

AC-02

Ver 1.4



Production of Animal Feed





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AC-02 : Production of Animal Feed

1. Introduction

This document deals with the specific food safety aspect during the production of animal feed, namely:

- Feed materials;
- Additives;
- Pre-mixtures;
- Compound feed.

2. Application scope

2.1. General

Producers of animal feed shall respect the provisions set out in document 'AC-02: Production of Animal Feed'. A producer of animal feed commercializes own production and stores them temporarily

A producer of animal feed may also receive products originating from primary producers (third parties) and store them in order to be subsequently processed in their own feed production.. Activities related to production (e.g. cleaning, crushing, storing, drying, packaging) are also covered by this document.

Storage and drying activities related exclusively to collection and drying of cereals, oil and protein seeds, are included in document 'AC-03: Trade in animal feed, unless associated with its processing into feed.

If the producer also provides services, such as trading in feed, produced by third parties, or storage and transshipment of feed, intended for third parties, he must specifically comply with the provisions of document 'AC-03: Trade in Animal Feed' and 'AC-04: Storage and Transshipment of Animal Feed'.

Road transport activities, performed by the producer, must comply with the provisions of document 'AC-05: Road transport of Animal Feed'.



Examples of scope

A compound feed producer must apply documents 'AC-00: Introduction', 'AC-01: General Provisions and 'AC-02: Production of Animal Feed'. Activities relating to trade, storage and transshipment of his own production, are also covered. For his road transport activities, the manufacturer must apply document 'AC-05: Road Transport of Animal Feed'.

If this producer commercializes feed originating from third parties (not from his own production), he must, additionally, apply the provisions from document 'AC-03: Trade in Animal Feed'. If performing storage and transshipment activities for third parties, then document 'AC-04: Storage and Transshipment of Animal Feed' will also be applicable.

A producer of maize (gluten) applies document 'AC-00: Introduction', 'AC-01: General Provisions and 'AC-02: Production of Animal Feed', for the production of the feed material.



Examples of scope

A company (not a primary producer) presses rape seed. The rape seed oil is supplied to the bio fuel industry, and the extracted rape seed to the feed sector (whether or not directly to the livestock farmer). This company will apply documents 'AC-00: Introduction', 'AC-01: General Provisions' and 'AC-02: Production of Animal Feed'.

During harvest, a producer of compound feed receives and subsequently stores cereals originating from local farmers. These cereals are then used in compound feed which he has produced. He must apply 'AC-00: Introduction', 'AC-01: General Provisions' and 'AC-02: Production of Animal Feed'.

If this same producer wishes to commercialize these collected cereals, he must, in addition, apply document 'AC-03: Trade in Animal Feed'.

A number of requirements listed in the AT-series must be taken into account within the organization inherent to the company, or are applicable to certain production activities:

- 'AT-01: Legislation';
- 'AT-02: Notification Requirement';
- 'AT-03: Standards, Action Thresholds and Notification limits';
- 'AT-04: Practical Realization of the HACCP-Plan';
- 'AT-05: Monitoring';
- 'AT-09: Management of Mycotoxins';
- 'AT-10: Management of Salmonella'.

These particular documents will have to be applied by a limited number of companies, depending on the produced animal feed and/or applied production process.

It concerns the following documents:

- 'AT-08: Cross-contamination';
- 'AT-11: Animal by-products';
- 'AT-12: Production of feed for pet animals';
- 'AT-13: Procedure for the use of a fine dosing device'.



Specific documents included in the AT series

The use of specific documents from the AT series, is also mentioned when treating a specific subject (e.g. reference to document 'AT-08: cross-contamination', is again mentioned in point 8.3 – cross-contamination).



Production of animal feed for account of third parties

It can happen that a company wishes to develop its own range of animal feed, but does not have the potential to do so. This company may then decide to outsource and entrust the feed production to a company with the potential to do it.

This may also occur when facilities (producer) have undergone one or other damage (longtime

breakdown, disaster etc.) and thus preventing the production on this line. He will then outsource the production to one of his colleagues, who will do the producing for him.

The production company, accepting « against payment » the production intended for a third party, should verify the compatibility of this request in relation to:

- The Legislation in force (country of destination, animal feed to be used, target animals, etc.);
- Their own possibilities and installations (cross contamination, management of inventory, etc.).

The company should also assess any potential hazards linked to this activity (e.g. use of new animal feed, such as additives or compound feed, unknown by the company) ('AT04: Practical realization of an HACCP plan'). The company should also communicate the minimum required information to third parties, in order to obtain a correct labeling of the thus produced animal feed.

2.2. Food companies

A food producer, producing feed materials as secondary by product, should apply documents 'AC-00: Introduction' and 'AC-01: General Provisions' as well as document 'AT-07: Product Sheet for Food Companies'. The provisions included in document 'AC-02: Production of Animal Feed' are not applicable to this producer, with the exception of the requirements in points 5, 8.16, 8.17, 8.18, 9, 10, 11, 12 and, if necessary, 14 and 15.

See also document 'AC-00: Introduction', application scope, where it explains as of when these documents will become applicable for a food company, producing feed materials.

Food Companies wishing to supply, occasionally, feed materials to the animal feed chain, should also comply with the documents 'AC-00: Introduction', 'AC-01: General Provisions' and additionally 'AT-07: Product Sheet for Food Companies'.



Example of application scope for a food company

A biscuits producer has regularly a residual flow of broken biscuits, that will be go to the animal feed sector. This producer must apply the prescriptions included in documents 'AC-00: Introduction', 'AC-01: General Provisions' as well as in document 'AT-07: Product Sheet for Food Companies'.

2.3. Specific technical documents

Producers of feed for pet animals ('pet food') should, in addition to the provisions already included in this document, also comply with document 'AT-12: Production of animal feed for pet animals'.

Companies, transforming animal by-products into animal feed, must also comply with the requirements included in document 'AT-11: Animal By-Products'.

Companies, using a fine dosage device, upon delivery of medicated animal feed must also comply with document 'AT-13: Procedure for the use of the fine dosage device'.

3. Product specifications

For both, ingredients and incoming products, as well as for finished products there should be a written specifications in place. These specifications should at least comply with the legislation (see 'AT-01: Legislation').

Per product or product group, there should be a description, highlighting the sensitivity to food safety hazards. This description must take into account, the components comprising the product (e.g. feed materials, additives and pre-mixtures) and the production process, up to, and including the distribution.

The product specifications shall at least contain:

- Characteristics of the product;
- Characteristics for its use.

The product characteristics shall include at least a description of:

- General information (description, code, etc.);
- Composition (chemical, physical, microbiological);
- Raw materials and processing aids (used);
- Standards (legal, regulatory, agreements with purchasers) and tolerances;
- Other characteristics (packaging amongst others).

The characteristics for use include at least a description of:

- Storage and preservation conditions;
- Transport and delivery conditions;
- Sustainability, if applicable.

Specifications may be drafted per product group. A product group is a group of similar products (e.g. extracted soy beans: soy 44, soy 48 and soy 50).

Products belonging to the same product group may:

- Originate from a similar process; and/or
- Have the same origin; and/or
- Have a similar composition; and/or
- Have a common destination (target animal).

It is important that the specific differences between the various products constituting the group, are examined in a critical manner.



Use of additives in animal feed

The use of additives in feed is strictly limited to those additives, included in the Community Register of Feed Additives pursuant to Regulation (EC) No 1831/2003). This register (positive list) is updated on a regular basis and can be consulted online:

http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm

A company wishing to make use of an additive, or wishes to formulate an animal feed should consider the specific characteristics relating to the objective pursued.

