform to the requirements specified by types and properties of the stored feed.

2.11 Requirements for feed stores with free storing

Silos, airshed stores or combined stores are mainly used for this type of storing. Their design should limit the effect of climatic conditions on the stored feed, the formation of uncontrolled residues in the storage area and allow cleaning of the storage areas. Construction materials used should not have any effect on the feed stored. As far as the airshed stores are concerned, they should also have baffles for separating the stock by type or quality of the feed. They should have sufficient-capacity transport routes or access paths allowing multiple handling of the feed at the same time (receipt, issue, stock treatment). The stores should have a suitable scale to ascertain the weight of received and issued feed and a cleaner for cleaning of crops. The traffic routes should be safe, i.e. they should provide placement of received feed in the appropriate storage area, minimise the residues of the transported materials on the routes and at the receipt point, they should have a device preventing penetration of macro impurities into the stocks (grids on the receipt containers). Travel paths to the receipt containers should be solid and sufficiently distant from the containers to avoid contamination of the receipt containers and storage floors.

2.2 Requirements on stores for packed feed

The airshed stores or floor stores equipped with cargo elevators or combined stores are mainly used for this purpose. These stores are used for bags or sack packed feed put on

pallets or in containers. Their structural design should influence the effect of climatic conditions on the feed, particularly entering of water. Their floor area and technology should conform to requirements for the storage method and handling of the feed in the storage. It is not allowed to store other materials not related to the feeding purposes in the feed stores.

2.3 Requirements on stores for additives and premixtures

The additives and premixtures should be delivered only packed in originally sealed and undamaged packaging. Therefore, airshed stores are mainly used, of which structure and design conforms to the storage of additives where one may expect, considering the temperature and moisture during the storage, the development of chemical reactions, changes to physical properties and changes to the additives content. Storing substances at temperatures ranging from 10 to 25° C at relative humidity 65% is usually recommended. The additives and their concentrated premixtures show an electrostatic charge and they may be explosive in powder form. Some additives may be dangerous to humans in case of direct contact and therefore stores for additives and premixtures should have a toilet with a source of potable water. When handling additives, the use of protective aids is required (e.g. a respirator, goggles, etc.). This information should be taken into account when designing new stores. Furthermore, the stores should be dry, ventilated, without direct sunlight, with suitable thermal insulation limiting significant temperature variation, with a non-permeable and easy-to-clean floor. Access by animals and unauthorised persons to the storage should be prevented. The stores should be lockable and it is not suitable to store other materials or feed there as well. All waste should be stored separately in non-permeable and sealed packaging and disposed of as hazardous waste (most additives are not bio-degradable and they are usually specifically toxic for some animal species).

3 Methods and conditions for the storage of feed, additives and premixtures

Generally, the storage method should be based on the knowledge of individual types of feed, additives and premixtures and their physical and chemical properties. Unless known, the producer should be asked for provision thereof. It particularly includes quality stability of the material with respect to moisture, its temperature upon receipt and during storing (with respect to safe storage, materials temperature may not exceed 40° C), its structure, if hygroscopic, explosive and under what conditions, what is the flash point or fire point or self-combustion point, whether hydrostatic charge is present, what is the chemical composition (the effect of higher fat and saccharides content) and what are the hygiene conditions for humans and animals (toxicological information).

In good practices, the storage operator specifies how and under which conditions the feed, additives and premixtures will be received, stored, checked during storing, treated (if applicable), modified and issued from this specific store. The storage methods and conditions specified below can be used as well.

3.1 The methods and requirements for storage of free feed (feed materials) or packed solid feed

Depending on the store type, its technologies and type of stored feed, the receipt procedure should be defined first, i.e. how individual supplies will be received and how

their weight and quality will be checked, what procedures will apply in case of a supply requiring treatment or separate storage or non-conforming to the quality declared. A procedure for packed feed supplies should be specified for cases where some packs will either be damaged or incorrectly labelled or the labelling will be missing. Prior to receipt of supplies, they should be visually assessed and moisture should be determined. Should a visual check detect the presence of live vermin or prohibited substances and products in the supply, it should not be accepted by the store and stored in separate spaces or the supply should be returned to the vendor. Should the supplies report increased moisture not corresponding to the storage conditions and where it can be corrected by drying, or should higher impurity values be reported, the supplies should be dried and cleaned before storing or stored separately and returned to the vendor.

3.11 Methods and conditions for the storage of cereals, legumes and oilseeds

This applies to the cereals, legumes and oilseeds which underwent post-harvesting treatment, i.e. in which moisture was treated by drying or preserved using approved additives designed to feed preservation, and they are cleaned, i.e. organic and inorganic impurities are removed in conformity with the good practices for the post-harvesting treatment.

Conditions for storage.

Cereals, legumes and oilseeds can absorb air moisture, particularly their parts such as sprouts and the aleurone layer; hulls are susceptible to a lower extent. Damaged grains have a higher ability to absorb moisture than non-damaged. The grain moisture is not stable even after the drying treatment and varies due to uneven moisture distribution in grain, different sorption capacity of differently grown grains, variable relative air moisture in the storage area and due to different temperature of the grain layers, which supports thermo-diffusion of moisture. These effects are highlighted by the technical condition of stores.

Suitable moisture for storage conditions is:

- for cereals and legumes stored in dry condition (without active ventilation or cooling), moisture up to 14.0%;
- for cereals stored using active ventilation or artificial cooling, moisture up to 17.0% at relative air humidity up to 75% (for artificial cooling, the stock temperature should not exceed 10° C) and should all risks associated with mould development be prevented, the moisture of the active ventilation and air moisture must not exceed 16.0% and 65% respectively;
- for oilseeds, maximum permissible moisture of 8.0% generally applies.

The cereals and legumes preserved using approved additives designed for feed preservation are usually stored at up to 30.0% moisture with respect to the increased consumption of preservatives and hence to the technical condition of the store and its technologies.

Uneven moisture distribution in the grains stock is supported by the presence of impurities showing different moisture when compared to the stored grains stock. They have different sorption properties and during storage, it is impossible to prevent their mixing in the grains stock and therefore development of potential clusters for the occurrence of moisture and temperature changes and mould development. Therefore, the impurities content should be minimised and acceptable levels are:

- for long-term storage (over 6 month), impurity content up to 1.0 %.
- for short-term storage (up to 6 month), impurity content up to 5.0 %.

However, the grain stock must not exceed bedstraw content 0.5% and alkaloid- or other poison-containing weed seed 3.0%.

Methods of storage

The cereals, legumes and oilseeds are usually stored loosely in a silo, airshed, and floor or combined stores. The storage area should conform to the general storage area requirements specified in 2.11. The storage areas should particularly prevent climatic effects. The silo and airshed stores are usually used for active ventilation storing and they are well equipped for this purpose with technology allowing equal distribution of the stock and air dispersion over the storage space area. The pressure of fed in air for the active ventilation should be at least 2.9 kPa, which conforms to a pressure drop of 300 mm of the water column. The volume of the air for active ventilation should be determined according to the estimated volume of the inter-grain space and to cool it down effectively, at least 200 and 800 air exchanges are required for stock moisture up to 15% and 17% respectively within 24 hours. Should the technology not provide such air exchange volumes, the stock height should be reduced or the stock must be dried. Should the design of the storage spaces with active ventilation allow mixing of grains upon their receipt to the storage area, the proportion of impurities should be minimized by cleaning, particularly as far as dust particles are concerned in order to improve air penetration and to avoid spots with steam condensation. When using active ventilation in silos, it is necessary to provide both sufficient air flow and arrange effective air removal from the storage space over the stock.

When using active ventilation with air cooling in order to stabilise grain with moisture up to 17%, it is more expensive as 10° C is required in the storage space in order to achieve stability at the moisture specified above. Therefore, the use of active ventilation with cooled air is suitable only for stocks of higher moisture before their post-harvesting treatment if the drying capacity is insufficient.

The use of preservation using approved additives designed for feed preservation is possible only when the cereals and legumes are intended for feed purposes. Suitable storage spaces with preservative dosing equipment maintaining the preservatives and their even distribution in the stock is required for storing. The storage spaces and their technology should be surface-protected against the effects of harmful exhalations from the preservatives, perfectly ventilated and equipped with a toilet with water source. Grain moisture should be detected for each supply, if delivered by different vendors, during the preservative application. If the same vendor is used, the moisture should be checked at least three times a day and dosing of the preservative adjusted according to the moisture detected. Therefore, airshed stores are most suitable for preserved crops and legumes. Meaning that the storage space is now not suitable for cereals and legumes intended for food processing.

Check of grains during the storage time

After loading the storage space with grains with maximum permitted moisture and temperature, it is necessary:

- a) during the post-harvesting maturing to check daily the temperature in at least three layers, particularly above the level of the conical part of the silo cell or floor, in the central and upper layer;
- b) after the post-harvesting maturing, to check the temperature at least twice a week in the layers described in a) above;
- c) if a temperature over 30° C is detected in any layer, the grains should be treated and following the treatment a daily temperature check should be done for at least one week;

d) during the treatment, samples are taken to be visually assessed with respect to the presence of live vermin and of strange smells. The summary and final sample is composed of partial samples to determine moisture or other features.

The grains quality control system as well as the numbers of the final samples taken, the types and frequency of tested samples and the quality features are defined in the operator's "Quality Control Plan", which is an integral part of the good storage practices.

Treating grains during the storage time

During the grains storage, the following measures are taken depending on their condition (presence of increased temperature, storage vermin):

In case of increased temperature

- a) if the storage areas are equipped with the active ventilation and the outer air relative humidity is less than 75% or 65%, the active ventilation will be turned on to work continuously until a temperature under 25° C is reached in all layers.
- b) if the storage areas are not equipped with active ventilation or it cannot be used because of increased relative outer air moisture or the active ventilation is not successful in reducing the stock temperature, then relocation (removing) to a free storage space under pre-cleaning and grain aerating is done in case the store is equipped with a cleaning station or the dryer is used without air heating. At the same time, partial samples are taken as well as grain moisture, and the presence of storage vermin is checked;
- c) if there is excessive moisture over 15% or over 17% in case of active ventilation, the grains should be re-dried.

In case of the presence of storage vermin

- a) relocation (moving) of the stock while cleaning and during the relocation procedure, application of approved disinfectants by an authorised person will be done. The waste from cleaning is immediately disposed of after relocation;
- b) if the decontamination cannot be done in the storage area or under prevailing conditions (unsuitable temperature), relocate the affected stock to a reserved, easy-to-clean store to perform the decontamination;
- c) following the decontamination and after the protective period defined according to the decontamination products, take final samples to check the presence of residues from the preparation. Release the stock for use provided that the maximum permitted residue content is not exceeded.

3.12 Methods and conditions for storage of mill products

This applies to mill products intended for feed purposes. In most cases, these are feed flours and specks delivered mainly loosely; less frequently, these are cereal sprouts and husks. The mill feed products containing a higher proportion of grain husk particles are highly unstable in moisture thanks to the grain moistening and conditioning prior to milling. This is due to unbound moisture, which releases locally particularly due to temperature changes during transport or storage and develops conditions for moulds, especially if transported and stored loosely. This fact should be considered when selecting the method and conditions of storage. Considering the high fat content, the cereal sprouts are hard to store in the long term.

Conditions for storage.

The principle for mill products is that they are not suitable for long-term storage in loose form and therefore, the received weight should conform to about a 14-day reserve. This similarly applies for cereal sprouts in packs. A visual check is performed upon receiving the mill products to check the presence of clods in the supply, typical colour of the products, strange smells and storage vermin (flour moth, floury mite). Should the visual check reveal any of the changes mentioned above, receipt of the mill product is stopped and the product is either returned to the vendor or stored separately and then the procedures of the "complaint rules" and contractual terms should be adhered to. The storage area should conform to general storage areas requirements specified in 2, 2.1, and 2.2..

Should the mill products be delivered in packaging, the packaging should be permeable (not PE packaging) and may be layered on pallets. Each piece of packaging must be properly marked.

Methods of storage

Loose mill products are usually stored in silos; the airshed stores are less suitable for the storage in loose form of the mill products. Cereal husks are an exception, which - if supplied in loose form - are stored in airshed stores. Floor or combined stores are the least suitable for storage in loose form. If the mill products are stored in silo bins without an insulated outer cladding or not walled all around, the products should be put in the central and not the peripheral bins. The silo bins should have flat walls and their output section should be at a 65° angle. In case of a lower angle there is a danger that the products will form arcs when discharged from the bin.

If the mill products are packed (in sacks, bags, containers), they should be put on pallets (except for containers) and depending on the store type, the pallets can be stacked, however only in two layers max. Only non-damaged packaging is received to the store and should it be damaged during handling in the store, repacking and labelling must be done immediately. Sweepings are disposed of as waste. Airsheds or floors or combined stores are usually used for storing. The stores for mill products should be dry and allow ventilation. If mill products are delivered in packaging, they may be stored to their best before date.

3.13 The methods and conditions for storage of extruded grouts and expellers

Extruded grouts and expellers, except for products where thermal treatment is done (toasting), can be considered moisture-stable and minimally hygroscopic. Some types of extruded grouts and expellers are delivered fully or partially peeled or not peeled. These particularly are products from soybeans or cocoa beans, sunflower seeds and cotton plant. Non-peeled products from sunflower seeds have lower looseness and therefore, their long-term storage in silo bins is not recommended. The same applies to expellers with fat content over 10 %. Generally, if expellers are not stabilised thermally or by antioxidants, they should be stored for a short time only as the fat oxidises quickly because of the technological processing and they are not suitable for feed purposes.

Conditions for storage.

For supplies of extruded grouts or expellers, it is necessary to check their temperature because temperatures over 40° C may occur particularly in supplies of extruded grouts immediately after their production. The supplies with increased temperature should be stored separately in a low layer and cooled down. Extruded grouts usually have higher dust level and when handling them, the traffic routes as well as the silo bins should be

exhausted. Because individual types of extruded grouts and expellers, including their technological treatment by peeling, are suitable for different types and categories of farm animals, it is necessary to create such conditions for separate storing and avoidance of mingling according to their type and technological treatment. Upon receipt of thermally treated extruded grouts, particularly of the soybean type, attention should be paid to moisture. A maximum moisture of 13.0% can be considered as stable. Should the extruded grouts report higher moisture, they should be separately stored in a layer not exceeding one meter and marked out for accelerated processing. The storage area should conform to the general storage areas requirements specified in 2, 2.1 and 2.11.

Methods of storage

Extruded grouts and expellers are mainly supplied in loose form or in bags or containers for smaller customers. Extruded grouts except for those from non-peeled sunflower seeds and expellers with fat content up to 10% can be stored in silo, airshed, floor and combined stores. Extruded grouts from non-peeled sunflower seeds as well as expellers with fat content over 10% may be stored loosely in airshed stores only. The stores should be dry and allow ventilation. If they are delivered in bags, the bags should be stored on pallets in the stores. The pallets can be stacked.

3.14 Methods and conditions for storage of drier products

The products obtained by artificial drying especially in hot-air dryers are highly hygroscopic. If the products are granulated, their hygroscopic nature drops but there is the danger of releasing unbound moisture during the storage and conditions for growth of moulds develop, including the potential of self-combustion. In addition to this, some drier feed report increased sugar content, which also influences their stability. These factors restrict the manner of storing and the type of stores. This group of feed includes most often haymaker drier fodder, dried sugar-beet slips, dried malt residues, waste malt products (malt blooms, malt dust, malt husks), dried potatoes, dried fruit extrusions and dried stillages.

Conditions for storage.