To this end, the company must take into account:

The authorization to use this substance in animal feed (additives used within the European Union, disposing of a legal authorization, published as a regulation in the Official Journal of the European Union;

The pursued objective (e.g. technological, nutritional, diet food, etc.);

The target animal (certain additives are authorized for all animal species, others are limited to specific categories (e.g.: chickens for fattening or piglets));

The minimum and/or maximum authorized level (this is of great importance in order to be able to determine the instructions for use for that feed) This will mainly relate to the level of additives (e.g. pre-mixtures or complementary feed);

The duration of the prescribed use;

The restrictions for use;

The compatibility of the additive with the other ingredients of the feed;

The specifics of its installation (including potential cross contamination, incorporation facilities, etc.).

The level of additives in certain animal feed is limited due to Legal provisions (Legislation (EC) No 767/2009 Art 8). These are mentioned here below.

| Animal feed | Maximum levels for a given additive |
|-----------------------------------|---|
| Feed material | 100 x the maximum level anticipated for the complete feed |
| | 5 x the maximum level in the case of coccidiostats and of histomonostats |
| Complementary feed | 100 x the maximum level anticipated for the complete feed |
| | 5 x the maximum level in case of coccidiostats and of histomonostats |
| Diet feed (feed or compound feed) | Value above, unless the composition of the products concerned, satisfy the particular nutritional purpose for which they are intended (see punt 15) |

Feed materials may contain additives.

They could be:

- 1) Added for a specific purpose. In this case the additive should have a specific authorization for its use in animal feed. (indicated in the Community Register) (e.g. addition of an antioxidant to the rendered fat);
- 2) Already present in the product, before this product had actually received a feed destination. This is particularly the case with former food products. They could contain additives intended for human consumption, but are probably not allowed in animal feed. Their presence is tolerated on the explicit condition that they have no influence on the animal for which the feed is intended.

4. Formulation of additives, pre-mixtures and compound feed

For the production of animal feed, a defined formula may be used, prescribing the proportions of the ingredients. This formula will be send on to the production department.

The formulation should at least consider the following:

- The legal requirements as regards the use of feed;
- The legal requirements as regards the finished products;
- The effects of the finished product on the health of target animals, and food safety for consumers of food products (animal origin).

The composition of manufactured mixtures should be kept, per production date, for a period of 10 years.

5. Purchase

The purchase of products is performed, based on the product specifications. The European Institutions of feed suppliers must, according to the European Regulation No 183/2005 laying down requirements for feed hygiene, be registered and possibly approved.

In Belgium, there is an intermediate level between registration and approval (company), as defined in the European Regulation (EC) No183/2005 laying down requirements for feed hygiene. This level is defined in the Royal Decree of January 16, 2006, laying down the procedure for approval, authorization and registration, issued by the Federal Agency for the Safety of the Food Chain, FASFC (see 'AT-01: Legislation').

A Belgian establishment of a supplier, supplying products or services, should be approved, authorized or registered, depending on the company's activities.

An evaluation of the suppliers may turn out to be a necessary measure in order to ensure food safety and quality as regards purchases of products and services.

6. Reception

Upon reception, one should verify whether the received ingredients are satisfying the requirements. Accompanying documents, and analysis documents, should be checked (e.g. for animal feed considered to be critical).

The product must satisfy the legal requirements (e.g. labeling). All products, present within a company, are deemed, unless proof to the contrary, to be kept in view of commercialization or use (possibly after reprocessing) for the feeding of animals within the country.

Upon reception, the animal feed will be subject to an entry control (e.g. odor, color, structure, moisture level, temperature, ...). The packaged products should be checked for potential damage.

Moreover, following a pre-established procedure, the buyer should take sufficient samples of the ingredients, in order to ensure traceability. The samples must be closed and labeled in a way that allows easy identification. These samples must be stored under conditions so as to prevent any deterioration, or changes in the composition.

For packaged products, and on the explicit condition, that this has been agreed in writing, with the supplier, and doesn't violate any legal provisions, the sample may be taken by the supplier, during the production process of the batch, to be delivered.

In any case, the sample must be sealed, and bear a label indicating the exact same references as the received product.

A procedure, describing the way to handle products not satisfying the requirements (e.g. refusal, conditional acceptance, giving another destination), should be in place and applied if necessary.

Upon receiving feed materials, additives, pre-mixtures and complementary animal feed, a register is to be kept by the company. The following data is to be recorded in the register:

- Name of product;
- Name and address of supplier;
- Date of reception;
- Quantity;
- Batch number supplier;
- Expiry date, if applicable.

7. Storage of products

All products, both bulk or bagged, must be stored in a way that:

- They can be easily identified;
- They are physically separated from other products;
- Mix-up with other products is excluded;
- Expiry date is not exceeded;
- They comply with the storage conditions indicated on the label.

The products should be stored in a way as to reduce the risk of damage to package and flowing or leaking of products.

Animal feed should be stored in an easily identifiable way, thus excluding any mix-up with other animal feed.

When a product, in transit or intended for export outside the European Union, is stored within the company, the stock should carry a visible label bearing the words "Export". The owner or holder of the product, should be able to prove its destination through means of substantiating documents, at the latest upon delivery.

The particular case as regards storage of medicated feed, intended for exportation, is treated in point 13.4 of this document

In order to minimize the extent of a possible recall, is it recommended, to empty completely, all silos and storage areas of dry products on a regular basis. Any emptying must be registered.

During storage, bulk feed for ruminants are stored in facilities physically separated from facilities storing animal proteins, authorized in feed for non-ruminants (in conformity with annex IV to Regulation (CE) No 999/2001), and feed containing these proteins are stored in bulk.

Fat blending establishments placing products intended for feed on the market shall keep all products physically separated from products intended for other purposes unless the latter products comply with the applicable requirements (cf. 'AT-01: Legislation' and 'AT-03: Table of Standards, Action thresholds and notification limits').

If a producer states on the label of the batch 'intended for technical use', this batch should never be used for feed.

Containers which are to serve for storage and transport of products intended for use in feed, (mentioned below) shall not be used for the transport or storage of products other than these, unless the products comply with standards applicable to the feed sector.

This applies to:

- Blended fats;
- Vegetable oils;
- Products derived from oils of vegetable origin.

These products shall be kept separate from any other cargo where there is a risk of contamination.

Where separation is not an option, containers shall be efficiently cleaned to remove any trace of products if those containers were previously used for products not complying with standards, applicable to the feed sector.

The applicable procedure must be established in writing.

Animal fats of Category 3 material, as laid down in Regulation (EC) No 1069/2009, intended for use in feed shall be stored and transported in line with the applicable standards (see 'AT-11: Animal by-products').

8. Production process



Preliminary remark

All substances and materials, used during different steps of the production process, should be evaluated, so that they do not become a source of hazard for the finished product. (AT-04: Practical realization of the HACCP plan). In this case, it could, e.g., relate to animal feed, but also to technical aids, lubricants, detergents, etc.

8.1. Processing of animal by-products and the use of feed materials from animal origin.

There are specific requirements for the processing of animal by-products, and for feed materials of animal origin, including its use.

These requirements may, e.g., relate to requirements for the obtaining of an approval, issued by the competent authorities or, e.g., use of certain feed materials of animal origin, may be prohibited in plants used for the production of feed for ruminants.

For any additional information, regarding the application of specific conditions related to these activities, the company must refer to the following documents:

- 'AT-11: animal by-products';
- 'AT-12: production of feed for pet animals';
- Regulation (EC) 1069/2009 and Regulation (EU) 142/2011;
- Regulation (EC) 999/2001.

8.2. Production order

The production order in the installation (compound feed with additives, (medicated) pre-mixtures etc.), should be defined in a way, so as to satisfy the standards (list of authorized additives and medicated pre-mixtures, undesirable substances, etc.) (cf. 'AT-01: Legislation').

The production order, must be defined and registered, so that it will be taken into account, upon transferring the formulation to the production.

The production order should be recorded and archived.