Considering the high hygroscopic nature of the products, dustiness, low volume weight and reduced free-flowing consistency, granulation treatment is required for bulky dried products (dried sugar-beet slips, malt residues, fodder, malt products, fruit extrusions). Should you intend to store the dried feed for the long term, moisture must not exceed 12.0% also under the assumption they are granulated and cooled down to maximum temperature of 25° C. For the short term, dried feed of moisture up to 14.0% can be stored, provided that the store is dry and ventilated. Balanced moisture of dried feed is achieved about three weeks from the production date if stored in suitable stores. The balanced moisture oscillates from 10 to 13% at relative air humidity 75% depending on the dried feed used. Should increased temperature or moisture be detected during the receipt of supplies, the products are stored separately, loosely in a layer not exceeding one meter. The storage area should conform to the general storage areas requirements specified in 2, 2.1, 2.11 and 2.2.

Methods of storage

The airshed stores allowing handling during the storage time are the best for long-term storing of packed or in loose form stored dried feed. The silo bins can also be used for short-term storage of dried feed provided that the temperature of the stock is checked daily. The dried feed of moisture up to 14.0% can be stored in packaging in the long term as well, e.g. on wall pallets, in containers, bags or paper packaging provided that the

pallets or containers are not stacked, there is a sufficient gap between the pallets/containers for handling and the storage space is dry and has ventilation. The storing dried feed with moisture over 14.0% is dangerous because of the potential of self-combustion.

3.15 Methods and conditions for storage of dried dairy products

This group of products mainly includes dried whey treated by using different technological methods (partially or fully de-sugared or de-mineralised), skimmed milk powder and dried buttermilk. Dried dairy products (particularly dried whey) in the powder structure are highly hygroscopic. In addition, they contain some substances with low melting point (e.g. the dried whey contains more than 65% of lactose) and they are difficult to store.

Conditions for storage

Dried dairy products, unless technologically treated using a fluid agglomeration or granulation, should be exclusively stored in packs of impermeable materials (bags with PE inserts or bags with impregnation layer), originally sealed. Hermetically lockable silo bins where dried dairy products in loose form can be stored are permitted provided that they are fitted with pneumatic transport with air closures. The temperature should not exceed 40° C in the storage space. Considering high hygroscopicity, the value must not exceed the following limits for receipt and storage:

- skimmed milk powder 5.0%;
- dried buttermilk 6.0%;
- dried whey including different technological treatments and milk albumin 8.0 %,
- casein 10.0 %.

The temperature of dried milk products must not exceed the air temperature. The storage area should conform to the general storage areas requirements specified in 2, 2.1 and 2.2.

Methods of storage

Airshed or floor stores are mostly used for the storage and their roof structure as well as the cladding have sufficient thermal properties for long-term storage. The stores should be dry and allow ventilation. The packs of dried milk products are put on the pallets and the pallets holding dried whey in the powder structure must not be stacked. The exception to the storage method are agglomerated or granulated dry milk products that can be stored in loose form in silo bins for the short term; the bins must have flat walls and thermally insulated cladding or be installed in a walled area. Under similar conditions, dried milk products in the powder structure in hermetically closed silo bins can be stored for the short term.

3.16 Methods and conditions for storage of fish powder

Fish powder is a less hygroscopic feed. Fat content oscillating from 8 to 13% depending on the fish powder and its structure influence the ability and the manner of storing. In addition to this, it must not be consumed by ruminants and therefore, if supplied loosely, it should be stored separately in an approved storage area while adhering to the requirements specified in the Regulation (EEC) No. 999/2001 (Annex IV).

Conditions for storage.

Fish powder is hygroscopic and if used for storing, its moisture must not exceed 10.0%. It is usually supplied in loose form, less often packed in bags or paper packaging with an impregnation layer. Fat content and the powder structure deteriorate the free-flow

consistency and it may develop discharging arcs after prolonged storage. If stored loosely, it should be placed in silo bins which are clad or thermally insulated or not placed in the storage's circumference. The store should be dry and allow ventilation. The store should conform to the general requirements specified under 2, 2.1 and 2.2.

Methods of storage

Fish powder can be stored in reserved and approved silo or airshed stores; floor or combined stores are less suitable. Considering the powder's properties, it may not be stored for the long term in loose form in silo bins. The best method for long-term storage (over 3 months) is storing in packaging (bags, sacks, containers).

3.17 Methods and conditions for storage of feed of mineral origin

Most frequently, the following feed types of mineral origin are used: calcium carbonate, calcium-magnesium carbonate, calcium di-hydrogenphosphate and calcium hydrogenphosphate, di-hydrogenphosphate and magnesium hydrogenphosphate, sodium hydrogencarbonate, sodium carbonate and sodium chloride. The feed is delivered in different structure, e.g. in powder with different fraction sizes, in crystals or granulates and the storage conditions and procedures should be selected according to their structure. Unless stabilised by approved anti-caking agents, sodium chloride may not be stored loosely. In no case may sodium hydrogencarbonate or sodium carbonate be stored loosely. No phosphates of crystalline structure can be stored loosely in silo bins for more than three weeks (danger of stuck material on the walls and formation of clot structure). The original moisture (except for crystalline water) does not usually exceed 1.0% for mineral feed. Sodium hydrogencarbonate, sodium carbonate and sodium chloride can be considered highly hygroscopic. All phosphates of crystalline structure can be considered less hygroscopic and non-hygroscopic are calcium carbonates and phosphates of granulate structure. When storing and handling feed of mineral origin, the responsible person should be familiar with safety data sheets.

Conditions for storage.

Should feed of mineral origin be stored in silo bins, the bins should have an air clarifying device in the discharge section. The reason is thickening in the discharge section if no discharge from the bin is done. Clarifying is required only at the beginning of the bin discharge and in cases when the arc formed needs to be removed during the discharge. Permanent clarifying is not recommended. Sodium hydrogencarbonate and sodium carbonate must not be exposed to temperatures over 60° C during storage because the structure changes and caking occurs. Both types react strongly with acids and release gas (CO₂). The stores intended for storing of feed of mineral origin should be dry and allow ventilation. Silo bins should be fitted with an exhaust if they are charged pneumatically. The storage should conform to the general requirements specified under 2, 2.1 and 2.2.

Methods of storage

Calcium carbonate is mainly stored in silo bins of sufficient capacity reserve, particularly when storing the powder structure because there is air flotation during charging that increases the volume by up to 30 %. The silo bins for phosphates, if not in granulate structure, should be either thermally insulated or walled to avoid direct bin wall heating and formation of stuck material. If calcium carbonates or phosphates are delivered in packaging in granulated structure (paper bags, sacks), the packaging is put on stackable pallets. Sodium carbonates and sodium chloride may be stored exclusively in packaging (sacks, bags) put on pallets; it is not suitable to stack the pallets. Mineral feed packed in

packaging may be stored in airshed, floor or combined stores provided that they conform to the above-mentioned storing conditions.

3.18 Methods and conditions for storage of other solid feed

They particularly include less frequently used feed, such as corn gluten, starches, sugars, maize sprouts, soybean-protein concentrate and potato proteins. The feed is hygroscopic and its moisture should not exceed 0.5% for sugar, 10.0% for other feed and 20.% for starches. Considering the hygroscopic nature and limited consumption, the feed are mainly stored packed in packaging (bags with impregnated insert or in sacks) stored on pallets. The airshed or floor stores are mainly used for storing; they must be dry, allow ventilation and conform to the general requirements specified in 2 and 2.2.

3.19 Methods and conditions for storage of dried yeasts

In most cases, this feed group contains dried beer yeasts containing *Saccharomyces cerevisiae* micro-organism and dried yeasts of the Vitex-type with *Kluiveromyces fragilis* micro-organism, obtained by fermentation of wood pulp hydrolysis product. Dried yeasts are mainly supplied in powder or fine flake structure and they are hygroscopic. Their moisture should not exceed 7.0% prior to storing. If in powder or fine flake structure, they cannot be stored in loose form in silo bins because of their hygroscopic nature. In case they are granulated, they can be stored in loose form in silo bins provided that the bins are thermally insulated or clad. The most suitable method for storage of dry feed yeasts is packaging (paper sacks with impregnation layer or bags). The packaging is put on pallets and can be stacked in two layers. For storage purposes, dry airshed or floor stores are suitable. The storage areas should conform to the general requirements specified in 2 and 2.2.

3.2 Methods and conditions for storing liquid feed (feed materials)

This group of feed usually contains animal fats, vegetable oils and beet or cane molasses. The animal fats and vegetable oils contain max 2.0% moisture. In liquid state, regardless of temperature, there are vegetable oils only except for palm seed oil, which transforms into liquid oil condition at temperatures higher than 45 – 55°C only. If present in non-stabilised form (stabilisation using permitted additives from the group of antioxidants), they can be stored for short periods of time.

Conditions for storage.

Storage tanks should be reserved for storing mixed animal fats and no vegetable oils may be stored in them without prior thorough cleaning. Oils and fats are stored at common surrounding air temperature and heating to 45 – 55° C is used when discharging the reserves of animal fats or palm seed oil. Heating is usually performed indirectly by steam and the heating equipment must not leak water into the fat or oils during the storage period. The storage tanks should be controlled and allow cleaning, i.e. safe access should be provided to the interior or the tank. Should the presence of sediment be detected upon emptying the tank, it should be discharged before receiving a new supply.

Methods of storage

The animal fats and vegetable palm seed oil are usually stored loosely in closed upright tanks equipped with a heating device for indirect heating of which the lower part is fitted with a sludge valve. The heating device is best made from stainless materials to avoid potential perforation and condensate penetration into the stored fat or oil. The tank draining is performed above the bottom level to permit some space for sedimentation of

solid particles. The bottom (heel) volume should represent at least 2% of the total tank storage capacity. Other vegetable oils can be suitably stored in similarly designed upright closed tanks without the heating device or in plastic containers located in airshed storage. For fire-protection reasons, the tanks should have an intercepting trap and the area for the container storage should be designed in a similar way.

3.3 Methods and requirements for storage of premixtures and additives in liquid or solid condition except for amino-acids, urea and ammonium salts

Everybody working or storing additives should be familiar with their MSDS. The reason is that some of them may be hazardous to humans or are not biologically degradable. Therefore, the additives should be stored separately in lockable stores and storing of feed or premixtures is not allowed in stores common with the additives. Most of the additives are hygroscopic and thermally-unstable already at 20 – 25° C. Upon certain concentration in enclosed spaces, the dust of some additives has explosive effects. These properties are partially transferred to their premixtures as well. The additives and their premixtures should be received for storage exclusively in originally sealed packaging (bags, cans, containers) and must not be damaged in any way.

Conditions for storage of additives and premixtures

The additives are stored in dry, ventilated, temperature-insulated stores with temperature control (temperature must not exceed 25° C) and surface water must not penetrate the storage. The floor of the additives stores should allow easy cleaning (limiting dustiness and potential of static discharge) and the spaces used for handling the additives should be exhausted. The premixtures can be stored in dry, ventilated, temperature-insulated stores and surface water must not penetrate the storage. The floor of the stores should allow easy cleaning. The stores of the additives and premixtures should be lockable and only authorised persons should be allowed to enter. The storage area should conform to the general storage areas requirements specified in 2 and 2.2.

Methods of storage

The additives and premixtures intended for storage should be packed into impermeable packaging (impregnated paper sacks, closable bags or containers) or cans. The packaging with the additives and premixtures is put on pallets in layers. The pallets must not be stacked and should be stored transparently and separately by individual type and batch of additives and premixtures. Ground-floor rooms of sufficient area for storing pallets on the floor or pallet racks accessible by suitable handling machines are the best for storing the additives. The premixtures of the additives are usually stored in airshed or floor stores of sufficient area for separate storage of premixtures pallets and the possibility of their handling.

3.4 Methods, requirements and conditions for storage of urea, ammonia salts and amino-acids in solid or liquid condition

Urea, ammonia salts and amino-acids are highly hygroscopic. Solid amino-acids are usually packed in impregnated and sealed bags or sacks. In liquid condition, they are usually available in closed plastic buckets or in loose form. Solid urea and ammonia salts are packed in PE sacks and closable bags with PE spray application. In liquid condition, ammonia salts are usually available in closed plastic buckets or in loose form. The packaging is stacked on the pallet and the pallet can be stacked in two layers. For storage of amino acids, urea and ammonia salts packed in packaging or cans or containers,

airshed or floor stores are used in most cases; they should be dry, well ventilated with sufficient floor area allowing separate storage of individual types and handling of pallets. Amino acids and ammonia salts in liquid condition delivered in loose form are stored in storage tanks made from stainless materials; the same should be used for traffic routes as well. The storage tanks should allow cleaning, control, be fitted with a filling indicator and should be placed in a space protected by a safety tub. Other feed can be stored in common in the same store provided that they are stored separately. The storage areas should conform to the general storage areas requirements specified in 2 and 2.2.

4 Procedure for storage of feed, additives and premixtures

The operator specifies in this section the methods and procedures for receipt, storage control and discharge generally for his stores, and should they be different for individual stores, for individual stores specifically. Furthermore, there should be a procedure for recalled products.

4.1 Procedure for receipt of feed, additives and premixtures

Prior to receipt, the responsible employee will check the cleanliness of the receipt container (for loosely delivered feed), setup of the traffic routes and silo tank (cells) condition to which the feed will be delivered, and following the inspection, the employee issues a command for unloading. Until that time, the carrier must not unload the material. In case a different feed type is loaded into the silo bin and the inspection finds residues in the bin, the bin will be emptied and cleaned, if necessary. A similar procedure is used when the same feed type is loaded into the bin but the inspection reveals there is stuck material on the walls or significant impurities volume (for grains) in the bins. For packed feed, additives and premixtures, deployment of individual component types to be adhered to is planned in the storage plan. Changes to the deployment of the silo bins and the area reserved in the storage plan in airshed, floor or combined stores for loose storing or storing in packaging may be made by the person responsible for the storage.

4.11 Receipt of feed, additives and premixtures

A procedure for checking weight delivered, provision of the supply document, taking a representative sample and visual inspection for the supply will be developed.

4.12 Weight of the delivered consignments

The weight of loose supplies is usually detected by weighing the transport vehicle before and after unloading using a calibrated pit scale at a place mutually agreed. Partial samples are usually taken from the supply after compilation of the combined and final sample. Temperature of the supplied product is checked as well. With the final samples, quality features declared by the supplier are checked for their conformity to the extent of the quality control plan. Depending on the analysis results, a decision on acceptance, unloading place and the method of storing is made. For supplies delivered by railway, the weight is checked similarly and unless no calibrated platform balances are available on the railway siding, the weight is indicatively checked using the technological storage balances and should the weight not conform to the mutually agreed tolerance repeatedly, re-weighing using calibrated platform balances is made. The partial samples are taken when unloading a wagon without turning the traffic routes on and at the same time it is

visually checked as to whether the supply conforms to the declared type, contains storage vermin, any foreign particles (glass, paper, wood, metal, plastic materials, mineral impurities), strange odours and temperature of the supply. The method of storing the supply will depend on the visual assessment of the supply. The supplies not conforming to the declared type and quality or those containing vermin, foreign particles and odour, will either be returned to the supplier or stored separately until settlement of the complaint or the product recall. Should the parcel report increased moisture higher than suitable for storing or increased temperature, the grains are dried again or ventilated or stored separately in a layer not exceeding 1 metre and these supplies will be labelled for preferential processing. Other feed types are intended for separate storage and preferential processing as well as in cases of increased moisture.

For supplies packed in packaging, weight by random re-weighing of the packaging is checked and their number is verified as well. Furthermore, the packaging is checked for damage and labelling in conformity with applicable legal directives. At the same time, partial samples for compilation of the combined and final sample are taken. When sampling the feed, visual assessment is made in order to check conformity of the feed to the declared type, particularly colour, structure, odour, attacks by vermin, foreign particles and increased temperature. If the feed packaging is labelled incorrectly or the label is missing or if the presence of vermin is detected or if the visual assessment does not conform to the declared one, the feed should be stored separately until settlement of the complaint. For supplies of increased temperature, the feed should be stored separately and the packaging will be distributed on the pallets. For the additives and premixtures, if the packaging is damaged or labelled incorrectly, they should be returned to the supplier.