8.3. Cross-Contamination

Certain additives, (medicated) pre-mixtures or other products may be left behind during the production process, and therefore, may end up in the next batch. This is called cross-contamination. Cross-contamination may be inherent to the installation, or may have been caused due to production or treatment of the ingredients.

It is necessary to limit the cross-contamination.

The gravity of the cross-contamination depends on:

- The characteristics of used product;
- The quantity of used product;
- The place where the used product is added: the longer the haul, the more substantial the cross-contamination;
- The cross-contamination inherent to the installation.

In order to minimize the cross-contamination, the producer must:

- Know the extent of cross-contamination in the installation (for the production of compound feed, additives and pre-mixtures);
- Apply a production order or well defined dosage. It should be included in the requirements, which will be communicated to the production team. The production order must be archived;
- Possible application of rinse charges;
- Incorporate additives and (medicated) pre-mixtures, as close as possible to the mixer, in the main flow.

Cross-contamination, should be an integral part of the HACCP study. The operator should consider any risks related to cross-contamination, and comply with the Legislation in force, such as, e.g., maximum authorized levels of additives for target species, or maximum authorized levels of coccidiostats residues for non-target species (cf. Community Register for additives, or Directive 2002/32/EC).

A cross-contamination test should at least be performed in the following cases:

- Every 2 years in case of production of additives (if a potential risk, related to cross-contamination, has been established (e.g. presence of a mixer for dry products));
- Every 2 years in case of production of pre-mixtures;
- Every 2 years in case of consecutive use of animal feed containing GMOs, and animal feed not containing GMOs;
- Every 2 years, if the compound feed producer disposes of an approval for manufacturing compound feed containing additives of the group of antibiotics (use possible, only for products, intended for export outside the EU);
- Upon the start of the installation, and then every 2 years, if the compound feed producer holds (or wishes to hold) an approval, for the manufacturing of compound feed, containing additives belonging to group 5 of the "Coccidiostats and other medicated substances" or belonging to group 4-d of the "growth factors" (see Community Register of Feed Additives);
- At the start up of the installation and subsequently every 2 years in case of production of compound feed containing medicated pre-mixtures;
- Also, at every major change to the system (mentioned above).

After performing the contamination test, it is important, to keep records of results, in a report.

Document 'AT-08: Cross-Contamination' describes the way as to how a cross-contamination test can, in practice, be performed.

If the company performs a cross-contamination test, they must also perform a homogeneity test.

However, the implementation of a homogeneity test does not require a cross-contamination measure.



Examples regarding the manufacturing of compound feed for pre-mixtures containing coccidiostats

The most effective measure to prevent cross-contamination is by defining and complying with a suitable production order. The approach may be different, depending on the type of substance.

Thus, for the production of pre-mixtures or compound feed containing coccidiostats, it is essential that standards related to the presence of coccidiostats in animal feed are always respected, namely:

- Respect of minimal and/or maximal levels for compound feed containing coccidiostats;
- Respect of maximal levels of coccidiostats (undesired substance according to Direction 2002/32) for feed materials, pre-mixtures and compound feed, which, given their formulation, should not be containing coccidiostats. In this case, dilution in other animal feed is prohibited.

All food placed on the market must satisfy these standards.

This way, if the next batch transiting the installation, is a compound feed which does not exceed the maximum content of undesirable substance for this coccidiostat (non-target animals), this batch can be commercialized as compound feed, if the entire set of requirements are satisfied.

8.4. Homogeneity

During production:

- A homogeneous distribution of components must be obtained, according to criteria, defined in the Legislation (see 'AT-01: Legislation');
- The dosing order is chosen in a way so as to obtain a homogeneous distribution;

The homogeneity must also be ensured upon delivery of the finished product.

Every 4 years a homogeneity test should be performed, or, upon any major changes to the installation. This test may be combined with a cross-contamination test. Results of these tests must be recorded.

8.5. Equipment for measuring, dosing and control

The company must have a list of any equipment for measuring, dosing, and control. These could be, e.g., weighing scaled, thermometers, hygrometers and dosage devices.

Of all the equipment, the following should be defined in a clear manner:

1. What is the minimum and maximum authorized load or range;
2. What is the accuracy of the equipment;
3. What is the authorized deviation as regards the equipment.

When accuracy of the equipment, exceeds the accepted deviation, it should be calibrated or replaced.

The equipment should be easy to clean. The weighing equipment must be adapted to the quantity to be weighed. Weighing equipment, used for the weighing of goods, intended to be sold (e.g. weighbridges, packing installations), should be calibrated every 4 years. This calibration, should be performed by a Controlling Body, approved by the authorities. Companies, established in Belgium, will find a list of approved Institutions, on the website of FPS Economy, Metrology Division.

The weighing equipment, reserved for internal use, should be controlled and calibrated on a regular basis.

The frequency as regards calibration and control, should be defined by the company (e.g. on the basis of a hazard analysis).

These prescriptions and frequencies should be implemented in procedures.

8.6. Drying

Drying consists of a mechanical phase of pre-cleaning (facultative), and a phase of drying. The air, conveying the heat through the product (to be dried), should be clean. It is important, that this air, does not form a source of contamination for the feed.

Control of water level (humidity) of the outgoing product, as well as the temperature of the product and air, allows this step be managed.

Attention, the products may be contaminated with toxic substances, through direct contact with the combustion gases during the drying process.

The following measures may help to eliminate or reduce this kind of danger:

- Ensure a good maintenance of the installations (e.g. burners);
- Opt for fuel sources, containing fewer risks (e.g. gas);
- Give preference to an installation, whereby combustion gases do not come into contact with the product;
- Control, if necessary, the dried products, for a potential presence of an identified hazard.

8.7. Cleaning and/or Sorting

This stage allows the elimination of foreign bodies, and/or the separation of animal feed among themselves. It is essential to ensure that the products, resulting from these processes (e.g. sorting residues), satisfy the aimed specifications. Their potential use in animal feed, should be subject to a specific evaluation.

Animal feed, must not contain any toxic substances, harmful to health of human or animals.

8.8. Grinding

Upon grinding, products are reduced to small particles, in a mill. Upon grinding, due attention should be given to wear and tear of hammers, and grids of the mill. The unclogging should take place, in as much as possible, in the batch to be grinded

8.9. Mixing

The mixing of ingredients, should be performed as to obtain a homogeneous distribution. The following parameters are important, in order to obtain, within the mixer, a homogeneous distribution:

- Degree of filling: this concerns the used volume compared to the volume available;
- Time of mixing: the total time needed for mixing. The mixing time will start once all products have been poured into the mixer. The optimal mixing time should be known. It will be either be provided by the constructor, or will be determined based on a homogeneity test (point 8.3 and 8.4);
- The product quantity to be mixed: it will be easier to obtain a homogeneous distribution, by incorporating a quantity of 10% instead of 0.1%, of any given product

These parameters should be situated between the established minimum and maximum (volume) values, depending on the type of mixer.

A maintenance schedule (mixers), should be implemented for the control and inspection, including the frequency and nature of the controls, e.g., control of abrasion, incrustation, the amount of residual material, etc.

8.10. Heat treatment

The product temperature is increased through direct or indirect contact with heat. The aim is to alter the physical, chemical, nutritional or microbiological characteristics of the product. When the heat treatment aims at controlling a chemical (e.g. anti-nutritional factor), or a microbiological (e.g. presence of micro-organisms) hazard, the efficiency of the treatment should be verified according to a frequency and procedure, established by the company.

Information, relating to the measures and control of salmonella, are included in Document 'AT-10: Control of salmonella'.

8.11. Pelleting

The transformation of meal into granules, is performed in a press, under high pressure and temperature.

During pelleting, the stability of processed feed additives and/or (medicated) pre-mixtures should be taken into account. The instructions for use, provided by suppliers of ingredients (such as additives and/or (medicated) pre-mixtures, should be respected.

8.12. Cooling

After a heat treatment or pelleting, follows a cooling process. The aim is to reduce the temperature and the moisture content, thus avoiding condensation. This is accomplished by circulating air around the product. The air sent into the cooling equipment must be clean.

The main risk consist of a failure of the system (insufficient cooling), or due to condensation in the installation. The temperature of the product, upon leaving the cooling equipment, should be close to ambient temperature.

8.13. Crumbling

Sometimes, an animal feed will be crumbled after pelleting.

Crumbling, e.g., is performed by crushing the granules between 2 rollers. The distance, between the two rollers, will make it possible to obtain the desired degree of crumbling.

As for all parts of the installation, it is important to ensure cleanliness, and absence of residues originating from previous loads.

8.14. Sieving (after cooling and/or Crumbling)

For the elimination of small particles, or to make a selection based on the particle particles, one may proceed with sieving. In most cases 2 or 3 screenings will follow.

Particular attention should be paid to the return flows arising from sieving, as well as to the cleanliness of the installation.

8.15. Coating

Granules may be coated with a liquid (e.g. a liquid feed material such as fat).

The nature of the coating substance, and the cleanliness of the installation, are major risk factors.

8.16. Packaging

The company must define, formalize, and respect weight tolerances, and control the weight units, as well as the legibility of the information affixed to each packaging unit. This control should be registered.

The choice as regards the packaging material is depending on:

- The nature of animal feed to be packaged;
- The management of risks linked to a contamination, of which the origin lies in the packaging material;
- The management of risks linked to contamination, via transfer through packaging material.

It is recommended, to pay attention to good storage conditions of new packaging.

In exceptional cases (e.g. liquid products), containers may be re-used. In this case, the company, should implement a cleaning method for containers, thus guaranteeing food safety of the packaged products.

During packaging, bulk feed for ruminants must be stored in facilities, physically separated from areas where animal proteins, authorized in feed for non-ruminants (subsequent to annex IV to Regulation (EC) No 999/2001), and feed containing these proteins, are stored in bulk.

8.17. Other process steps

In addition to the process steps mentioned above, other steps may occur. If they compromise the safety of the animal feed, the company must also take them into consideration.



Production of feed materials and/or additives

For certain companies (food industry, auctions, biofuels, etc.), the main process is not directly linked to a production of feed. It concerns residual flows of the main flow (e.g. downgraded foodstuffs, surpluses, various chemical substances, etc.).

The feed material or additive may show up during any stage of the main process (e.g. after sorting, or downgrading of foodstuffs, or after extracting oil intended to be valorized into fuel).

The related company must consider, not only the installations which are in direct contact with animal feed, but also the steps preceding the product from appearing, as it may compromise the safety of the food.

8.18. Return flows

There are 2 types of return flows: internal return flows, having its origin within the company itself (e.g. dust in filters, sorting residues, sieving residues) and external return flows (e.g., products, retrieved from customers).

The production process should be organized in a way, so that the return flows are reduced to a minimum.



Return flows and dust

Dust, originating from sweeping floors or other surfaces, must not be incorporated in animal feed. Here it specifically relates to dust accumulated over time within the company, and not to an occasional emission of dust, arising from powdery or mealy (flowered) feed, e.g., during crushing or delivery. After discharging a “dusty” product into the collection bunker, there are usually some remnants of the product remaining behind in the truck or on the grids. It usually concerns large amounts of the product swept into the bunker, and thus returned to the batch.

Areas, where return flows are stored, should be registered.

Return flows should, if possible, be incorporated in the original batch.

The following should be inferred from the traceability data:

- Quantity and location of each return product;
- Batches, in which return products have been incorporated.

For external return flows, the biological, chemical and bacteriological quality should be known. One must verify whether cross-contamination took place in an external company. A recall procedure should be in place. For external return flows, an updated complaint administration will be kept.

In the procedure should be defined, which are the return flows, in which compositions have they been incorporated, and to what maximum percentage, can this be produced. In any event, they should not be in conflict with the requirements, regarding the list of authorized additives, and medicated pre-mixtures.

The procedure, should at least include the determination of the production sequence, the implementation and monitoring as regards the reuse of the return flows. This procedure should

describe, the actions taken in order to prevent the incorporation of products, not intended for a specific target animal.

9. Control and analysis

9.1. General

In addition to the necessary sampling as part of the traceability (points 6 and 10), the company, may need to take samples for analysis purposes. These analysis should be considered as a means of control, which allows to:

- Demonstrate, that the animal feed, satisfies the requirements;
- Demonstrate, that the food safety system, satisfies the requirements;
- continuously improve the food safety system.

Analysis, as part of the auto-control, may be performed in an internal laboratory, having sufficient material and means at its disposal, and are working according to internal procedures, for performing these analysis (applicable methods, calibration of the equipment, etc.).

The laboratory, inherent to the company, performing analysis as per instructions by the company, or for account or third parties, should participate in ring test.

A monitoring at the level of the European Union has been developed, which relates particularly to the monitoring of dioxins and dioxin-like PCBs, applicable to certain kinds of establishments (see point 14).

In Belgium, laboratories are required to respect the principle of mandatory notification (see 'AT-02: Notification requirement'), e.g., by notifying the FASFC of any results exceeding maximum authorized levels.

When a feed business operator mandates a laboratory to perform an analysis, he shall instruct the laboratory to communicate the results of that analysis to the competent authority in case the levels of dioxin or dioxin-like PCBs are exceeded. (see point 14.2),

Three cases may be identified:

1. The laboratory is located in the same Member State as the feed business establishment. In this case, the competent authority is that of the Member State (in Belgium the FASFC);
2. The laboratory is located in a Member State other than the feed business establishment. In this case, the laboratory shall notify the competent authority of his country, which shall inform the competent authority of the Member State where the feed business establishment is located;
3. The feed business establishment shall inform the competent authority of the Member State where they are located if they mandate a laboratory located outside the European Union in a third country. Evidence must be provided that the laboratory performs the analysis in accordance with the European Regulation (see 'AT-01: Legislation').

The notification performed by the laboratory does not exempt the feed business operator from his obligation to also inform the competent authority.

In Belgium, there are legal texts making the analyses for specific parameters mandatory.

For these identified cases, the law states first and foremost, to make use of a laboratory having a FASFC approval or ISO 17025 accreditation for the parameter in question.

If a Belgian company, approved or authorized, does not have themselves sufficient means of control, it must be in possession of a copy of the contract by which it entrusts this control to a laboratory able to perform these analysis. The written analysis order (letter, e-mail, fax) may replace the contract.

The contract and the orders, should include a list of analysis to be performed.

The following table contains mandatory analyses, laboratory requirements and legal references.

| Mandatory parameter(s) | Scope | Qualification Laboratory | Legal Reference |
|--|--|--|--|
| Dioxins and dioxin-like PCB's | Feed business operators processing crude vegetable fats and oils Feed business operators producing animal fat including animal fat processors Feed business operators producing fish oil Oleochemical industry placing feed on the market Biodiesel industry placing feed on the market Fat blending establishments Producers of compound feed for food producing animals (other than fat blending) Importers placing feed on the market (for details: see point 14) | FASFC approval or accreditation | Regulation (EC) No 183/2005 Royal Decree of 21/02/06 - Annex IV |
| Dioxins | Additives E559, E561, E566, E598 and E568 of the group of «binders, diluents and coagulants» (see point 14) | | |
| Medicines (level of active substances) | Medicated feed (see AC-02 point 13) | approval FASFC or laboratory inherent to the company | Royal Decree of 21/02/06 – Annex III |
| Animal proteins (sampling BSE) | Compound feed and pre-mixtures (production) (see AT-11) | Not specified | Royal Decree of 21/02/06 – Annexes I and II |
| Salmonella and Enterobacteriaceae | Animal feed for pet animals (see AT-12) | Approval | Regulation (EU) No142/2011 |

| Mandatory parameter(s) | Scope | Qualification Laboratory | Legal Reference |
|---|--|--------------------------|----------------------------------|
| Depending on the type of control by the FASFC | Counter-analysis, performed following an official control by the FASFC | Approval | Royal Decree of 15/04/05 – Art 2 |

The company is developing a control plan, which will include different process-critical control points, from reception until delivery of the animal feed. There should be, minimum, a monitoring of the critical control points. This can be done, for instance, on the basis of an analysis, a visual control, or by measuring a parameter such as temperature or pH.