4.13 Consignment documents

Together with receipt, the supply documents are accepted, i.e. delivery bill contains data on type, weight delivered, supplier (producer), delivery date and if the parcel is loose, the delivery bill should also indicate data on quality, safe use instructions, best before data; for fish powder and yeast also the part number and the content weight for packed products. The data can be replaced by a label attached to the delivery bill. For the additives and fish powder, there should also be the additives or fish powder analysis report and international business delivery bill for receipts from abroad.

4.14 Taking of samples

If the storage receives the feed, additives or premixtures recalled based on a complaint from a customer, they should be stored separately and should no sample be taken upon recalling, partial samples will be taken to create the summary and final sample. Until completion of the sample analysis and adoption of the decision on use of the recalled feed, additives or premixture the products should be stored separately and further changes to their quality should be avoided.

4.15 Consignment check

Upon receipt of the delivery, a record in auxiliary books for the silo bins will be made for loose receipts on the delivery date and weight, and should the silo bin be empty and without labelling, the feed type loaded into the silo will be indicated in the deployment plan. For receipts in packaging, the receipt will be indicated by a table showing receipt date, product type and its weight, whether processing is postponed or permitted and whether preferential processing is required ("Do not store, process immediately"). The writing on the table should be clear and legible.

4.2 Inspections performed during the storage time

For grains, the inspection method is contained in the requirements, conditions and methods for storage under 3.11. For other feed, additives and premixtures, the stock inspection is performed as follows:

The inspection of other loosely stored feed in the silo bins focuses on temperature in the bottom layer, middle layer and upper layer using temperature sensors installed in the silo bin. If no temperature sensors are installed in the silo bins, the temperature in the bottom layer is checked by discharging the stock or by re-releasing the stock and during the re-releasing, partial samples are taken in order to perform visual assessment of odour, the presence of vermin while at the same time, measuring the temperature. The inspection is conducted quarterly provided that no increased moisture exceeding the limit specified in 3.00 was detected during receipt or when the stock received in the silo bin did not exceed 30° C. Should increased moisture or temperature be detected during the receipt, the temperature should be checked at least monthly. At the same time, rain penetration in the silo cells is checked (check on the upper access manhole) and whether exhaust (either passive or active) is operational.

The check of other loosely stored feed in piles in airshed or floor stores focuses on the temperature check in the bottom, middle and upper layer of the piles. Depending on the type of feed stored, air temperature in the storage is checked permanently over the summer months. Furthermore, the presence of vermin, strange odours, ventilation of the storage, and surface water in the stock are checked (the latter particularly applies to multi-bay airsheds on roof drains and rainwater drains from roofs). Mixing of stocks is also checked. The frequency of the checks is identical to 4.21. Should a visual inspection not be sufficient, partial samples from different layers are taken in order to check quality. Regularly scheduled checks are made of the tidiness of the floors.

The check of feed, additives and premixtures in packaging is focused in stores on the check of the best before dates, labelling of individual types or parts of the stock and at the same time, changes to labelling according to the verified quality and discovered best before dates are made, e.g.: "process preferentially" or "postponed" in cases when the best before date is over. Also check the location of individual types in the determined area according to the deployment plan if no packaging is damaged by storage handling. Particularly in the stores of additives and premixtures, measure temperature permanently and should the permitted temperature limit be exceeded, modify the storage ventilation of the air conditioning. Also assure that there is no rainwater coming in and regularly check the tidiness of storage floors.

In addition to the stock inspection, continuous checks of the technology used, e.g. of the receipt containers, traffic routes, exhausts, and scales are made and repairs, adjustment and cleaning are performed depending on the conditions detected.

A record is made on the checks performed either in writing in the stock operation journal or the records are maintained in electronic form.

4.3 Procedure for cases of detecting temperature or product quality changes during storage

As grains are stored mainly for long periods, the procedure with respect to the methods of storage is described in 3.11. For other feed, additives and premixtures, the procedure is as follows:

In case of stock temperature exceeding the permitted limit, relocation of loosely stored products to other silo bins will be done (as far as airshed and floor stores are concerned, to other reserved areas). For packed products, they will be re-layered on the pallet

including re-stacking of the pallets. The product must be repacked in case of a change to the structure (formation of clots). At the same time, the products are assessed by the senses with respect to changes of colour or odour. Should changes be detected, stop dispatching, take a sample and store the stock separately until the quality is verified.

In case of the presence of vermin, the feed dispatch should be postponed and the loosely stored products relocated if it is stored in silo bins and at the same time, application of an approved disinfectant by an authorised person should be done. If the feed are loosely stored in airshed or floor stores and if the climatic conditions of the storage are acceptable to the application, inject the disinfectant directly into the feed and cover the affected pile with a tarpaulin. Following the decontamination time, the feed should be sampled in any case in order to determine the decontaminant residues and if no residues are detected, the feed will be released for dispatch. Should residues be detected, it is necessary to relocate the feed to other free storage spaces and at the same time to repeat the sampling to verify the decontaminant residues.

Should the analysis inspection carried out on the samples during storage reveal that the feed or the additives or premixtures contain prohibited substances and products or undesired substances exceeding the maximum permitted limit or the products were contaminated by the additives that may not be present in the product, or should stored additives and premixtures be mixed, the product must not be dispatched but be determined for disposal as waste.

Should feed be mixed during storage, the extent with respect to the stored weight will be assessed and in case this is not marginal mixing only, the dispatch will be prohibited, partial samples will be taken and they will undergo a visual assessment. The identical samples based on a visual assessment (colour, odour, structure) are combined in a combined and final sample. For the final samples, we will carry out analyses suitable for determination of the usability of the feed mixture and the feed will be labelled and dispatched depending on the determined usability.

Should increased moisture be detected during the feed inspection, the feed will be intended for preferential processing and they will be marked "Do not store, process immediately".

4.4 Release of feed, additives and premixtures from the store

Only batches of additives or parts of feed and premixtures intended for dispatch will be released. The dispatch is conducted by an authorised person, who must check the dispatched weight by weighing using a calibrated scale or by recounting the packs delivered. At the same time, the person checks proper labelling and non-damage of the packed products. Incorrectly labelled packaging (either due to damage or the label not being legible) will be newly labelled with the same data with the original marking or are rejected from the dispatch and stored separately until the labelling is corrected. Damaged packs must not be dispatched; they will then be re-packed into new packaging including new labelling. The procedure above does not apply to additives and premixtures where damaged packaging including contents are disposed of as waste or are returned to the producer if contractually agreed. If the quality control plan determines the requirement for sampling during dispatch, the authorised person takes a sample which is then stored in a determined location according to the plan as a backup sample for potential disputes with the customer.

Each delivery dispatched from the store is completed with a delivery note containing data at least on the dispatch date, dispatch weight, packing method (number of packs), name of the dispatched feed, additives or premixtures, name of the storage organization, signature of the storage dispatcher. If the feed are dispatched in loose form, the delivery

note should have attached a sticker containing additional data to be contained in the feed description. In addition, for the supply of additives and powdered fish, a copy of the analysis certificate and the powdered fish analysis from the producers respectively are delivered.

5 Keeping stock records on feed, additives and premixtures

The feed business operator should keep records on feed, additives and premixtures in a way allowing full traceability from the receipt until the final destination. The records are maintained in written or electronic form. In addition to the storage account records, they should maintain the required operation records on the stock balances inspections including temperature detected by product types, decontamination of the stocks saying by whom and when the decontamination was conducted, what decontamination product was used and quantity per ton of stock, analysis results from the quality control including analysis for residue presence following decontamination, stock treatment, store rat extermination (conducted by whom and when), complaints and recalls of supplied products. Furthermore, the feed business operator will indicate:

5.1 Maintaining of records

If the additives are stored, the feed business operator should also keep the following data:

- a) on the supplier of the additives and if substances of the same type are delivered by different suppliers, data from suppliers of individual customers (business name and registered office or name, surname and address of a natural entity, ID number or registration number);
- b) on the weight of individual types of delivered additives by the delivery dates, with the batch numbers and production date;
- c) on customers (business name, office of the operating unit or name, surname and address, ID or registration number) by individual supplies;
- d) on weight delivered by dispatch dates, type of additives and batch numbers.

If the premixtures are stored, the feed business operator should also keep the following data:

- a) on the names and addresses of suppliers by type of premixtures delivered and if the premixtures of the same type are delivered by different suppliers, by supply types and ID number or registration number;
- b) on the weight delivered by premixture type and delivery dates;
- c) name and address of the plant to which the premixtures were delivered, including data on individual types and dispatch dates, including batch (part) number of the premixture.

If feed is stored, the feed business operator should also keep the following data:

- a) on the names and addresses of their suppliers by supply delivery date;
- b) on the weight delivered by supplies;
- c) on the names and addresses of their customers by supply and dispatch dates.

5.2 Methods and retaining of records

The operator determines the methods and retaining time for the records. For records according to 5.1, the retention time is at least 3 years. At the same time, the operator must define a person responsible for retaining the records. Should the operator have shredding

and archiving rules defined with the registration specified, the references thereto are made herein and only the name of the person responsible for keeping the records is given.

6 Methods and procedures for cleaning, treatment, decontaminating and rat extermination of stores

This section specifies what methods, procedures and frequencies are employed for cleaning and decontaminating of the stores including the technology involved.

6.1 Cleaning of storage areas

The cleaning is performed by sweeping or vacuum cleaning of free floor areas of the store using an industrial vacuum cleaner. It is usually conducted daily if there is receipt and release of stocks in the store. The occupied floor area is cleaned always following the release. The sweepings, except for the stores for the additives, are disposed off as other waste. The sweepings from the stores for the additives are hazardous waste.

6.2 Treatment

The treatment of the stores includes, in addition to the treatment of the storage areas, treatment of the technology and related areas, e.g. dust chambers for the exhaust fall-outs.

For silo stores, treatment is always conducted after emptying the silo bin in case there is feed stuck on the walls or the presence of vermin. It is usually a dry, mechanical treatment or with the use of compressed air and if vermin is detected, the treatment is complemented by disinfection. The treatment of storage tanks is usually conducted by wet techniques following removal of sediments. The waste generated from treatment is considered other waste.

For feed stores of airshed or floor or combined type, treatment depends on their structure and it is conducted usually by mechanical means or compressed air with subsequent vacuum cleaning of the released particles using an industrial vacuum cleaner or water jet cleaning following their discharging. If vermin are detected in the store, the treatment is usually associated with disinfecting. If a water jet was used for treatment, it is necessary to consider sufficient time delays for drying out the storage space. The treatment is usually conducted once per year. The waste generated from treatment is considered other waste.

For the stores for premixtures and additives of the airshed or floor type, the areas are treated mechanically or using a suitable industrial vacuum cleaner. Treatment is conducted following emptying of the store at least once per year. The waste generated from treatment is considered hazardous waste.

6.3 Rat extermination of the stores

The rat extermination is conducted as needed, usually twice a year and may be performed by an authorised person only. A decoy should be placed on a fixed pad modified so that it is impossible to disseminate the decoy on the store floor. The places with decoys should be clearly identified and the storage operators should be trained how to use the decoy installed during cleaning and treatment.

7 Methods of collection, storage and disposal of waste generated upon receipt, treatment, release of stocks and cleaning and treatment of the store

The operator must include this chapter in the good practices in case he does not have a waste management plan or it is not included therein. If the waste management plan is available to the operator and the plan contains provisions stipulated under 7.10 to 7.30, the good practice will include a reference to this plan only, which is also contained in the chapter of referenced directives.

7.1 Types of generated wastes and their classification

Other waste includes waste generated during the receipt procedure, separated on grids (foreign particles) and during cleaning of grains, stock treatment (particularly crops where dust particles are separated including impurities such as husks, hulls, ears or corn cobs and straw, empty grains and weed seeds). Other waste includes sweepings generated during storage cleaning, including content lost from damaged packaging, residues from cleaning of the stores for feed and premixtures, including their technological equipment and separated sediments from the storage containers generated from cleaning of the containers.

Hazardous waste includes sweepings and residues generated during cleaning of the store for additives, as well as residues lost from damaged packaging of additives.

7.2 Concentration of waste

The waste is concentrated according to the waste classification on the site of its generation, where it is also stored until final disposal.

The other waste generated by cleaning of received or treated grains is collected and stored until final disposal in dust chambers or bins in loose form or if the storage is not equipped with dust chambers or bins, collected in reserved containers installed under the air closures of the exhaust cyclones.

The other waste generated from the store cleaning or treatment is collected in a container where it is also stored. The container is located in a reserved storage area and labelled by waste category.

The other waste generated in the form of sediment from storage of liquid feed or cleaning of a storage container is collected in a sludge container and is immediately disposed of during sludge removal or container cleaning.

The hazardous waste generated from the store cleaning or treatment is collected in a container where it is also stored. The container is located in a reserved storage area and labelled by waste category.

7.3 Waste disposal

The waste disposal is carried out according to waste categories. Other waste can be used for further processing, e.g. by composting for fertilising or granulating for use as fuel. The waste must be disposed of by a person authorised based on an agreement concluded. The disposal is confirmed by a document from the receiving party giving its name, the type and class of waste, weight taken, date of waste removal and signature.

8 Complaints, recalling of feed, additives, premixtures delivered and register of complaints

If the operator has complaint rules or complaint procedures and recall of supplied products developed and included in agreements and keeps complaint records in conformity with this act, shredding and retaining rules, this chapter does not have to be processed but only a reference be made on the complaint rules, act, shredding and retaining rules or the agreements concluded. The chapter of referenced directives, the complaint rules, sample agreement, shredding and retaining rules are given therein. Both rules become an appendix to the good practices.

8.1 Complaint rules

The complaint rules or a sample agreement should, in addition to the provisions related to the commercial code, contain the following:

- a) what defects of products supplied are considered to be apparent, e.g. different product type than that contracted, non-conforming weight, unsuitable packing and labelling of products, damaged packaging, improper grain grade, increased crushing level, presence of vermin, foreign odours and particles;
- b) to what extent the customer has the right to demand product recall;
- c) what defects are considered to be hidden and to what extent the customer has the right to demand product recall (usually by the best before date) and how a complaint with recall request should be lodged (i.e. in writing or in electronic form with subsequent confirmation or electronically with a signature);
- d) if the defects contained in the complaint are removable without recall (weight, labelling), to what extent such defects are removed by the customer (e.g. immediately upon lodging the complaint);
- e) in what cases and to what extent the customer has the right to claim compensation for damage;
- f) what procedure will be used for recalling a supply, e.g. what time must lapse from the moment of asking for recall, whether technical assistance from the customer of the supply will be required, how and where the weight of the recalled supply will be checked, how and where the samples from the recalled supply will be taken including the issue of the recall protocol. For supplies delivered in loose form, it is suitable to find out the weight using calibrated balances and sampling including the issue of the protocol should be made following placement in a suitable customer's store (airshed store is the best).
- g) what procedure will apply for the alternate performance;
- h) how and who will check the quality of the recalled supply;
- i) how and until when will the costs associated with the product recall be paid, including verification of quality if it proves that no reasons for the recall were found and the product conforms to requirements in conformity with legal directives.

8.2 Removable quality defects

The removable quality defects, in contrary to agreed or standard requirements, can be:

- increased grain moisture; rectified by re-heating;
- increased graininess (presence of imperfectly treated components); rectified by re-treatment and if compound feed is concerned, the content of unstable additives should be checked as well;

- increased proportion of crushed material not conforming to granulate size or increased proportion of crushed material; rectified by repeated granulation to the required granulate size under excellent crushing removal. At the same time, the content of unstable additives should be checked as well.
- reduced content of nitrogen substances or fats or macro-elements or additives, except for coccidiostatics, is modified by adding a suitable component in concentrated form provided that the product does not contain coccidiostatics. In these cases, verification of the declared quality features should be made.

8.3 Non-removable quality defects

If it is impossible to remove the defect, a procedure will describe the method of disposing of the supply, e.g. by composting.