This control plan strongly depends on the company's internal processes. The control, as regards the CCPs linked to the process steps, are not required to respect the conditions included in document AT-05, as opposed to the monitoring of CCPs linked to the product. The Company will define the control frequency as regards the process steps in function of the final control and the hazards that might appear in the finished product.

Example

A company, performs a heat treatment on feed. According to the HACCP-analysis the microbiological hazard "salmonella" is under control, if, given the duration of the exposure, the temperature exceeds a value of T1. The temperature, in the installation, will be monitored at all times. If the temperature falls below T1, there will be an acoustical warning signal.

The company has determined, through means of a batch par batch measurement, the control frequency of temperature T1.

The potential occurrence of the hazard 'salmonella' will only be present in batches, where the required temperature has not been reached. Only those batches should be part of the monitoring plan "finished product".

It is however recommended, for reasons of auto control, to check occasionally, a batch for which the control signal did not go off. The analysis result will confirm the evaluation performed by the HACCP team.

The control plan will also include the monitoring plan (see 9.2), performed in conformity with document 'AT-05: Monitoring'.

Depending on the company, the control plan will relate to:

- Purchased (incoming) and sold (outgoing) products (see point 9.2);
- Control imposed by the legislation in force (e.g. the European monitoring of dioxins and dioxin-like PCBs);
- Sampling and analysis of parameters related to processes developed in the company and identified in the HACCP-plan;
- Monitoring of parameters, as requested by the customer (e.g. in the context of a commercial question).



Legal analysis requirement and HACCP plan.

The application of certain legal requirements makes analyzing mandatory (e.g., looking for the presence of animal proteins, or dioxin monitoring). These laws are not necessarily applicable to all operators (e.g. applicable only for producers) and definitely not if located outside the European Union.

For the monitoring of dioxins, the legislation requires that producers analyze each batch of certain incoming products (cf. point 14.2.4). There is a derogation allowing sufficient supervision via their HACCP plan, but only if they can prove that this batch has already been submitted, in a previous step, to a legal monitoring (e.g., by a certificate of analysis).

If a batch, originating from a third country (direct import or, whether or not, via an intermediate European), it is necessary to check whether the batch has been submitted to such a monitoring. If the monitoring has not been performed (e.g. absence of analysis certificate), it will be up to the producer to perform the analysis upon receiving the batch (incoming product).

9.2. Monitoring

If, in the context of auto-control, the analysis are used as a means of control or management, the company should include them in an individual monitoring plan. This should be established in writing, and should be respected.

This plan should concern purchased (incoming) and sold (outgoing) products, in conformity with document 'AT-05: Monitoring'.

The analysis results should be registered.

The company must keep an overview of analysis results.



Individual monitoring plan versus sector based monitoring plan according to document AT-05

Certain sectors may develop a statistically documented sector based monitoring plan. Such a plan should be drawn up conforming the principles included in document 'AT-05: Monitoring'. In such a sector based plan, common parameters are identified for incoming and/or outgoing products, which will be monitored and analyzed. By acting in group, a representative overview of the analysis results, is obtained.

Companies participating in a sector based plan may, for parameters identified in their individual plan but also included in their sector based plan, refer to the sector based plan.



Analysis results

If the company has the analysis results following the application of a mandatory legal monitoring, the batch in question is not required to be re-analyzed as part of another section of his control plan (e.g. as CCP) as the result for this batch is already available.

This is only possible if:

- The link between the analyzed batch and the analysis report can be established without any ambiguity (e.g. by indicating the batch number on the analysis report);
- The laboratory, who has performed the analysis, satisfies all requirements (e.g. accreditation);
- The supplier satisfies the requirements as listed in point 5.

10. Labeling, delivery and purchase by the customer

Upon purchase or delivery of product by the client, the legal notices (see 'AT-01: Legislation') are clearly indicated on packaging and/or accompanying documents.

Possible waiting periods, administration methods, and specific conditions as regards storage and use, arising from the characteristics of the animal feed, should be clearly indicated.

The exact denomination of the feed material is extremely important. It is recommended, where available, to use the denominations as laid down in the European Catalogue of feed materials.

Legal requirements for labeling and delivery of animal feed, are mentioned in the following documents (see 'AT-01: Legislation'):

- for feed materials:
 - o Regulation (EC) No 767/2009 as regards the placing on the market of animal feed;
 - o Ministerial Decree of 12/02/1999 related to the placing on the market and use of animal feed (namely Chapter II of this Ministerial Decree).
- For additives:
 - o Regulation (EU) No 1831/2003 related to additives on additives for use in animal nutrition;
 - o Regulation (EC) No 767/2009 on the placing on the market and use of animal feed;
 - o Ministerial Decree of 12/02/1999 related to the placing on the market and use of animal feed (namely Chapter II of this Ministerial Decree);
- For pre-mixtures:
 - o Regulation (EC) No 1831/2003 regarding additives intended for animal feed;
 - o Regulation (EC) No 767/2009 as regards the placing on the market of animal feed;
 - o Royal Decree of 8/02/1999 as regards trade and use of products intended for animal feed (in particular Chapters VI, VIII and IX of this Royal Decree and Chapter 4 of annex to this Royal Decree);
 - o Ministerial Decree of 12/02/1999 as regards the placing on the market and use of products intended for animal feed (in particular Chapter II of this Ministerial Decree).
- for compound feed:
 - o Regulation (EC) No 767/2009 as regards the placing on the market and use of animal feed;
 - o Royal Decree of 28/06/2011 regarding the placing on the market and use of animal feed;
 - o Ministerial Decree of 12/02/1999 on the placing on the market and use of animal feed (in particular Chapter II of this Ministerial Decree).



Labeling and claims

The communication of information, users of animal feed (companies, cattle holders or individuals), is performed through various channels (labeling, technical documentation, publicity, internet, etc.).

The information indicated on the label is very important, as it is often the only source of information

available to the user, particularly for non professional users. The Legislation defines three concepts: labeling, the label and presentation.

- Labeling is the attribution of references, indications, trade names or trademarks, images or symbols, to animal feed, by placing this information on any data carriers relating to animal feed, or accompanying them such as a packaging, a container, an instruction leaflet, a label, a document, a band, a collar, or the internet, including purposes as regards advertising;
- The label is defined as a brand, a trademark, an image, or any other document, written, printed, stenciled, marked, engraved or attached to the packaging, or to the container with animal feed;
- The presentation represent the shape, appearance or packaging of the feed, and the packaging materials used for this purpose, as well as the way in which they are arranged, and the setting in which they are displayed.

The contents, indicated on the label, is specifically described for each type of animal feed (see above)

The labeling and presentation of the feed, must not mislead the user (e.g. concerning the destination or characteristics of the animal feed, particularly the nature, method of manufacturing or production, properties, composition, quantity, durability, and species or category of animals for which it is intended). One must, by no means, attribute any effects or characteristics which it does not possess, or suggest that it possesses special characteristics, when in fact all similar kind of animal feed possess the same characteristics.