9 Related directives

For example, the following directives are referenced, if processed by the operator and the good practice make references to them:

- quality control plan;
- waste management plan;
- safety sheets of the components;
- complaint rules or sample of an agreement;
- act, shredding and retaining rules;
- organisation chart with indication of the names of responsible persons;
- in case of stores equipped with technology, technological schemes of the store with a description is given.

If the operator is a producer as well, production directives should be specified as well.

SECTION– D

GOOD PRACTICE PRINCIPLES

for production of premixtures and compound feed

1 General

The purpose of the good production and hygiene practice for the production of premixtures and compound feed is to provide grounds to producers for development of their own good production and hygienic practice and to help them in their implementation.

The purpose of the good production practice in the production is to manufacture feed in conformity with the applicable requirements and to maintain the procedures specified for their production. The requirement is that the businesses where premixtures or compound feed with the use of additives or premixtures will be produced should be approved or registered by the applicable administration office.

1.1 Importance of good production and hygiene practice

The goal is to ensure feed safety monitoring at each stage that may negatively influence the feed and food safety or that may have a negative impact on the environment.

1.2 Applicability of the principles

The principles apply to all producers of premixtures and farm animal feed with the use of additives or premixtures producing them for the purpose of marketing.

1.3 Grounds for processing

The base for creation of the good production practice is verification of the production technology and of the production procedures, usually prior to launching the production of identical production procedures, and furthermore in cases of preparing a new product launch requiring a change to the production procedures or in any case of technology changes with a potentially high effect on the product quality and safety (e.g. a change to the weighing system, a change to the mixing device, etc.).

1.4 Adherence to production procedures

The producers conduct audits to see whether their production procedures have been obeyed by employees at all levels. The audit results should be critically assessed and documented by authorised employees. Their frequency should not exceed yearly intervals.

2 Definitions and terms

For the purposes of this part, the following definitions and terms will apply:

Production type –production of feed, premixtures, feed production with the use of additives or with the use of premixtures.

Handling – holding of feed, additives or premixtures associated with changes to packaging, labelling or other modifications that do not change the product composition or quality.

Traceability of origin –finding out the origin of the feed or substance that are or might be included in feed in any stage of production, processing or delivery.

Homogeneity of the additive in a part –acceptable variation of values applicable to the monitored additive detected via partial samples taken from the part in the required quantity.

Working accuracy - ability of the mixing equipment to mix the determined weight of an indicative additive in the batch within a certain time to ensure homogeneity.

3 Production areas and technologies of the producer

The provision on production areas and technologies is common for feed producers with the use of additives or premixtures as well as for premixture producers.

The producers usually document the production processes by ground plan placement of the production areas with a description of what purpose individual buildings are used for. The production equipment is documented by an accurate and complete technological scheme with a description of the positions so as it is possible to clearly assess individual production sections and phases from the scheme.

The principle is that buildings and technologies are placed, designed and maintained to suit requirements for processing and production of all feed groups or types or of selected feed types or for premixture production only.

When designing a new or preparing the reconstruction of an old feed or premixture business facility, the following should be focused on:

- 1) excellent discharging of the traffic routes including the storage and dosing bins and other technology, particularly of that processing hazardous additives or premixtures containing them;
- 2) selection of suitable balances for dosing of components with respect to the weight of the required batch. The balances should allow weighing of set weights in the full range without any weight created being influenced by an error.
- 3) selection of a mixing equipment with corresponding working accuracy for the production type, or for the type of mixed components, particularly additives;
- 4) possibility of separate storing of the used components or the final products while avoiding the possibility of their potential mixing;
- 5) separate exhaust of the production facility with exhaust dusts always put in places from which they originated and separately according to production phase. They are disposed of if the above cannot be guaranteed. It is unacceptable to mix exhaust dusts originating from places where there already are dosed additives, with dusts where additives are not present yet.

These requirements are particularly focused on:

- a) avoiding or substantial limitation of cross contamination;
- b) provision of maintaining the limit requirements for additive content;
- c) provision of homogeneity of additives in the feed part.

Regular cleaning should be arranged in the production business area, in the production areas, stores and laboratories and no waste may be accumulated there. The producer must implement the cleaning and treatment plan for the production areas and technology. The cleaning and treatment is conducted regularly at intervals corresponding to the production type and maintaining safe operation. The cleaning and treatment plan is usually a part of the production procedures. The plan also includes disinfection and rat extermination of the areas and technology. The disinfestation is usually associated with mechanical cleaning of all production areas.

Records are maintained on the inspections and cleaning containing information on measures applicable to non-conforming cleanliness level. This documentation also includes records on disinfestation or rat extermination, including all agents used for this purpose and the follow-up inspection.

Production areas should be suitably illuminated and ventilated. No surface water may penetrate the production areas and the producer must prevent access of animals to these areas. Only authorised employees of the operation may enter the production facilities. Outside employees may enter the facilities via the operation manager only e.g. for repairs or maintenance, and their presence should be monitored by a delegated employee. The central administration office employees may enter the facility only under the supervision of the production manager or of an authorised employee.

The structure and surface of the floors in the production facility should conform to the operations performed. The floors inside the production area as well as exterior access paths should be kept clean to avoid potential accumulation of production residues and handling of components.

The walls and ceilings of the production areas including the storage bins should be clean to avoid reproduction of vermin and danger of fire or explosion.

The cleaning frequency of the production areas and technology should conform to the production type and intensity.

The production areas must not hold waste generated during the production for a long term. The waste is sorted and accumulated by their hazard and regularly removed from the production areas to reserved locations and disposed of from there. Records by the responsible person are maintained on the waste disposal. For these purposes, the producer has a waste management plan available.

3.1 Relation to the designing of a production area

When designing a production area, in the plans for any technology installations consider potential errors, and modify the design to minimise the occurrence of errors.

3.2 Structure and arrangement of the production facility

The structure and arrangement of the production facility must allow its control and effective cleaning including the maintenance. The design must not contain equipment allowing no control or cleaning. For this purpose, all accumulating areas used for the processed materials in the production are equipped with sufficiently dimensioned access holes with tight closures and these holes are fitted with quick-closing devices if frequent inspection is necessary. Should there be locations allowing no control or cleaning, the producer must manage them within the system of critical control points and if the danger cannot be minimised in the system, technical correction of these locations must be done.

3.3 Inspection of production facilities

The production facility should undergo a regular audit by the production area operator where the frequency of the inspection depends on the hazard type. The focus and the manner of auditing the facility, including frequency thereof, are usually part of the

production procedures. If necessary, a record on inspection including the inspection results is made for selected inspected locations.

The production facility is designed to prevent cross contamination. If cross contamination cannot be avoided through the structural design, the facility should be cleaned following the feed production and the waste generated disposed of.

3.4 Balances and the dosing device

The balances used must conform to the entered components loaded as far as their upper and lower limit and working accuracy. It is not permitted to use balances of which parameters do not conform to the entered components loaded. The balances used should be fitted with a record on actual component load or the weight of the component load as well, and the permitted load variation.

The balances and other gauges used for dosing of components should be calibrated at least annually by an authorised company and rated gauges should be calibrated at intervals specified by the metrological rules. A calibrating company will issue a record on calibration or verification with the data required by applicable laws. Balances reporting increased error when compared to the permitted tolerance defined by production procedure and laws must not be used for production.

3.5 Monitoring of production facility failures

If absolutely necessary, the operation of the production facility should be monitored by devices able to record the necessary parameters from a selected production section or to record and warn of occurrences of technology failures.

3.6 Inspection of technologies

The critical technology will be checked or cleaned at defined intervals and a record including findings will be created thereof. It particularly includes the technology for cleaning of impurities of all kinds (particularly ferro-magnetic impurities). The balances used for the dosing of components will be checked indirectly using a control production and should variations exceeding $\pm 1\%$ be detected, the scales must be adjusted and calibrated. With the mixing device, tightness (whether or not the agitated components leak) and consistency of the mixing element are checked. The mixing device, must not be used for production in case a leak or inconsistency is detected.

Balances corresponding to requirements specified in laws and produced by a company authorised to produce the balance can be used for the production.

3.7 Mixing device

The mixing device can be used for feed production only when its working accuracy is certified for the production type in which the mixing device should be used. For production of feed using additives or premixtures reporting increased concentration of additives and dosed to the production batch at a proportion under 0.2%, or for the production of premixtures, a mixing device of the working accuracy 1:100,000 will be used. For the feed production with premixtures of additives dosed at a concentration over 0.2 %, a mixing device of working accuracy 1:10,000 will be used.

The above-mentioned requirements for control of the production facility, including determination of the control frequency and documenting of the control, are usually specified in the production procedures.

The method of maintenance, including determination of its frequency and specification of responsibility, is usually specified in the maintenance plan or the operation rules.

4 Employees in the production

The employees in the production of feed and premixtures should have suitable abilities and qualifications necessary for the production types. The producers create an organisation chart defining the qualifications and skills (length of practice) which are necessary for certain positions in the production, and at the same time, they specify responsible persons. The organisation chart should be available to the authorised bodies of the central supervision. A detailed definition of the rights and liabilities, particularly with respect to achieving the quality of products and their hygiene safety, will be specified in the job specifications for the employees they confirm.

Should there be changes to the production or related directives, the employees should be informed about these changes in a demonstrable way.

For better understanding of knowledge of production procedures, their control, quality control, as well as related records, the producer regularly conducts training of employees and the employees confirm that the problems discussed during the training were understood by them. The training should take place at least annually and always in cases of a change of personnel.

Each new production employee should be informed about all related directives of the producer prior to commencement, and the employee should confirm it.

4.1 Qualification requirements

The qualification requirements and abilities of the production employees will be specified by the producer by the job position the employee performs in the production. In case of an employee responsible for production according to legal directives, the requirements specified by these legal directives should be met. A permanent exception to these requirements as far as a responsible employee is concerned is not acceptable.

4.2 Organisation chart

The organisation chart of a production business should clearly determine competencies at different management levels. The production rights and liabilities should be unambiguously specified in the job descriptions or may be specified in general in the job descriptions but with a reference to the internal directives of the producer, including the names of such directives, e.g. production procedures, storage rules, etc. It is not permitted to define a team responsibility in the producer's directives (the service operators are responsible for the production) or no responsibility.

5 Production of feed and premixtures

A detailed description including the control mechanisms is usually specified in the production procedure. The managing position should indicate the person responsible for the production (a role), e.g. production manager or production foreman including his/her rights and liabilities. Generally, the following producer's liabilities can be specified that should be taken into account when compiling the production procedure :

The feed producers using the additives or premixtures containing particularly the additives from the coccidiostatics and histomonastatics group or medicated premixtures, and the premixture producers using the additives from these groups or medical substances should arrange in their production procedure that the individual production phases are conducted in conformity with the laws and directives that lead to the definition, control and management of critical control points in the production process.

The technical or organisational measures should be realised to avoid and to minimise any cross contamination or production error. During the production, there must be adequate and sufficient control measures.

Monitoring of the presence of feed materials, of which circulation and use in animal feed is prohibited, including undesired substances and pathogens (e.g. the presence of salmonella) in relation to human and animal health, should be ensured. At the same time, a suitable control strategy for minimising such risks should be adopted.

Waste and material that cannot be sold should be isolated and identified. Any such material containing the risks under 5.03 or the risky additives or medical substances or potentially contaminated material should be disposed of in a suitable way and must not be used as feed (disposal usually by burning as a dangerous waste).

5.1 Production procedures

The production procedures should be developed according to the production line technology and if more production lines are operated and each of them has a different design or different feed-premixture or the group of feed-premixtures is produced, a stand-alone production procedure should be created for each such line. The production procedures, if required by variations in the feed-premixture type or group of the feed-premixture, will be processed not only according to the technology but according to the type or group of feed or premixtures. In this case, there must be a principle that determines that the critical control point within the production procedure must be fully audited and if impossible, a stand-alone production procedure must be developed for this production section specifying the critical control points.

The production procedure is usually divided into the following sections depending on the production technologies:

- a) receipt of components for the technology;
- b) processing of components if processed;
- c) dosing of components both in solid and liquid condition;
- d) mixing of components in the batch;
- e) granulation or extrusion of products - usually specified as an independent production procedure;
- f) storing, packing, dispatching and delivery of the final products;
- g) exhaust of the production technology;
- h) cleaning and disinfecting of the production facility and technologies, including rat extermination if the production operators are authorised for it.

Each of these parts of the production procedure should describe in more detail what operators have to do, at what time intervals an audit needs to be conducted and how the audit has to be documented.

5.2 Parts of the production procedures

Receiving the components for the technology

- a) checking the receipt bin for the component, particularly always when a different component is to be stored in the bin;
- b) checking the receipt container to see whether it is empty and has a protective grid;
- c) check of the traffic route selection;
- d) prior to discharging the component into the receipt container, the component delivered will be checked using visual control to see whether it conforms to the type declared or whether there are some apparent defects (presence of foreign particles, live vermin or modified structure or colour);
- e) during the transport, the operators check the function of the traffic routes, especially whether the shutters are tightly sealed and whether the component particles are not stored in bins other than those specified;
- f) if the operators are required to take samples from the received part, the samples will be taken using the procedure specified in the quality control plan and the sample will be labelled identically with the component and delivered to the person responsible for the sample retention.

For packed components, the operator will usually check the labelling of the received packaging, whether the type conforms to the required component and whether the latter was released for production or not.

The processing of the components usually includes the following tasks for the operators:

To check prior to the production start:

- a) installation of suitable sieves onto crushers including the control line crushers or setting of the crushing gap for roller crushers depending on the production order or experience of operators;
- b) setup of the traffic routes for the transport of components to the container above the crushers and from the crushers to the grouts container above the mixing device;
- c) separators of ferro-magnetic impurities and their cleaning, if needed;
- d) exhaust system and its cleaning, if needed and if it is a part of the treatment line.

To check in the course of the treatment

- a) treatment of grouts visually or with the use of a sieve of relevant mesh size according to the type of products;
- b) function of the separators of ferro-magnetic impurities and their cleaning;
- c) function of the traffic routes, particularly shutters and whether the grouts are collected in the specified bins.

Dosing of the components usually includes the following tasks for the operators:

- a) check of the components volume in the dosing bins and if necessary, replenishment during the production;
- b) if a component is included in the production order which has not been included in the bin deployment scheme in the control room yet, the operators will first check discharge of the bin and depending on the dosing element type, it is decided whether a newly received component will be placed or not;
- c) for automatic dosing systems, the production order is controlled in the control computer, whether the mixture is adhered to the given formula, whether the sequence of the types produced respects the decontamination programme and whether the component will be dosed by a balance of corresponding weighing capacity. Furthermore, the sequence of dosing of the components will be defined with the components of the highest dosed weight being put at the beginning of the

dosing, whereas the components with the lowest dosing weight are put in the centre of the dosing process. At the same time, the specific weight of the components is taken into account (the component of the lowest specific weight must not be dosed at the end);

- d) in manual dosing, the balance used for weighing the additives or premixtures is checked using calibration weights and $\pm 1\%$ will be checked, and if the weight shows higher variation, the balance is rejected from use;
- e) in manual weighing, the component is checked in a visual manner for differences between the packaging or foreign particles in the component;
- f) actual measured weights of the components are recorded and compared to the production order to see whether there is a variation higher than the deviation permitted. A similar procedure will be used for the weight systems working in automatic mode;
- g) for manual dosing, the hopper is cleaned always after the end of the production of a particular product type;
- h) the production procedure also determines the control productions for the weight systems working in automatic mode with determined frequency and scope when the actual dosed weight of the components for a certain part is compared with the detected weight of a part on the calibrated balances. If a deviation higher than $\pm 1\%$ is detected repeatedly, the whole balance system should be recalibrated.