However, the labeling and presentation of feed materials and compound feed, may draw the attention to the presence or lack of a substance in feed, to a specific nutritional process, or to a specific function related to any of these elements, provided the following conditions are met:

- The claim should be objective, verifiable and understandable;
- The person, responsible for the labeling, should be able to provide a scientific substantiation of the claim (through publicly scientific information, or documented researches performed by the company);
- The scientific substantiation should be available at the time the animal feed is marketed.

Claims, regarding the optimization of food, and the support or protection of the physiological state are authorized, unless, they contain a claim, creating the impression that the food contains properties for the prevention, treatment or cure of a disease (with the exception of coccidiostats and histomonostats, authorized as additives).

Claims, regarding the prevention of an unbalanced diet are allowed, provided no link is made to any pathological symptoms.

In order to clarify this subject, The Belgian Federal Service of Public health, Security in the Food Chain and environment, has provided an indicative list of claims, available to operators. It concerns claims, that are not considered as descriptions inherent to the prevention, treatment or cure of a disease. This list may be downloaded via the link here below:

http://www.health.belgium.be/filestore/11782447_FR/allegations%20sante%202008-03_0_11782447_fr.pdf.

The labeling and the presentation of feed materials and compound feed, must not create the impression that this feed has a specific nutrition purpose, as laid down in the Legislation (see point 15) unless they satisfy the indicated requirements.

Labeling and destination of product

The labeling of the products shall clearly indicate whether they are intended for feed or other purposes. It is mainly for this reason that the legislation imposes indications such as «additives», «premixtures», «feed materials», « compound feed », etc.


If a certain batch of a product is declared not intended for feed use, this declaration shall not be subsequently altered by an operator at a later stage of the chain.

Animal feed which consists of (or partly) genetically modified organisms (GMO), or animal feed produced from GMOs, should be labeled as laid down in Regulation (EC) No 1829/2003 and (EC) No 1830/2003.

Animal feed, other than feed for pet food, containing animal proteins, authorized only in feed for non-ruminants (subsequent to annex IV to (EC) Regulation No 999/2001) should only be delivered to institutions, where no ruminants are held, fattened or reared.

Prior to delivery, a sample of each batch is taken. This sample should be stored in optimal conditions, for a period as is indicated in the table here below. The sample should (unambiguously) be traceable to the produced batch.

Sampling of produced animal feed is mandatory for Belgian producers, approved or authorized, and is recommended to other production companies.

|  Sampling of produced animal feed (cf. Royal Decree of 21/02/06 – Annex I. I and Annex III.IV) | |
|---|--|
| Finished product | Storage period |
| Feed material | 6 months starting from the date of putting into circulation |
| Special nitrogenous products | |
| Additive | Until the guaranteed minimum expiry date and in any case during at least three months starting from the date of putting into circulation |
| Pre-mixture | |
| Compound feed | |
| Medicated animal feed | 4 months starting from manufacturing date (cf. point 13) |

Upon delivery of additives, pre-mixtures and compound feed, the following data must be recorded in a register:

- Product name;
- Name and address of the customer;
- Delivery date;
- Quantity;
- Batch number;
- Expiration date.

If the compound feed purchaser is a livestock farmer having a herd number allocated by the authorities, the herd number must be mentioned with each delivery of compound feed.

When it comes to delivery of:

- Products covered by the European monitoring (see point 14.2), received by the oleochemical and biodiesel sector;
- Products covered by the European monitoring (see point 14.2) received by establishments producing blended fats;
- Products covered by the European monitoring (see point 14.2) received by compound feed manufacturers, other than fat blending establishments;

Any delivery of products shall be accompanied by a proof that these products or all components thereof have been analyzed;

When it comes to animal fats (see point 14.2.4.2) or fish oil (category «other fish oils » see point 14.2.4.3), the supporting evidence may only specify that these products are in compliance with the requirements of a representative analysis per 2000 tons.

11. Nonconforming Products

When a batch does not meet the criteria laid down, it should:

- Undergo, within the company, a treatment until the food is safe again. If an adequate treatment is not possible, the batch should not be used within the animal feed sector; or
- Receive another destination (within or outside the company). If sold to another company, the salesman is obligated to inform the customer, in writing, regarding any non-conformities; or
- Be destroyed.

Installations (e.g. storage areas) where contaminated batches have been detected, must be thoroughly cleaned, to avoid re-contamination of the next batches. To this end, a procedure should be in place.



Production of feed materials

For a foodstuff, or residual flow, originating from the food industry, intended for feed, a hazard analysis should be performed. This should determine whether the product as such can be used as feed material.

12. Adaptation of products or the production process

Upon developing new products, food security must be safeguarded. This can be achieved by applying the HACCP principles.

When adjustments are made to already existing production processes or formulations, HACCP principles should be applied.

These changes must be duly examined, verified, validated, qualified as suitable and approved prior to implementation. Results shall be kept in writing, and all necessary actions shall be registered.



Very Small Companies are not required to keep records of these, though they should be able to motivate the changes in the framework of food safety.

13. Specific provisions for medicated feed

Special provisions are applicable to companies, putting medicated animal feed into circulation. These requirements are mainly based on the provisions set out in the Royal Decree of December 21, 2006 – Preparation, putting into circulation and use of medicated feed. For further details it is recommended to consult the legislation (cf. 'AT-01: Legislation').



Compound feed manufacturers making use of a fine dosing device

Compound feed manufacturers, making use of a fine dosing device, for the production of their medicated feed, should apply the procedure, as regards this dosing device. The procedure is described in 'AT-13: Procedure for the Use of a Fine dosing device'.

In Belgium, the Federal Agency for the safety of the food chain (FASFC) and the Professional Association of Manufacturers of compound feed (APFACA) have signed the Convention on medicated feed.

Belgian manufacturers of medicated feed, concerned by this Convention, must also apply document 'AT-14: Target values for medicated feed'.

13.1. Responsibility

A person having the competences, as described in the legislation for medicated animal feed, should supervise the manufacturing of such animal feed.

On Belgian Territory, the person responsible for the production of medicated feed may:

- a. Offer his services only to one single establishment in the feed sector, approved for the production of medicated feed;
- b. Not be holder of a pharmacy;
- c. In his capacity as a veterinary, non prescribe medicated feed originating from the establishment, where he himself controls the production.

Copies of diploma and contract between the company and responsible person must be available within the company.


13.2. Purchase of medicated premixtures

In Belgium, medicated animal feed may be manufactured exclusively, on the basis of medicated pre-mixtures:

- For which an authorization, as regards the placing on the market of medicated feed conforming the Belgian legislation in force, has been issued; or
- For which an authorization, as regards commercializing has been issued in a Member State of the European Union; or
- Used, in conformity with the prescription issued by the veterinary, and relating to the treatment of animals, by means of exception under his direct personal responsibility (application of the cascade system (Royal Decree of 14/12/2006 on medicinal products for

human and veterinary use – art. 230 and 231)).

For each batch of medicated pre-mixture, a sample of 50 grams must be taken, which is to be stored during 3 months, counting from the last supply of the produced medicated animal feed.

|  Sampling by the Belgian producer of medicated animal feed | | |
|--|-------------|--|
| Incoming Product | Quantity | Storage life |
| Medicated pre-mixture | 50 g /batch | 3 months, starting from the last supply of a batch of medicated animal feed. |

The following elements should be indicated on the sample:

- Name of medicated pre-mixture;
- Producer's name and address;
- Date of reception;
- Quantity;
- Registration number;
- Batch number;
- Invoice number.

Sample must be sealed conforming conditions indicated in the instruction notice.

13.3. Storage of medicated premixtures

Medicated pre-mixtures shall be stored in secured rooms clearly separated from other pre-mixtures in conformity with storage conditions which may mentioned on the label.