Mixing of the components

This section usually determines the following obligations for the operators:

To check prior to the production start

- a) whether the mixing element of the device is in good condition and whether the mixing device is empty, including related bins above and under the device; at the same time, the operators check air connections, if installed;
- b) cleanliness of the dust filter of the mixing device and cleaning and replacement, if needed;
- c) setup of the mixing time, if not determined in the control system as fixed;
- d) function of the shutters or valves by the bin above the mixing device or in the traffic routes;
- e) for rotary mixing devices, setting the drum orifice against the mouth of the traffic routes or the bin;
- f) if the mixing device and the related traffic routes contain an automatic sampler, setting of the production weight used for the number of partial samples taken will be defined in the control system;

To check in the course of the production

- a) whether the mixing device is tight and does not leak;
- b) whether the discharging is perfect, including the bin under the mixing device;

After finishing the production:

In case the operators are authorised to make samples from a part, the homogenisation and reduction of the summary sample taken by the automatic sampler will be done and the final sample created, which is immediately sealed and marked with the product type, production date and the part production weight.

Product granulation

The following operator tasks are specified in most cases in this section:

- a) to check discharge of the main and levelling bin over the granulation press before and after the production, discharge of the feeding screw conveyor into the conditioner and discharge of the conditioner, cooling column, cyclones and the dispatch bin for the granulate;

- b) according to the production order, the granulation press mould as well as the sorting sieve for the granulate are installed, the steam temperature is set according to the order;
- c) setting of the traffic routes is done according to the bins reserved for the product before and after the granulation;
- d) if the granulation line is controlled automatically, the required press output is set including the product steam temperature and if possible, the down pressure of the rolls;
- e) during the granulation process, the operator checks adherence to the steam temperature set, granulate coherence, granulate temperature after cooling, and the frequency of discharging of the cooling column or the press power is adjusted depending on the temperature measured;
- f) the operator checks the function of the cyclones, their air closures and the sorting sieve function;
- g) after the end of the granulation, the operator will check the discharge of all parts of the granulation line, cleaning of the granulation press, including the feeding screw conveyor and the conditioner.

Transporting, storing, packing, dispatching and delivery of the final products

This section of the production procedure usually contains the following obligations:

Product transport

- a) before the production start to check of the setting of the traffic routes and bins into which the products will be placed;
- b) during the production, to check the function of the traffic routes, particularly the tightness of the shutters to make certain that they do not leak products into bins other than those specified;
- c) after the production, there is a time interval set for which the traffic routes should be on in order to place the remaining products in the bin.

Product storage

- a) the bins intended for storage of products or for packing or dispatch in loose form are usually determined permanently for products containing risky additives. If a change to the bin allocation is made, the change should be approved by the responsible employee and the bin should be cleaned before changing the allocation;
- b) the operators will regularly, usually following the bin discharge, remove dust from the upper wall sections and ceiling and put it into waste.

The following checks apply for packing of products into packaging

- a) balance check, their cleaning, including a bin;
- b) balance setup according to entered packaging content and tare;
- c) selection of suitable packaging for the product, unless specified in the order;
- d) if the balances are not calibrated, the packaging weight is randomly checked during the packing and the balance setting is corrected according to the results;
- e) check of the packaging marking and whether the packaging conforms to the type of product packed and whether the data is correct;
- f) removal of damaged packaging during packing or handling from the storage with subsequent replacement packaging including marking;
- g) visual check of the packaging content before sealing (colour and structure must not change between packaging). Should changes be detected, the packaging must be replaced and then must be stored outside the dispatch area.

The dispatch of final products includes

- a) if the products are dispatched in loose form, the responsible person checks whether the bin is fully discharged;
- b) in the course of the bin filling, if the operators are authorised to do so, they take samples from the supply according to the procedure specified in the quality control part and seal the sample immediately, mark it in conformity with the product and submit for retention; at the same time, visual changes are checked - if observed, the product dispatch is stopped;
- c) if operators are authorised to issue documents required for the supply, they attach labelling of the products to the loose form for transportation;
- d) at the dispatch of packed products they check the damage to the packaging; if damaged, it must be removed from the dispatch. Furthermore, labelling on the packaging and their numbers are checked.

Exhaust of the production technology

The following operator tasks are specified in most cases in this section:

- a) to check the function of the passive and active exhaust, including frequency, and for passive exhaust, beating of the dust bags (usually after completion of the production of a product containing risk additives);
- b) to clean the active exhaust system in case there is substantial dust clogging in the system;
- c) to adjust intervals of automatic cleaning of the active exhaust according to the production cycle length;
- d) to maintain fabrics of the dust bags or cartridges with a filtration fabric in the active exhaust at regular intervals.

Cleaning of the production areas and technologies, including disinfection and rat extermination

This section defines the methods and frequency for cleaning of production facilities and technology and if permitted for the operators, for disinfection and rat extermination. The cleaning is specified for technology for which it is not explicitly defined in individual parts of the production procedure. First and foremost, the areas and technologies where the additives or premixtures are either processed or handled must be cleaned. The determined cleaning frequency should conform to the quantity of products processed and hygiene, safety and fire requirements must be taken into account.

The disinfection should always be associated with complete mechanical cleaning of the production area and the frequency should depend on the visual detection of the presence of live vermin or their sub-life stadiums of development. Mechanical cleaning and ventilating of the area where the disinfection was done should be ensured. The rat extermination should take place depending on the presence of rodents or as prevention. The decoys used as well as the residues from cleaning due to disinfection are disposed of as hazardous waste by burning.

5.3 Critical control points in the production procedure

Based on verification and evaluation of the hazards and risk, see Part F of the Codex, the producer defines critical control points and arranges their auditing according to a plan, which is part of the system for audit and verification of the critical control points.

In the production procedure for production of feed containing additives or premixtures, particularly hazardous additives, the critical control points will usually be placed in a phase where it is possible to control adherence to the dosing of the additives or premixtures, their homogeneity in the batch and part and cross contamination of the

products. Therefore, it is useful to put the critical control points for the products produced in the grouts structure in the batch mixing phase and in the dispatch phase. With both critical control points, it is possible to monitor all hazards mentioned above and check whether the preventive inspection is adhered to for all the critical control points specified for each part of the production procedure. For the production of granulated or extruded feed, an independent production procedure should be identified as this production has more critical control points. The other critical control point is usually where the cooled but unsorted granulate or extruded products can be checked to find out potential losses of additives caused by granulation (extrusion) and cooling, and making certain that this phase does not create cross contamination.

In the production procedure for premixture production, the critical control point will likely be put in the phase where it is possible to monitor both adherence to dosing of the additives as well as their homogeneity and potential cross contamination in the production batch.

6 Quality control

The producer of premixtures or feed with the use of additives or premixtures must elaborate a written quality control plan as a part of the quality-safety system. One of the conditions is that the producer either owns or has arranged laboratory inspection of the components and final products. The laboratory must be fitted with a suitable device and have qualified staff controlling adherence to the specified attributes, and it verifies whether the components and products tested in the laboratory conform to the declared values and are eligible for production of the mixtures or premixtures of that type and animal category.

A qualified person delegated by the producer is responsible for the quality control.

6.1 Authorisations and responsibilities of the qualified person

Authorisations of the qualified person

- a) possibility to control all employees involved in the quality management system and their adherence to liabilities;
- b) to design and discuss corrective measures adopted upon the quality audit and critical control points audit and to follow up on their performance;
- c) to define attributes to be checked for the components and the final products, including determination of the check frequency;
- d) to define the sampling points and sampling procedures for quality check purposes;
- e) to define the test methods for testing the attributes specified;
- f) to check the laboratories involved in the quality control system and the safety of components and products;
- g) to define attributes tested in recalled products;
- h) to define procedure for defect removal in defective products;
- i) to submit proposals for verification of the critical control points system and proposals for the quality control plan.

Responsibilities of the qualified person

The qualified person is responsible for:

- a) audit of adherence to the quality control plan;
- b) audit of adherence to the products verification system in the critical control points;

- c) keeping records defined by the quality control plan and the critical control points verification system throughout the term specified in laws;
- d) update of the quality control plan and the critical control points verification system plan;
- e) factual correctness of the test results from the internal laboratory and of the documents on the component and product quality control, including documents on the check of the critical control points;
- f) adherence to the legal directives in the field of quality control;
- g) unless the sampling is conducted in conformity with legal directives, the qualified person is responsible for auditing internal procedures and their adherence.

6.2 Requirements for own or third-party laboratory staff

Own or third-party laboratory staff should be qualified in the execution of the determined attributes of the quality control or the critical control points system control. Therefore, the staff must know and have managed the test methods of these attributes. The staff systematically extends its knowledge and the knowledge is tested accordingly, e.g. in the form of certification or the putting of samples in circular tests, etc.

6.3 Requirements for own or third-party laboratory equipment

The laboratory equipment should conform to the determined test methods in the quality control plan and should ensure quantitative attribute definition within the specified repeatability and reproducibility for the test method used. The equipment is maintained and regularly checked by a responsible laboratory employee. Defective equipment must not be used for testing. A record is kept on the function of the equipment and if defined, the equipment should be calibrated by an authorised person.

6.4 The quality control plan should include the following:

- a) explanation of abbreviations used and definition of terms, particularly definition of the term "part" for various components and final products;
- b) definition of the sampling method, sampling aids and sampling points within the range of the quality control plan;
- c) determination of the minimum weight of samples, method of packing, sealing, labelling and retaining of samples, including definition of places where the samples will be retained, how long and who is responsible for the samples;
- d) determination of sample disposal, including documentation and responsibility for disposal;
- e) determination of methods for sample testing;
- f) determination of attributes to be tested and frequency of testing the attributes for the samples taken;
- g) determination of attributes to be tested in contractual laboratories and the manner of checking the results from these laboratories;
- h) determination of record types in the field of quality control and retention time, including retention responsibility;
- i) determination of the check procedure for recalled products (the methods for sampling, tested attributes, how the defects will be resolved, etc.);
- j) what defects will be considered removable for the components and products and what the reason for disposal of a component or feed will be;
- k) authorisations and responsibilities of the qualified person responsible for quality.

In addition, the quality control plan may include the critical control points control plan where the critical control points will be identified, the control frequency specified, attributes to be checked in the critical control points will be indicated as well as the manner of sampling in the critical control points, methods for evaluating the results from the critical control points and who will be notified on the results and who will decide on corrective measures and who will follow them up.

7 Storage and transport of components and products in the production operation

Generally, the following requirements can be specified for storage and transport:

- The final products are separately stored in a reserved area in the production area. They are usually stored in a separate store where the components intended for production are not stored.
- The final products must not be packed in used packaging.
- The final products are stored and transported in suitable packaging or in case of loose form, in suitably designed bins (silos) that are designed, adapted and maintained to ensure good storage conditions.
- The components and the final products are transported on a clean and dry transport platform of a road vehicle to avoid cross contamination or deterioration. If packed, they should be delivered so as to be easily identifiable and to avoid any confusion.
- The packaging and devices used for transport, storage, handling and weighing are kept tidy. For these purposes, the producer will implement cleaning programmes and they will be a part of the good storage and transport practices; if they apply to the final products, they will be included in the good production practices. The cleaning methods given in the programme should minimise the presence of cleaning products.
- Adequate temperature is maintained in the stores for the components and products. The stores should be dry and allow ventilation.
- The presence of store vermin should be monitored in the storage and in case of any attack on any component or product, it will be re-separated from the other stock and treated using an approved insecticide.
- The obligations for store operators are usually defined by the good storage practice (storage rules, silo operation rules). These documents are usually created for a specific operation and their provisions are based on the store design and the design of related operation areas and other processed documentation (production procedures, quality control plans).
- The store is accessible by persons authorised by the producer only or the person of central supervision in the attendance of a delegated employee.

7.1 Receipt and storage of feed materials, protein feed, additives and premixtures in the production technology

These components should always be stored separately from the final products.

- For storage of the feed materials containing animal proteins, a separate storage area should be reserved. The feed materials containing animal proteins stored loosely should be fed to the production technology using an independent traffic route not used by other components while adhering to the requirements defined in regulation (EEC) No. 999/2001.
- To store the additives or premixtures, the stores should have a separate area ready for separate storage of the additives and premixtures by types. For the additives and premixtures it is not acceptable to use those for production which are packed in damaged packaging and then re-packed in non-genuine packaging or the full packaging is not perfectly labelled or the labelling is missing. In these cases, the defective packaging will be returned to the store.
- When storing components in the production technology, their fire-safety properties are taken into account and they should be available to the person responsible for the storage.

7.2 Storage of final products

The section of the production procedure devoted to storing includes obligations of the operators and instructions for storage according to the general principles defined under 7.

7.3 The operators should perform and adhere to the following principles when storing final products

- a) to provide storing of feed containing animal proteins in a stand-alone storage area separate from other feed;
- b) to provide separate storing in a reserved area for feed containing hazardous additives;
- c) to check cleanliness of the storage areas or bins prior to their filling and after discharging;
- d) to check the transport area of the RVs prior to loading to see whether they are empty and dry and if drawbacks are detected, the vehicles should be rejected from the loading;
- e) to check the consistency of packaging and return damaged packaging for re-packing;
- f) to check labelling of products as regards conformity of the dispatched product and certified properties;
- g) to check the number of dispatched packages and verify the weight of the whole road vehicle after deducting its weight and the weight of packaging;
- h) to issue documents required for dispatch and if products in loose form are dispatched, identification of the product should be attached to the documents, if not contained therein;
- i) to keep the feed store clean and to control the presence of vermin, residues from cleaning should be stored in a determined area in reserved packaging and disposed of;
- j) to avoid access by animals depending on the storage design;
- k) to clean the store mechanically according to the frequency stipulated and to disinfect it;

- l) to regularly renew the decoys for rodents and burn used decoys including waste from storage disinfection.

8 Keeping producers' records

All producers must register records containing relevant data on components and final products due to reasons of traceability from production to end usage. The producer will appoint persons responsible for the records and their retention and determine their obligations and authorisations. When retaining the documents, the producer adheres to the provision of laws on keeping and retaining records in the feed, additives and premixture areas. The producer determines the records keeping procedure (in written or electronic form).

8.1 Documentation related to production and control of the critical control points

The producer of the premixtures and feed has implemented the documentation system used for definition and control of the critical control points in the production process and for development and implementation of the quality control plan. He collects the results from relevant audits and evaluates them. This documentation is retained for a defined time as specified by laws to trace the production of each product part marketed retrospectively and to define responsibility in case of a complaint.

This area includes documentation containing:

- a) production order for each product, including an optimising calculation used for the order and production data (production protocol, optimisation output);
- b) produced weight of individual product types;
- c) name and address of the entity or business name and registered office of the producer, vendor or importer of the premixtures and their customers;
- d) name and address of the entity or business name and registered office of the customers of feed with the additives and premixtures;
- e) documentation specified in related instructions should be maintained (production procedure, quality control plan, good storage and transport practice and complaint rules).

8.2 Documentation kept by the producer of premixtures or feed using the additives and with premixtures for traceability purposes

In addition to the documentation under 8.10, the producer keeps the following documentation:

- a) names and addresses of producers of the additives, premixtures or their vendors;
- b) production date of the additives, part number, type and weight of the used additive substance or premixture for the part of production;
- c) type and weight of produced premixtures, complete or complementary feed according to the date of the production and parts;
- d) records on the supplies of premixtures, feed with additives and premixtures containing the name and address of the customer, production and delivery date, type of product delivered and weight.

9 Complaints and recalling of final products

For this purpose, the producer has usually prepared complaint rules defining the conditions and procedure for handling complaints, claims and recall of products. The producer informs the customer about the complaint rules upon signing the contract or submits it upon request. The complaint rules should conform to the provisions of the Commercial Code and applicable laws in the field of feed.

9.1 Complaint rules

The complaint rules usually contain:

- a) how the supplies of the premixtures or feed are carried out;
- b) under what delivery conditions the supplies are made;
- c) responsibility for quality of the products;
- d) how the product is documented upon delivery;
- e) what are the obligations of the customer upon receipt (determination of apparent defects and their assessment), including the obligation to notify producer of the defects;
- f) responsibility of the seller for defects;
- g) what the buyer may apply for during the defective goods purchase, e.g.:
 - removal of defects by delivery of a defect-free product;
 - if a lower weight was delivered, immediate supply of the agreed weight;
 - to require removal of defects;
 - to require an adequate price discount;
 - withdrawal from the purchase contract, etc.
- h) the manner of payment of costs incurred by the customer because of a defective supply;
- i) what procedures will be used for a complaint about a product for other defects and in case of product recall, e.g.:
 - whether the customer will provide technical assistance in the product recall;
 - to what extent a defective-free product for the product recalled will be delivered;
 - where the samples will be delivered from the recalled product, who will make the sampling and who will check their quality;
 - if damage occurs, what is necessary to document from the customer's side and to what extent the supplier will be responsible for the defect.

9.2 Keeping records on complaints and on recalling the marketed product

The producer keeps records:

- a) on complaints and registers the complaint lodging date and who will manage the complaint and when the complaint was settled;
- b) on recall of the product and registers what product was recalled, production and delivery dates, delivered and recalled weight, what attributes of the recalled product will be verified, quality check results for the recalled product, conclusion of the recalled product, if it is going to be reworked and how or whether the product will be disposed of.

SECTION – E

GOOD PRACTICE PRINCIPLES

for transport of feed, additives and premixtures

1 General provisions

The good practice for transport of feed, additives and premixtures is intended for all feed business operators conducting transport of their products to customers or for contractually arranged transport operators who, based on a contract, provide transport services for producers and customers of feed, additives and premixtures. The good practice for transport is based on Regulation of the EP and the Council No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. At the same time, the Regulation defines references to the feed, additives and premixtures. The Regulation is then related to the Regulation of EP and the Council No. 183/2005, laying down requirements for feed hygiene. In this good practice part, the transport operator specifies to what transport the good practice applies to, what requirements and conditions will be respected for the transport of feed, additives and premixtures and what will be the liability of the carrier and driver. It also references related laws. It is based on the provisions mentioned in the principles below.

1.1 Good practice for transport of feed, additives and premixtures

Good transport practice for feed, additives and premixtures applies to:

- a) contractual and own transport of feed, additives and premixtures within one feed business or its operation. This applies to primary producers except for transport of own bulky feed;
- b) contractual and own transport of feed, additives and premixtures between feed businesses or a feed business and primary producer.

For contracted transport of feed, additives and premixtures by their producer or supplier or customer, the contractual carrier should have clear instructions and focused conditions in addition to generally applicable requirements, on:

- a) cleaning of the transport platform and accessories (loading screws, air closure, pipeline and hoses) of the road vehicle using a dry method (or wet method when using liquid forms) so that the platform is free of any residues prior to loading feed or additives or premixtures.
- b) checking of the transport platform and accessories of the road vehicle prior to loading by the producer or supplier. For this purpose, the road vehicle driver should allow safe access to the transport platform and the accessories. Should the producer or vendor find out the transport platform or the accessories is soiled, the producer or vendor has the right to either stop or cancel the loading and apply for compensation of expenses associated with the loading delay or arranging a different carrier;
- c) the necessity, if RVs are used for transport of different materials prior to loading feed or additives or premixtures, of cleaning the transport platform and accessories using the wet method with the use of detergents and dried;
- d) the fact that the producer or vendor or customer is not obliged to provide free technical assistance to the carrier for cleaning the transport platform including removal of residues from the cleaning;
- e) the necessity to respect specified quarantine measures for producers, vendors and customers notified by the producer, vendor or customer;
- f) the necessity that RVs have to be covered, lockable, dry and if equipped with accessories for discharging in the transport area, the input and output holes should be closed during the transport. This similarly applies to the connection hoses, unless stored in closed sleeves;

- g) the fact that the quality of transported feed, additives or premixtures must not change during the transport or unloading;
- h) information on the properties of the feed, additives and premixtures transported, in which the producer or vendor or customer has specified the safety conditions, i.e. whether the materials are flammable, reactive, corrosive, etc.;
- i) potential requirements of the customer, such as if the customer requests re-weighing of loosely delivered products on certified balances outside the unloading site should be met and the costs incurred are covered by the producer-vendor.

1.2 Responsibility and rights of the carrier and driver

The responsibilities and rights of the carrier in transportation of the feed, additives and premixtures

The carrier decides on the:

- type and suitability of the road vehicle to be used for the transport;
- equipment of the road vehicle used for the transport;
- driver who will carry out the transport;
- traffic route for the cargo transport from the producer - vendor to the customer.

The carrier will be responsible for:

- technical driveability of the road vehicle used for the transport;
- adherence to specified transport conditions;
- adherence to the arranged time for loading and unloading in case of a contractual transport;
- delivery of transported feed, additives and premixtures in weight and quality and if transported in packaging, consistency of the packaging and pallets;
- informing the driver on the conditions of the producer, vendor or customer;
- creating the procedure and the manner of cleaning the road vehicle and accessories.

Rights and liabilities of the driver

The driver decides on:

- rejecting transport by a road vehicle of which condition does not allow safe operation on the road;
- the method of loading and placing of the load on the road vehicle;
- rejecting a part or full cargo in the case of breached packaging or pallets in the cargo;
- rejecting transport of cargo not conforming to the type or suitability or driveability of the road vehicle, e.g. transport of cargo weight higher than permitted by technical conditions or transport of loose feed without the possibility of covering the transport platform;
- rejecting of loading or unloading of the road vehicle in cases in which the location does not conform to conditions suitable for loading or unloading, or which does not allow safe loading or unloading of the cargo.

The driver will be responsible for:

- the technical condition of the vehicle;
- making the vehicle available for loading and cargo transport on time;
- fixing of the cargo on the transport platform;
- closing of the transport space or covering thereof with a tarpaulin;

- cleanliness of the transport area including accessories before loading where the cleaning is carried out according to the carrier's instructions;
- consistency of the transported cargo as far as quality and stock during the transport is concerned;
- adherence to agreed conditions between the carrier and producer - vendor or the customer
- adherence to quarantine measures noted by the producer - vendor or customer.

2 Definitions and terms for the good practice

Carrier – means a natural or legal entity operating transport of feed, additives and premixtures.

Contractual carrier – means a carrier who provides transport of feed, additives and premixtures to other producers or vendors based on a contract.

Primary producer – means a legal or natural entity producing farm plants, including harvesting, drawing milk, breeding animals, and fishing, and the products of the producer's are no longer treated except for simple physical treatment.

Road vehicle – a truck or semi trailer or trailer with a transport platform or closed box superstructure or a tank of suitable structure with accessories for charging/loading and discharging/unloading.

Transport platform – means the area of the platform or volume of a box or tank of a road vehicle into which the transported cargo is placed.

Box superstructure – means suitably designed cladding of the transport area of an road vehicle, fitted with closable holes for charging and discharging and usually equipped with accessories.

Tank – means a container, usually pressure-tested, fitted with airtight closable input and output holes and equipped with accessories.

Accessories – means loading screws, air closures and hoses of the box superstructure or the tank used for charging or discharging of loosely transported feed.

Loose form of transport – means transport of feed loaded without packaging on the transport platform.

Contractual transport – means agreed transport of feed, additives and premixtures by their producer or vendor with a contractual carrier within its operations or to customers.

Dry cleaning – means cleaning of the transport platform or the box superstructure or the tank by brush or vacuum cleaner without the use of liquids.

Wet cleaning – means cleaning of the transport platform or the box superstructure or the tank with a cold or hot water jet with/without detergents or disinfectants.

Quarantine measure – means a measure adopted by the State Veterinary Administration in order to avoid spread of infectious animal diseases. They usually define requirements for hygienic cleaning of RVs prior to arrival at the producer or vendor or the primary producer, or they totally ban the entrance of vehicles and determine the manner and place of transshipment.

Extraordinary event – means non-negotiability of roads, road vehicle accident, incapacity of a driver to drive a road vehicle, damage to the transported cargo.

3 Requirements for RVs for transport of feed, additives and premixtures

3.1 Requirements for cleanliness, tightness and ability to disinfect

The transport platform including the inner part of the tarpaulin should be dry and clean, covered with a consistent tarpaulin, should permit safe loading, transport and unloading of packaging and pallets without breaching their consistency. Box superstructures or tanks including their accessories should allow closing, must not leak the cargo transported and their design must not deteriorate the quality or contaminate the cargo transported. The transport platform should be safely accessible and designed to allow both dry and wet cleaning and disinfecting.

3.2 Effects causing change to quality and transport safety

During transport, the quality may be most influenced by:

- a) moisture in the form of rainwater, penetrating the transport platform due to poor tightness or due to water residues from the platform cleaning;
- b) contamination of transported products by foreign particles following imperfect cleaning or contamination due to mixing of transported products due to breach of the packaging during the transport or due to poor tightness of separated areas for transport boxes or tanks or due to improper cleaning of the transport platform and accessories of previously transported products;
- c) improper design of accessories for box superstructures or tanks causing e.g. higher proportion of crushed material or segregation of particles in the transported product.

3.3 Methods of loading and unloading

The loading or unloading of the packed products stored on pallets or in containers is usually made using pallet carriages so that the pallets or containers are evenly deployed on the width or length of the transport platform. The packaging on the pallets should be consistent and the layers reinforced by shrink-wrap foil or glue. Individual pallet lines should be secured against movement using removable barriers or fixing strips on the TPs. The pallets must not be damaged. The carriage operators must be qualified and skilled with the use of the carriages and pallets during loading or unloading.

The loading of the loosely transported products is exclusively used for feed and it is usually done using a device in the storage limiting dust or other contamination of the area when filling the transport platform and allowing even distribution. The loading place should have a suitable pit scale allowing the weight to be checked and assuring that it does not exceed the maximum permitted load of the road vehicle. The unloading is done upon approval of the customer on a site clearly specified in the delivery note or noted to the driver by the customer and confirmed on the transport sheet that remains with the carrier. If the customer is not available for the unloading, the driver will sign the delivery note and put date and time of the unloading including a note the customer was not available. The unloading is done either by direct discharging after opening of the box superstructure or tank to the receipt container of the customer or relocating the cargo from the box superstructure or the tank to the silo bins using the accessories or in case of liquids, to the customer's storage tanks. The driver may refuse the unloading in case e.g. the receipt container is not emptied or is contaminated or the volume of the silo bin does not conform to the volume of the tank in which the feed are transported.

4 Methods and conditions for the transport of feed, additives and premixtures

The feed is usually transported in loose form, less frequently packed in packaging (bags or sacks) on the pallets or in containers. The additives or premixtures should always be transported in originally sealed packaging stored on the pallets.

4.1 Transport of feed in loose form

To transport the feed in loose form in solid or pasta-like condition, the RVs with tilting transport platform are usually used; the platform is covered by a consistent tarpaulin both during the ride with/without the cargo or with tilting lockable box superstructure or tilting lockable tank. The transport platform as well as the inner part of the tarpaulin or the box superstructure or tank should be clean and free of residues. If identical feed type from the same producer or vendor is transported repeatedly on the same day, no cleaning of the platform and tarpaulin is required between the transports. Similar conditions apply to transport of liquid feed for which the tanks are used.

4.2 Transport of packed feed

The transport of packed feed, additives and premixtures (bags, sacks, containers), the RVs of which transport platform is covered by a consistent tarpaulin when riding with/without the cargo is always used. The road vehicle should be equipped with removable barriers or strips (belts) for fixing the cargo (the pallets with packaging or containers) to avoid movement on the platform. The transport platform as well as the inner part of the tarpaulin should be clean and dry. On the transport platform with the feed, there must not be additives or premixtures or other materials transported at the same time and identical requirement apply to the transport of additives or premixtures.

5 Transport of feed, additives and premixtures

The transport can be divided into four phases:

- preparation of the road vehicle for transport and receiving the transport documents;
- loading and taking over of the cargo;
- transport from the producer or vendor to the customer;
- unloading of the supply and delivery to the customer.

5.1 Preparation of the road vehicle for transport

Prior to making the road vehicle available for the loading, the driver performs the following:

- a) check of the consistency of the transport platform, its tightness and consistency of the tarpaulin;
- b) operation check of the accessories;
- c) availability of the barriers or strips (belts) on the road vehicle in case of transport of packed products on the pallets;
- d) check of the cleanliness of the transport platform, inner part of the tarpaulin and accessories and should impurities be detected (also presence of water, snow or ice),

the cleaning with adherence to defined procedures and methods of the operator will be made;

- e) check that the output holes of the accessories are closed;
- f) verification of the transport documents containing clear indication of the loading and unloading site. What product type (products) and what form (loose, packed) will be transported including their fire-safety properties in case the driver is inexperienced with their transport. The above-mentioned usually applies to contractual transport.

5.2 Contractual transport

With contractual transport, the driver makes available the road vehicle for loading on time and place specified. Generally, following making the road vehicle available for transport, the driver prepares the transport platform for loading (removal of the side parts of the tarpaulin, opening of input holes for the box superstructures and tanks, removal of obstructions from the transport platform). The loading occurs following the check of the transport platform by a responsible person of the producer or vendor. If, pursuant to the contractual provisions, the producer or vendor requires provision of a certificate on the transport platform cleaning, the driver will issue the certificate to the responsible person of the producer or vendor. The certificate should show the method of cleaning and if disinfection is performed, the product used for disinfecting, cleaning date and whom the cleaning was performed by. The loading occurs only at the attendance of the driver of the road vehicle used for transport and the driver may refuse loading of the loosely transported product in cases in which the loading occurs on a site not providing protection against rainwater. Prior to loading, the driver will take over the documents for the products transported (e.g. delivery note; in three copies for the contractual transport, one of them for the carrier) and the following is checked according to the documents provided:

- a) number of transported pallets or packaging;
- b) consistency of packaging and pallets;
- c) weight of the products for those delivered in loose form.

When loading the packed products, the pallets are secured against movement by the barriers or strips. If the packed products loaded on the platform are intended for more customers, they should be stored in sequential order to avoid any further handling on the transport platform and to arrange easy unloading.

5.3 Transport

It is carried out at the time agreed between the producer - supplier and the customer. In cases in which the driver cannot deliver on time, it is his/her responsibility to inform both the parties and give the reason for being late. This reason is then given to all copies of the product transport documents (delivery note) intended for the customer, producer-vendor and, in cases of contractual transport - to the carrier. In case of an extraordinary event during the transport (breakdown or accident or the roads not being in condition for safe operation at the customer or incapacity of the driver to drive or damage to the cargo during the transport), the carrier should be notified accordingly. The transport respects the quarantine measures the driver noted prior to the transport or if discovered during the transport (e.g. a closure of a municipality, unloading site, disinfection).

5.4 Unloading of products

It should usually be conducted under the presence of the customer's responsible person only. Therefore, the driver must:

- Announce its arrival upon entering the unloading site, note what product is intended for unloading and ask for the presence of the customer's responsible person. If, for feed transported in loose form, the customer requires certification of weight, the driver should respect the request and if authorised by the producer or vendor, the driver will confirm a weight certificate. According to instruction from the customer or if not present according to the unloading site as indicated in the delivery note, the driver makes the road vehicle available on the unloading site.
- Following making the road vehicle available with the feed in loose form to the unloading site, which is equipped with a receipt container, the driver will make a check of the container and if pollution is detected (including water or snow), the customer will be notified and the driver may reject the unloading. If the customer insists upon unloading, the findings are written on all copies of the delivery note. Following the customer's instruction for unloading, usually after starting the traffic paths, the driver will, prior to tilting the transport platform, open the discharge hole of the box superstructure or the tank to start discharging the contents to the receipt container. The tilting speed is adjusted to the discharging of the receipt container. At the end of the unloading, the product residues are swept to the receipt container.
- When unloading feed transported in loose form into the receipt silo bins, the driver will check whether the bin corresponds to his documentation and in case of discrepancy, the customer is notified. Should the customer not be present, the driver will unload to the silo bin identified in the delivery note. Prior to unloading, the driver will establish tight connection of the accessory of the box superstructure or tank using the hoses with the air pipeline of the silo bin and start discharging. At the same time, the driver tilts the box superstructure or tank (for granulated feed, tilting should be slow to avoid crushing). When discharging, the driver checks the overflow pipeline of the silo bin to make sure no overfilling is taking place.
- Should the silo bin be fully loaded, a responsible person will be notified by the driver and the driver will ask for allocation of a new silo bin to unload and the procedures will be identical to the first bin. If no responsible person of the customer is present, the driver will take back the unloaded part of the feed cargo to the producer or vendor; the driver must determine weight and deliver the cargo to the producer - vendor according to applicable instructions.
- When unloading the packed products, the transport platform must be accessible (the side sections of the tarpaulin are removed and the side walls are opened, the barriers or strips are removed) and controls the unloading to avoid damage of the transport platform or walls of the road vehicle. At the same time, the driver will check consistency of the packaging or pallets following the transport. Following the unloading, the driver will dry clean the transport platform and remove dust from the inner side of the tarpaulin. The sweepings are stored as waste in the customer's container. Following completion of the loading, the delivery note will be handed over to the customer and receipt will be confirmed on all copies with description of potential reservations of the carrier or the customer.