Equipment, used for storage of medicated pre-mixtures, must be cleaned before re-use, to avoid cross-contamination.

13.4. Production and storage of medicated feed

Medicated feed may only be manufactured by an approved manufacturer on the basis of a prescription, issued by a veterinary.

In Belgium, the prescription will be valid for maximum 15 days, starting from the date of its drafting, and this for one single treatment.

In some well defined cases (see 'AT-01: Legislation'), the veterinary in charge of guiding the livestock farm, will hand over the prescription (not signed by the livestock holder) directly to the medicated feed manufacturer.

The Belgian compound feed manufacturer must respect:

- The composition and the quantity prescribed by the attending veterinary;
- Any additional conditions. These conditions may be laid down by FASFC or may relate to conditions linked to the use of the medicated pre-mixture.

In his production of medicated animal feed, the producer will only use animal feed which can be mixed with medicated pre-mixtures in order to obtain a stable and homogeneous product.

When manufacturing one medicated feed, only one legally registered medicated pre-mixture may be used. By way of derogation, several medicated pre-mixtures may be used at the same time for manufacturing one single medicated feed, if prescribed by the veterinarian.

During formulation and manufacturing of medicated feed, the producer must ensure that the animal feeds to be used does not contain the same antibiotic or coccidiostats as those used as an active substance in the medicated pre-mixture.

When producing medicated animal feed, the manufacturer must ensure that the daily dose of active substances is contained in a quantity of animal feed corresponding to at least half the daily feed ration of the animals treated. For ruminants, this is at least half the daily requirement of non mineral complementary feeding stuffs.

If the medicated pre-mixture is incorporated by way of a fine dosing device, upon delivery of the compound feed, then document 'AT-13: Procedure for the Use of a Fine Dosing device', is applicable.

If it concerns a 'manufacturing' intended for shipment, from Belgium to another Member State of the European Union, the use of medicated pre-mixtures, authorized in this particular Member State, are authorized.

Batches of medicated animal feed, intended for the intra-Community trade, are stored separately, in a clearly indicated manner. In order to avoid confusion, any batch shall be accompanied by a clearly visible panel, indicating in a legible "export".

13.5. Registrations

In Belgium, the white and yellow sections of the prescription must be completed by the medicated feed manufacturer and indicate:

- Name and address of the medicated feed manufacturer;
- Batch number;
- Production date;
- Storage life;
- Date of supply;
- Signature of the medicated feed manufacturer;

These sections must accompany the delivery.

For electronic prescriptions, all sections may be white. In this case, below each section, the reference «copy for producer of medicated feed» (equivalent white section) and « Copy to person responsible for the animals» (equivalent yellow section), should respectively be indicated.

The person responsible for the production of medicated feed, must ensure that details and date of operations and analyses are registered, in compliance with the legislation on medicated feed.

The register is updated daily, and kept by the company for five years, after its closing date.

For each medicated pre-mixture, following data must be registered:

- Supplier's name and address;
- Purchased quantity of the medicated pre-mixture, with invoice number, batch number;
- Quantity of the used medicated pre-mixture and batch number, plus the quantity, type and batch number of the produced medicated animal feed;
- Quantity of the medicated pre-mixture in stock.

For medicated feed, following data must be registered:

- Type, quantity and batch number of produced medicated animal feed;
- Type, quantity and batch number of supplied medicated animal feed, with:
 - o Name and address of the receiver;
 - o Number of veterinary prescription;
 - o Veterinary's name and address;
- the quantity of the medicated animal feed in stock.

These records are kept on a separate sheet for each medicated pre-mixture and each medicated animal feed. The accounting is updated daily, without blanks and without erasing or overwriting, and thus kept at the disposal of FASFC for five years.

The company will keep all veterinary prescriptions ranked in chronological order for 5 years.

The manufacturer of medicated feed, located in Belgium, must also make a declaration, to the Federal Agency for Medicines and Health Products (FAMHP), by means of an ad hoc form (cf. 'AT-01: Legislation'), conforming modalities provided by the FAMHP:


- for each medicated pre-mixture:
 - o the name of the pre-mixture;
 - o the quantity used (weight).
- for each medicated animal feed produced:
 - o species and animal categories, for which the feed is intended;
 - o the quantity produced weight;
 - o the batch number.

13.6. Control of medicated feed

For the production of a medicated animal feed, a sample of 500 grams per production must be taken. Sample must be kept during 4 months, starting from the production date. Sample should include the following:

- name of medicated animal feed;
- production date;
- quantity;
- registration number;
- batch number of incorporated medicated pre-mixture;
- active substance content.

This sample must be sealed and stored in optimal conditions.

|  Sampling of medicated animal feed by a Belgian producer | | |
|--|----------------------------------|---|
| Outgoing product | Quantity | Storage life |
| Medicated animal feed | 500 g / manufactured batch | 4 months starting from the manufacturing date |

 **Analyses of medicated animal feed**

| Parameter | Frequency |
|--|---|
| Active substance content (with the aim of assuring stability and homogeneity) per medicated pre-mixture used | once per 100 tons of manufactured medicated animal feed; or if this quantity is not reached, every 6 months. |

13.7. Supply of medicated animal feed

The medicated feed manufacturer (Belgian operator) must have the white and yellow sections of the prescription, signed by the livestock farmer, responsible for the animals. He will keep the white section.



Absence of farmer

Last name, first name and/or the signature for receipt, of the responsible person who is absent (or of his delegate), are not required, if the latter has been informed prior to the delivery. In this case, the supplier will replace these indications, by the delivery hour.

The labelling of medicated feed must comply with the labelling requirements detailed in Section 10 (see Regulation (EC) No 767/2009 – Chapter IV).

The following, additional, information must also be included on the label:

1. indication: «Medicated animal feed intended for ...» (indication the animal species for which it is intended);
2. approval number of the medicated feed manufacturer;
3. potential precautionary measures;
4. the active substance expressed in milligrams per kilogram of feed, the user manual and the method for conservation as well as the indications required in the authorization for marketing the medicated pre-mixture(s) used, and required by the regulation in force, including the waiting period.

When using containers, the information indicated on the accompanying documents is sufficient.

The medicated animal feed must be supplied directly from the production area to the livestock farmer, in a, previously, emptied silo. After filling, the inlet opening of the silo will receive a label indicating the above mentioned information. Once this is done, the driver will indicate this information on the transport document.

The delivery of medicated animal feed, must be performed in packages or containers, closed in such a way, that upon opening, the seal will be broken and therefore cannot be reused.

In order to prevent cross-contamination, the containers and vehicles, used for transport of medicated animal feed, must be cleansed after use.

If the incorporation of the medicated pre-mixture is performed by way of a fine dosage apparatus,

then upon delivery of the compound feed, document 'AT-13: Procedure for the Use of the Fine Dosage Device' must be applied.

14. The placing on the market of animal feed considered to be critical OR animal feed subject to monitoring OF «dioxin and dioxin-like PCB's»

14.1. Additives belonging to the group «binding agents, anti-caking agents and coagulants» (Additives E559, E561, E566, E598 and E568)

14.1.1. Specific conditions

A Belgian company using for own production or for placing on the market,, additives E559, E561, E566, E598 en/of E568 , which have not been purchased from a supplier (e.g. import) authorized conforming the Belgian legislation, must satisfy the following specific conditions:

- Have a representative sample taken, at the operation site, by an inspection body accredited conforming ISO 17020 standards, or an ISO 17025 accredited laboratory who will be performing the analyses, in 3 specimen of 500 grams, of each batch of "animal feed considered critical", placed on the market for the first time in Belgium . The sample must be sealed and labeled by the relevant institution, and should be kept in storage conditions, excluding any abnormal alteration or decomposition;
- Entrust the first specimen to a laboratory, approved by FASFC, or accredited pursuant to ISO 17025 standards;
- Have the laboratory determine the level of dioxins (for additives E559, E561, E566, E598 and E568);
- Notify the FASFC, in case of exceeding standards of undesirable substances, and keep the related batch readily available;
- keep second specimen for the purpose of traceability (readily available for subsequent control), and third specimen for the defending of his rights, this for a period of six months following the date of marketing;
- If, product is intended for own production, keep the analysis report, and indicate name of institution who performed the sampling;
- For the marketing of a batch of feed considered critical, add the analysis report, and indicate name of institution who performed the sampling.