5.5 Defects found during unloading

If, during the unloading, the driver finds out:

- a) absence of the customer's responsible person; or
- b) discrepancy with the unloading site mentioned in the delivery note, e.g. a different storage or silo bin; or
- c) the receipt container is polluted; or
- d) the full delivered weight cannot be put to the determined silo bin and the unloading should be completed to a different silo bin; or
- e) no alternate silo bin is determined because of absence of the customer's responsible person,

the driver will note these facts to the copies of the delivery note. The notes are confirmed by his/her signature and the driver lets the customer confirm it, if present.

6 Complaints

This applies to a contractual carrier and is specified in the good practice provided that this is not contained in the complaint rules of the carrier or in the contract. This section should, in addition to general legal provisions, contain the following provisions related to the procedure in the following cases:

- a) there is a difference between the cargo weight in the delivery notes and the reality found at the customer after the transport;
- b) the packaging or pallets have been damaged during the transport as discovered during the unloading;
- c) the customer detects apparent defects of the products in loose form, e.g. presence of foreign particles, obviously moist feed due to poor tarpaulin, box superstructure or tank tightness;
- d) moist packaging on the pallets detected by the customer;
- e) unloading was conducted on an incorrect site (storage, silo bin) than specified in the transport document without informing the customer.

7 Related directives

If the good practices are prepared by the contractual carrier, which is neither a producer nor vendor nor customer, the carrier defines its own directives, e.g. the ones on cleaning of the transport platform and accessories, legal directives for road transport etc. If the good practices are created by a carrier, which is either producer or vendor or customer, the carrier defines the reference directives, e.g. good storage practice (the storage rules), procedure for cleaning of the transport platform of the road vehicle used for the transport of feed, additives and premixtures, the waste management plan indicating the points for collecting waste generated following the cleaning of the transport platform, the act, shredding and retaining rules, etc.

SECTION - F

PRINCIPLES

for the analysis of potential risks and hazards in compound feed and premixture production, for implementation of the critical control points (HACCP) system and its verification

1 General

The Regulation of the EP and the Council (EEC) No. 183/2005 stipulates in Chapter 6 that feed business operators should implement, perform and retain a written procedure or procedures based on the hazard analysis and critical control points (hereinafter HACCP) system. The provision does not apply to those feed business operators who:

- a) perform activities at the primary production level as well as the following associated activities:
 - transport, storage and handling of primary products on the production site;
 - transport activities for delivery of primary products from the production site to the processing site;
 - mixing of feed for exclusive requirements of their own holdings without the use of additives or premixtures of the additives except for additives for ensilaging.
- b) For activities other than those under a), including mixing of feed for the exclusive requirements of their own holdings while using additives or premixtures of additives except for additives used in ensilaging, feed business operators should adhere to the provisions of Appendix II. Of the Regulation, if applicable to the activities conducted.

1.1 Goal of determining the critical control points

The goal of determining the critical control points is to ensure the monitoring of feed safety at each stage that may negatively influence the safety of feed and food or that may have a negative impact on the environment.

The base for processing of the HACCP system in the production of premixtures or compound feed is the verification of the production technology and of the production procedures, usually performed by the producer prior to launching the production of products using identical production procedures, and furthermore in cases of preparing a new product launch requiring change to the production procedures or always in cases in which there are changes to the technological equipment with a potentially high effect on the quality and safety of the products by the producer (e.g. change to the balances system, change to the mixing device, etc.).

2 Definitions and terms

For these purposes of this part:

Risk –likelihood of an adverse effect on health, and the seriousness of this effect as a consequence of the real existence of danger.

Hazard – biological, chemical or physical factors in feed products or the condition of feed products with the potential to influence health negatively.

Hazard analysis – the process of collecting and assessing information on various hazard types for feed, premixtures or food safety and on conditions permitting their presence in feed necessary for a decision on their importance for the feed, premixtures safety and on their classification in the critical control points system.

HACCP (Hazard Analysis Critical Control Point) – a systematic approach to the identification and assessment of risks at all levels of the production of feed, additives and premixtures, including definition of means for their control and definition of the critical control points.

Control point (CP) – a place defined in the production procedure where employees of the production business should perform defined control tasks with preventive effects on failures during the production.

Critical control point (CCP) – a procedure or operation of the highest feed or premixtures safety danger risk, breach of feed safety and quality and where these risks can be avoided or excluded or mitigated to an acceptable level.

Critical limit – an attribute and its content which is limited and if exceeded, the feed or premixture are considered cross contaminated, non-homogeneous, not corresponding to the declaration in attributes influencing its use and therefore, it can be indicated as a feed or premixture conditionally usable or corrupted.

3 Critical control points in production

The goal of critical control points system is preventing, identifying and evaluating the risks of animal health safety with the potential of threatening the human food chain before the hazard can occur. The goal of the system is not substituting activities included in the continuous meeting of requirements defined for producers.

The nature of the critical control points system is a control system of feed, additives and premixtures, a system of the control on production process, product handling, the environment and employees, which can enable avoidance of the potential of creating a hazard that might threaten animal health or quality of food or the environment. At each production activity stage, this system implements such methods of monitoring and control that guarantee the effectiveness of the preventive system.

3.1 Principles of the critical control points system control

- a) to make the hazard analysis based on the description of the properties of the feed, additives and premixtures processed, on the procedure for preparation, individual stages of the production operations and of the final product that the hazards of the animal health or the food quality or environment will apply to;
- b) to avoid occurrence of these hazards through continuous assessment of the management procedures and the production section controls from the receipt of feed, additives and premixtures up to the dispatch of the final products as far as their reliability is concerned;
- c) to determine the critical control points for procedures and operations based on the analysis of the sites where the risk occurrence can be forecasted and where the risks can be partially or fully removed;
- d) to determine attributes and their critical limits which will be the subject of the critical control points control and which assumes selection of such attributes that are directly related to the detection of risks associated with threat to animal health or the environment;
- e) to determine the method and frequency in the critical control points system with respect to such situations in production and in production procedures where it is possible to clearly distinguish whether the production follows the production procedure defined;
- f) to implement documentation - records on the critical control points control, including the values of the monitored attributes and remedial measures;

- g) if the determined critical limits are exceeded, to determine the procedures for removal of the reasons causing the exceeding of the critical limits and to document these procedures as a part of the remedial measures;
- h) at least annually, to fully check the technology and production procedures in order to ascertain their reliability;
- i) the producer must appoint a suitably qualified person to manage the critical control points system control and to lead a team of employees with particular knowledge and skills for assessment of various risks at all areas of the production process. For example, knowledge of the production facilities, procedures, components used in production, the effect of components on animal feed and adherence to the quality of the final products.

3.2 Identification of risks to be avoided

The risks in the production of premixtures with the use of additives, premixtures or complementary feed are:

- a) the use of feed and additives not approved for feeding of animals, i.e.
 - feed materials or certain protein feed where suitability for animal feeding was not verified or the additives not listed in the list of the regulation;
 - feed materials or certain protein feed or additives showing over-limit content of undesirable substances.
- b) non-adherence to the determined limit content of the additives in feed or non-adherence to the declared content of additives in the premixtures due to:
 - improper function of the balances used in automatic mode, including permitting unacceptable variation in the dosage of components in general or in specific cases (some balances only), particularly when weighing additives or premixtures;
 - the use of balances for manual weighing of components, of which working accuracy does not conform to the weighing of components and their error exceeds the permitted variation, particularly when weighing additives and premixtures;
 - the use of balances in contradiction with applicable metrological directives, i.e. the balances are not regularly calibrated, their working accuracy has changed and despite this, they are still used for dosing;
 - losses (particularly of additives) during the production due to improper exhaust of the production technology or non-adherence to instructions for their processing in feed or premixtures.
- c) non-homogeneity of additives in premixtures or feed is influenced particularly by:
 - improper function of the mixing device (mixing device with damaged mixing element or leaks) or the mixing time does not conform to the relevant product (the effect of the structure of components, application of liquids during the mixing time);
 - inaccurate dosing of additives or premixtures to batches where the dosing error for individual batches exceeds the permitted variation of values of the content detected in partial samples;
 - unsuitable design of traffic routes or bins for transport and storage of final products (routes or bins cause segregation of premixtures or feed particles).
- d) cross contamination of final products caused particularly by:
 - non-adherence of production procedures, i.e. no control or cleaning of the technology is performed after completed production of premixtures or feed containing risky additives, or the additives or components are used for production for which the operation was not verified or approved;

- the order of production of individual products is not specified properly to prevent the occurrence of cross contamination (a decontamination programme) or the procedure is not adhered to (e.g. by inserting contingent productions);
- the use of unsuitable or unverified technology of which design or structure causes cross contamination;
- no thorough input check of the components used in feed production is made, e.g. of premixtures whether they contain polluting additives or other components, e.g. unwanted or prohibited substances.

3.3 Procedure for development and implementation of the critical control points system

The development and subsequent implementation of the critical control points system for production is based on the assumption that the good production practice of the producer meets general requirements resulting from legal directives in the field of feed and the producer has material and organisational premises for the production of quality and safe premixtures and feed. If these conditions are not met, the development and implementation of the critical control points system is impossible.

The assumption applies particularly to the fact whether the producer has:

- suitable production facilities and areas for storing and production, including developed technology and production area maintenance schedules;
- processed and implemented production procedure (production procedures) and storage rules;
- a processed and implemented quality control system;
- a plan of training and lifelong education of employees covering particularly the description of the tasks of the employees in production and the system, the production management, hygiene principles of good production practices, etc.;
- determined hygienic conditions for production containing the methods and frequency of cleaning of production technology and areas, disinfecting, rat extermination and the manner of collecting and disposing of the waste generated during storage and production;
- determined the manner of handling complaints (the complaint rules) and the procedure for product recall determined, including resolution of their potential treatment or disposal;
- an implemented system for storage, production and complaint records including retention for the term required.

3.4 Developing of the critical control points system

The critical control points system should be developed by a team of skilled employees or external experts who are familiar in:

- production technology for premixtures or feed, including knowledge of the technology used;
- quality of feed materials, specified protein feed, additives and premixtures;
- animal feed and their reaction to additives used or undesirable substances, if used;
- the effect of feed and additives on the quality or health safety of the animal products used for food production;
- verification of the feed, additives and premixtures quality;
- the team should be led by an employee responsible for control and maintenance of the critical control points system at the producer.

When developing the system, the team should focus on obtaining the following documents:

- 1) definition of the production activity, which will be focused on:
 - types of technology and its suitability for production of premixtures or feed;
 - capacity of the technology;
 - group description of final products;
 - groups of processed feed materials, specific protein feed, additives and premixtures including their properties;
 - assumed classification of the critical control points in the production process and justification of the classification.
- 2) description of the products or their groups of similar risks (they contain the same groups of hazardous additives or, due to the effect of the feed materials or specific protein feed used, it can be predicted that they may report the presence of undesirable substances of over limit content) the product will contain;
 - name of the product or the product group of approximately identical properties, e.g. products containing coccidiostatics or products containing hazardous additives but which may contain over limit content of undesirable substances or products where no hazard is forecasted;
 - the use of products (group of products) containing a description of correct and safe use;
 - basic physical and chemical properties of the product or group of products (requirements for their processing, further technological processing e.g. by granulating or expanding, including the limit temperatures during and after these processes prior to dispatch, structure of the final product, dry matter content, the use of preservatives, etc.);
 - method of packing and dispatching the products (group of products);
 - method of labelling the products (based on laws);
 - further information the producer will provide on the products to its customers;
 - feed materials, specific protein feed, additives and premixtures used for production, their chemical, physical or microbiological properties, methods of transport, packing, storing and labelling.
- 3) Determination of the product use usually relates to the method of labelling the products where the method of safe use should be specified. For products with potential hazard due to the customer's failure, to consider methods how to avoid this failure, e.g. by highlighted marking of the risks or by the manner of delivering the product to the customer etc.
- 4) Compilation of the production process scheme or text-based production scheme highlighting individual process steps from the receipt of components up to the dispatch of the final product. The scheme or the production procedure should clearly show what the operators have to do in individual production process steps. The scheme or the production procedure should be related by a schematic depiction of individual positions of the technology, including their description and indication of assumed critical control points.
- 5) Verification of the scheme or of the production procedure during operation under usual production conditions, i.e. without creating e.g. time delays in production or in the selection of such products for verification not containing any risks, etc.
- 6) Conducting hazards analysis, which is usually based on the following options at the premixtures and feed producers:
 - the use of prohibited feed materials, specific protein feed or additives or premixtures containing prohibited additives;
 - the use of feed materials, specific protein feed, additives or premixtures with over limit content of undesirable substances or those contaminated with prohibited substances;

- non-adherence to the limit content of the additives in the premixtures or feed;
- formation of a non-homogeneous product in the additives content;
- occurrence of a cross-contaminated product.

3.5 The hazards analysis particularly assesses:

- 1) the effect of feed materials, specific protein feed, additives and premixtures on feed or premixtures and here, the following should be particularly focused on:
 - a) what feed materials, specified protein feed, additives or premixtures are used for the production and in what volume;
 - b) whether some feed materials, specified protein feed, additives or premixtures may have toxic properties;
 - c) whether some feed materials, specified protein feed, additives or premixtures may have negative impact on the animal products intended for food production;
 - d) whether some feed materials, specified protein feed, additives or premixtures may contain pathogenic or conditionally pathogenic micro organisms, e.g. salmonella;
 - e) whether some feed materials, specified protein feed, additives or premixtures may contain undesirable or prohibited substances of which volume exceeds the limits, e.g. mycotoxins;
 - f) whether the feed materials may contain unsafe impurities of which volume exceeds the limits;
 - g) whether auxiliary technical substances with potentially hazardous effect on animal health or negative effect on the quality of animal products or negative effect on the use of the additives or nutrients from the feed materials and specified protein feed are used for the feed materials, specified protein feed and additives;
 - h) whether additives such as preservatives in higher volumes are used when producing or storing feed materials or specified protein feed and how the concentration reflects in the final products;
 - i) what technological procedure was used to obtain feed materials or specified protein feed and whether this procedure might have a negative effect on their use for animal feed;

- 2) the effect of production technology on feed or premixture and subsequent concerns should be focused on here:
 - a) may, in the course of the production, there be an uncontrolled mixing of the feed materials, specific protein feed, additives or premixtures due to imperfection of the traffic routes, unsuitable exhaust, non-adherence to production discipline upon receipt, selection of bins depending on their design for a certain type of feed materials or the specific protein feed;
 - b) may there be uncontrolled adherence to the production order in dosing of individual components and if so, in which one;
 - c) may there be an uncontrolled breach of the production cycle duration (production cycle of one batch being shortened, particularly during the mixing of components);
 - d) may there be contamination of a product by prohibited feed materials or additives and if so, in what parts of the production cycle;
 - e) may there be loss of additives, particularly of hazardous ones, during the production and if so, in what production sections, and may these losses be the cause of consequent cross contamination of the products;

- f) the effect of temperatures used for feed treatment using granulation or extrusion on some additives and what their maximum permitted temperatures are, e.g. for vitamins, micro organisms, enzymes);
 - g) the effects of preservatives used for the stability of additives in the feed;
- 3) the effects caused by marketing the premixtures and feed and here, the following concerns should be focused on:
- a) method of packing and labelling of the product, may there be mixing with other products during the packing, cross contamination, incorrect labelling of the product;
 - b) method of transporting the product, whether the traffic means used particularly for transport in loose form are clean and fully emptied;
 - c) whether there may be confusion during the product transport in loose form at the customer (potential mixing of feed delivered with other feed);
 - d) whether it is necessary to improve the knowledge level of customers (above the extent of the labelling) about some premixtures or feed (especially premixtures and feed containing hazardous additives);
 - e) what other defects can be predicted at the premixtures or feed customers.

3.6 Risk analysis

The risk is the level of likelihood of a hazard and the severity of the consequences resulting from the presence of hazards in the premixture or feed. The risk analysis is important when preparing the critical control points system and implementing it particularly for the preparation of the documents for definition of the critical control points. When operating the system, it is used as a part of the verification procedure for the critical control points system.

The risk analysis follows the hazards analysis in which all hazards to the health of animals, quality of animal products and the environment in relation to the final products, components used and the production procedure were summarised. The risk analysis considers the likelihood level at which the identified hazard can be applied (frequency of application of hazards is analysed) and at the same time, the consequences of application of said hazard are assessed.

The goal of the risk analysis is to prepare the documents for decision making - determination of the critical control points. The risk analysis allows the producer to:

- compile the order of products, used feed materials, specified protein feed, additives and premixtures from the risk occurrence point of view;
- compile the order of production phases with respect to the risk occurrence and based on the risk importance, to decide whether there will be only a critical point or a control point of an operator;
- determine the urgency in preparing the reconstruction of the technology.

3.7 Quality risk analysis

To determine the likelihood level of the risk occurrence, a quality risk analysis is conducted, which is based on biological, physical and chemical danger of feed materials, protein feed, additives and final products at producers of premixtures and feed. The risk level is usually expressed by letters where the highest risk level is indicated as A and the other letters indicate lower risk levels.

3.71 Quality risk analysis for producers of premixtures

Properties of the products from the biological hazard point of view

- A) Special group of products intended for consumption by the risk group of animals. Usually, these are products containing risk or limit additives intended for a certain category of animals.
- B) Products with potential cross contamination during production or packing and which may influence applicability of the premixture or feed.
- C) Products containing unstable additives, substances of limited stability, which may influence the quality of final products during production or marketing.
- D) Products with potential possibility of unskilled handling during marketing or use, which could threaten the health safety of the feed.

Properties of the products as far as the chemical or physical hazard is concerned

- A) Special group of products containing risky or limit additives that may threaten the health of animals in case of their presence or under or over limit content or that may threaten the health of humans in case of their presence in a product intended for a different category of animals.
- B) The premixture contains unstable additives of limited stability, which may influence its quality and application in the production of feed or their structure.
- C) The production procedure does not include such operations which would exclude the possibility of inaccurate dosing of components, particularly of the additives, to a production batch or cross contamination or the production procedure provides a chance not to adhere to some of the determined operations or shortening the length of one production cycle e.g. at the expense of mixing.
- D) The premixture may contain unwanted substances in an over limit volume, which may influence its best before date.
- E) For the premixture, there is a real possibility of unskilled handling during the storage at the producer, e.g. incorrect or incomplete labelling, change to quality due to unsuitable storage, breach of packaging during the storing, etc.
- F) There is no possibility for the customer (the feed producer) to find out and eliminate the presence of some unwanted substances of over limit volume or of prohibited substances of additives in the premixture.

3.8 Quality risk analysis for producers of feed

Properties of the products from the biological hazard point of view

- A) Special group of products intended for feeding risk groups of animals. This is usually a group of products containing risk additives or animals for which the risk additives are unsafe and must not be present in feed for animals, or feed materials which must not be fed to these animals, e.g. all feed for young animals containing risky substances or feed materials and certain salmonella-containing specific protein feed.
- B) Products with possible cross contamination during the production or dispatch (the products produced after those containing the risky additives).
- C) Products of which composition is unstable and may result in change to quality during production or dispatch, e.g. products with highly variable graininess of components without protecting their stability using a physical treatment or adding of feed materials of agglomeration effects, products containing temperature-

unstable or chemically-unstable additives, e.g. some vitamins, micro organisms or enzymes.

- D) Products with the potential of interfering with their health safety during unskilled handling, transport or marketing.

Properties of the products as far as a chemical or physical hazard is concerned

- A) Special group of products intended for feeding a risky groups of animals and containing risky additives or additives for which minimum and maximum permitted content in the feed is determined. These particularly are feed used for feeding young animals.
- B) Products of which physical properties result in limited stability and may cause segregation of particles during the production and storage resulting in non-homogeneity of the additives. For example, mixtures of components treated by crushing with other non-treated components and premixtures or increased proportion of crushed material in granulate or extruded products causing its segregation during storage, dispatch and transport.
- C) The production procedure does not include such operations which would exclude the possibility of inaccurate dosing of components, particularly of additives or premixtures, formation of cross contamination or non-adherence to some of the determined production procedure operations or uncontrolled shortening of the length of one production cycle e.g. at the expense of mixing, etc.
- D) Due to the use of feed materials, specific protein feed or premixtures, some selected groups of products may cause exceeding of the limit content of undesirable substances, e.g. increased content of arsenic in calcium carbonate in the feed for layers causes exceeded maximum permissible arsenic content in the final products.
- E) For a product or group of products there is a real chance that quality will change due to the storage conditions. For example, storing of non-cooled granulate - extruded product or products with higher moisture level, etc.
- F) There is no way how the supplier can ascertain the presence of a prohibited substance or over-limit content of unwanted substances or non-adherence to the content of risk substances or the presence of cross contamination, and how to eliminate these defects.

3.81 Classification of the risk of products analysed according to the points 3.71 and 3.8.

Based on marking of the products by potential risks specified under A to F above, the products or the components will be classified and the classification usually divides the products into 6 categories, whereas the category with the highest number (VI) is the highest-risk category.

The individual categories include products classified under letters:

Analysed product	Category	Hazard characteristics according to letters A to F
premixtures and feed used for young animals and containing risk DL and then (x)	VI	premixtures or feed are characterised by ad A and all those specified under letters B to F
premixtures and feed (x)	V	premixtures or feed are characterised by all characteristics specified under B to F
premixtures and feed (x)	IV	premixtures or feed are characterised by 4 of 6 characteristics specified under B to F
premixtures and feed (x)	III	premixtures or feed are characterised by 3 of 6 characteristics specified under B to F
premixtures and feed (x)	II	premixtures or feed are characterised by 2 of 6 characteristics specified under B to F
premixtures and feed (x)	I	premixtures or feed are characterised by 1 of 6 characteristics specified under B to F
premixtures and feed (x)	0	premixtures or feed are characterised by none of the characteristics specified under A to F

Note: (x) to be filled in by the feed business operator according to his analysis

3.82 The classification of products or product groups of characteristics ad A to F

The classification of products or product groups of characteristics ad A to F is usually processed in the form of a table and the product or product group is in addition assigned either a plus (+) if classification according to the category can be made or (-) if it is not the case. The risk analysis follows the hazards analysis and precedes determination of the critical control points.

4 Quantity risk analysis

It particularly applies to individual phases of the production procedure but it may also be used for products or components used. The result is a numerical expression of the significance of the hazard. The significance of the hazard is the likelihood that the hazard will occur, including the severity of the hazard.

Of the general quantitative methods of risk analysis, the procedure according to Failure Modes and Effects Analysis (FMEA) may be used as a tool for the implementation and operation of the critical control points system, which is the analysis of possible defects and their consequences.

The above stated stems from the assumption that the failure modes of operations or defects of components are known and based on the knowledge of potential failures, the failure causes can be assessed within a production operation in relation to the technology from the point of view of the failure consequences and the failure effects on the next parts of the production procedure and the system as a whole. The FMEA checks the effect of failure of individual system parts; however, it does not cover issues caused by a combination of failures of individual system parts. When implementing and operating the critical control points mode, the FMEA can be used for quantification of the risk and consequences level, e.g. of individual production procedure steps.

The FMEA includes all risk analysis elements, ranging from definition of the scope through identification of possible error types, assessment of severity of the error consequences, the use of procedures for resolving potential consequences, identification of root causes, identification of likelihood of errors (their frequency), risk calculation, up to measures for mitigation of the risk.

For the purposes of implementing the critical control points system, the following is done from the FMEA procedures:

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

Individual identified hazards of each production procedure phase have assigned the values of monitored attributes (indicators). The attribute (indicator) is assessed using numbers from 1 to 10. The risk level "R" is calculated as the multiplication of three values of monitored attributes (indicators), which are the risk category "K", hazard frequency "Č" and likelihood of detection "S".

4.1 Risk categories

They indicate the severity of hazard consequences.

An example of the classification and assigned values

severity	Assigned value
Death of animals or damage to animal health followed by death (fatal consequences for a consumer). Fatal consequences for the producer e.g. high penalty, cancellation of registration or revocation of approval or registration for operation, criminal proceedings for damage caused by the product.	10
Negative effect on quality of animal products by feed or up to deterioration (stock).	8
Sickness of animals without death but reduction of their efficiency (stock).	5
Individual occurrence of negative effects on quality of animal products or animal sickness.	3
No danger imminent.	1

Severity and the values assigned may be adapted depending on the production type and production conditions.

4.2 Frequency (likelihood) of occurrence of the hazard

It may be considered depending on the number of demonstrated occurrences of the defective products while taking into account the severity of these defects expressed as a % of the number of checked cases or based on the frequency of occurrence of these defects expressed by the number of defective products e.g. per year.

Example of frequency of the hazard	Value assigned
- very high frequency (more than 50% occurrence)	10
- high frequency (35 to 50% occurrence)	8
- medium frequency (20 to 35% occurrence)	5
- low frequency (10 to 20% occurrence)	3
- very low frequency (less than 10% occurrence)	1

4.3 Likelihood of detection (control measures)

It defines whether the production process is controlled manually using relevant controls (control measures included in the production procedure and allowed control) or whether the production process is controlled automatically and the controls are part of a programme which allows control throughout production as well as retrospectively.

Example of the detection reliability	Value assigned
- the production process has minimum controls or the controls cannot be detected (the process is out of control)	10
- the production process allows 50% control	5
- the production process allows full control, e.g. it is fully automated or the controls are under full control of operators and the controls allow demonstrable control	1

The quantitative risk analysis is given by the sum of $K + \check{C} + S$, where:

K = risk category;

\check{C} = risk frequency;

S = reliability of detection.

The quantitative risk analysis procedure according to FMEA can be considered an aid under the conditions of premixtures and feed production and the need to determine the critical control points system is better met by the quality risk analysis provided that it has been processed by qualified employees.

5 Determination of the critical control points

When determining the critical control points, knowledge of the operating technology, the production procedure as well as a description of extreme situations that may happen is the cornerstone. When determining the critical control points, it is possible to use the following decision-making scheme as a supporting tool. In fact, the whole production procedure is inspected and it is considered which production phases or handlings may be associated with occurrence of the hazard and where the latter can be prevented by

monitoring and adopting a remedy measure preventing occurrence of the hazard and threat to health of the or feed.

Should the production procedure define the critical control points for operation personnel and measures for the personnel to be performed in these control points to mitigate the risk occurrence as prevention, it has no meaning to define the critical control points in these points.

5.1 Decision-making scheme

It is a tool for determination of the critical control points and when using it, the process starts at the beginning of the production and ends at dispatch in individual steps with the identified hazard where individual scheme questions are responded in the order as they are until "stop", when the next identified hazard in the next step of the production procedure is considered.

5.11 Example of assessing the receipt of additives, feed materials and specific protein feed for production using the decision-making scheme (first production phase):

Question 1 – Are there preventive measures for the identified hazards?

No – define how and where the hazard can be controlled (sensory control of the type by marking, check of discharging the receipt container, check of selection of traffic routes, check of the receipt bin) and should variations be detected, no receipt must take place.

Yes – the measures have been met, go to question 2.

Question 2 – Is this operation specially designed to eliminate hazards or to reduce risk to an acceptable level?

No – go to question 3 (there is no hazard imminent in this step, therefore, this is not a critical control point).

Yes – this is a critical control point.

Question 3 – May cross contamination occur or may the risk increase to an unacceptable level?

No – not a critical control point.

Yes – go to question 4 (cross contamination may occur in the receipt phase).

Question 4 – Do the measures eliminate hazards or reduce the risk to an acceptable level in the next step?

No – this is a critical control point.

Yes – this is not a critical control point (provided that the measures have been obeyed).

5.2 Determination of attributes and values of critical limits for each critical control point

When determining the attributes to be verified in the critical control points, it should be focused primarily on risky additives or additional additives or selected undesirable substances or animal proteins or micro-organisms (salmonella) as they are mainly those causing the hazard. Their critical limits including tolerances are specified by laws. The protocol from the critical control points control must contain the numerical values observed, permitted limit content including tolerances for the content detected upon cross contamination and maximum permitted content not considered to be cross contamination yet (the limit of determination and the tolerance determined from this limit).

5.3 Definition of the system of monitoring a managed condition in the critical control points

When monitoring the critical control points (controlling), monitoring is required for all critical control points in order to assess in an unbiased way the attribute being monitored (the additive, undesirable, prohibited substance, micro-organism) in all production phases and to confirm the finding (the reason is potential occurrence of errors in sampling and testing).

The control system for each critical control point is defined so that:

- a) monitoring is capable of revealing each threat to the managed condition within the critical control points and enabling the production procedure corrections required depending on the data observed to ensure staying within the critical limits;
- b) the control results allow correction of the production procedure also in cases where there is a negative trend towards exceeding the critical limit only;
- c) the control results have been assessed by a qualified employee authorized by the producer and capable of adopting the corrective measures;
- d) the critical control points control related protocols are confirmed and discussed in time with competent employees and the corrective measures are realized within the deadlines specified.

5.4 Determination of corrective measures

Corrective measures mainly include measures for handling products produced under non-managed conditions (recall, reworking, disposal of the product) and measures how the critical control point (critical control points) will be put under managed conditions. The corrective measures are parts of the protocols and are retained for a specific time separately as a part of the critical control points documentation.

5.5 Determination of verification procedures

The monitoring effectiveness of the critical control points control plan is determined by defined verification procedures and their frequency. The above-stated is usually included in the producer's quality control plan.

The verification function of the system also usually includes:

- reviewing the system and its records;
- finding out whether the critical control points are under managed conditions;
- monitoring the development of verified values in the critical control points;
- assessing the monitoring function (of the plan) according to the control results using different test approaches independent on the test methods used for the control;
- reviewing variations and methods of the product evaluation;
- confirming correctness of the critical limit values;
- monitoring of complaints.

6 Documentation associated with the critical control points

The documentation listed below should be maintained by the producer's qualified person and retained throughout the term defined by applicable laws and if not stipulated, throughout the term defined by the producer.

The documentation is as follows:

- plans of the critical control points system control;
- documentation of the system development (documentation for product specification, hazards analysis including the control measures, determined critical control points, critical limits, monitoring procedures (controls));
- documentation of the system operation (protocols on the critical control points control, test results, records on verification procedures, records on disposal of a product in non-managed condition);
- production procedures, formulas used (production orders) when controlling the critical control points;
- emergency rules defining procedures e.g. for power failures, etc.
- job descriptions of competent employees in production related to the critical control points system control;
- test methods to be employed for the critical control points control;
- the method and records on training of employees working in production, storage and quality control.

The above-mentioned documentation can be replaced by the production procedures, quality control plan, storage rules and organizational rules if they describe these areas.

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