14.1.2. Register

A Belgian company, purchasing or producing animal feed considered to be critical must keep a register, with indication of:

- Nature and quantity of produced or purchased animal feed, considered to be critical;
- Manufacturing or reception date;
- In case a company purchases this feed: if applicable, number of batch or production part, in case of continuous production, as well as the precise indication of the storage area (tank number, silo number, etc.) in case of bulk storage;
- In case of placing on the market, following production of this feed: name and address of the purchasers and batch number or the production part, in case of continuous production as well as the precise indication of the storage area (tank number, silo number, etc.) in case of bulk storage.

14.1.3. Samples

A Belgian company should keep, during 6 months, a representative sample of 500 g of each batch of animal feed considered to be critical, and should keep it available for any controls. The analysis report accompanying the batch, must also be kept.

| ! Sampling of animal feed considered critical by a Belgian company | |
|---|---------------|
| Incoming product | Storage life |
| Feed materials: animal fat, fish meal, fish soluble (concentrated), fish oils and fish oils, refined, hardened) | min. 6 months |
| Additives belonging to the group 'Binders, diluents and coagulants': E559, E561, E566, E598 and E568 | min. 6 months |

The samples, should be identified in a clear manner, and stored in such a way so as to exclude or reduce, any modification as regards their characteristics, to a minimum.

14.2. Monitoring of dioxins and dioxin-like pcb's

14.2.1. Definitions

Products derived from Category 3 animal fats:

Feed materials derived from animal fats and processed in accordance with Regulation (EC) No 1069/2009. This definition is not applicable to processed animal proteins.

Representative analysis per 2000 (or 5000) tonnes:

This notion does not define the size of the batch, but rather the minimum analysis frequency. The representative analysis per 2000 (or 5000) tonnes is independent of the batch size. A batch may be smaller or larger than 2000 (or 5000) tonnes while the representative analysis has an upper limit of 2000 (or 5000) tons. A sample is called representative if it has the same characteristics as the products under examination.

| i How to interpret a 'representative analysis per 2000 (or 5000) tonnes' in practice? |
|---|
| <p>For a representative analysis per 2000 (or 5000) tonnes, as referred to in the monitoring, one should ask the question whether a correct image can be formed of those products for which the sample is required to be representative. If one can only produce a homogenous batch of 500 tonnes, an analysis per 500 tonnes should be performed. If one can produce a homogeneous quantity of 2000 (or 5000) tonnes, but only wishes to determine 4 (or 10) batches of 500 tonnes, than 1 analysis shall be sufficient for the entire production of 2000 (or 5000) tonnes. If one wishes to produce a homogeneous quantity of 3000 tonnes, than 2 analysis should be performed on 2 different parts of this batch. The representative analysis per 2000 tonnes indicates the upper limit to be analyzed.</p> <p>The operator should be able to demonstrate in his Auto-control system, that the analysis are representative per maximum 2000 (or 5000) tonnes.</p> |

14.2.2. Animal feed concerned

Feed⁷ concerned by the monitoring established in the European Union are:

- Crude coconut oil;
- Products derived from oils and fats of vegetable origin;
- Animal fats;
- Products derived from animal fats;
- Fish oils with the exception of refined oil;
- Products derived from fish oil, with the exception of refined oil;
- Fats and oils recovered from the food industry;
- Blended oils and fats;
- Products derived from oils and fats ;
- Compound feed for food producing animals (other than blended oils and fats).



Fat blending and compound feed

In accordance with the definition of a compound feed (see AC-00: Introduction¹), certain mixtures of fat should be considered as compound feed.

They may e.g. include the following mixtures:

- Oil or fat with one or more fatty acids;
- Fat of animal origin (terrestrial animals) with fish oil;
- Vegetable oil with animal fat or fish oil.

A blending of products belonging to the same entry in Part C of the European Catalogue of feed materials (same number) which are derived from the same plant or animal species must be considered as a feed material. If known, the label should indicate the species, from which the product is manufactured. The same principle applies for a mixture of two animal fats or two fish oils.

If this mixture of fats is to be considered a compound feed, this will also mean that all standards and intervention thresholds applicable to compound feed, will also apply to this fat mixture.

14.2.3. Type of establishment subject to monitoring

The establishments listed below, placing feed on the market, are required to check the levels of dioxins and dioxin-like PCBs of different products entering or leaving their installations:

- Feed business operators processing crude vegetable fats and oils;
- Feed business operators producing animal fat including animal fat processors;
- Feed business operators producing fish oil;
- Oleochemical industry placing feed on the market;
- Biodiesel industry placing feed on the market;
- Fat blending establishments;
- Producers of compound feed for food producing animals (other than fat blending) ;
- Importers placing feed on the market (cf. document 'AC-03 : Trade in animal feed').



Production process applied within the company

¹ In Belgium, these different feedingstuffs, with the exception of compound feed are also considered as «Animal feed considered critical» within the meaning of Royal Decree of 21/02/2012 and accompanying Annex V.

Such monitoring should be applied regardless of the production process applied in the company. Any process, making use of incoming products and/or resulting in outgoing products may be affected, as soon as they receive a destination for use in feed.
E.g.: animal fat is the main production for a fat rendering institution, and is affected by the monitoring. Animal fat can also be a by-product, obtained during the production of gelatin. Also this fat should be monitored if the company places the «feed material» on the market.

14.2.4. Products to be analysed

The monitoring may vary, depending on the production and import activities of the company. The table below provides an overview of the monitoring in function of the activity and nature of the products in question.

In some cases, a distinction is also made between incoming (purchased) products and outgoing (manufactured) products.

Unless specified otherwise, the control must be exerted on incoming and outgoing products as listed in the tables.

Control of incoming products should be performed regardless of their origin (EU or non-EU).

The maximum size of the batches received must, under no circumstances be exceeded, unless demonstrated that the volume of a homogeneous load, exceeds the maximum size authorized for a batch, and that the batch was the subject of a representative sample. In that case, the analysis results of the representative samples of this batch, are acceptable.



Derogation

1. Where a feed business operator has documentary proof that a batch of a product or all components of a batch entering his establishment has already been analyzed at an earlier stage of production, processing or distribution, or are in compliance with the requirements, the feed business operator shall be released from the obligation to analyze this batch and shall analyze it according to the general HACCP principles (see 'AT-04: Practical realization of the HACCP-plan');
2. If all incoming batches of products, mentioned in point 14.2.4.7, entering a production process of compound feed have been analysed in accordance with the European monitoring, and if it can be assured that the production process, handling and storage does not increase the dioxin contamination, the compound feed manufacturer shall be released from the obligation to analyze the final product (1% of outgoing batches), and instead analyse it according to his own HACCP plan.

The participants concerned shall have their products analyzed in an accredited laboratory in order to determine the sum of dioxins and dioxinlike PCBs.

The analysis must be performed according to the methods of sampling and analysis laid down at European level (See Regulation (EC) No 152/2009).

Any batch of products analysed shall be accompanied by documentary proof that these products, or all of its constituent components, have been analysed or have been submitted for analysis to an accredited laboratory.

The proof of analysis shall unambiguously link the delivery and the batch or batches tested. In particular, when the delivery is obtained from more than one batch or component, the documentary

proof to be provided shall be a proof for each of the components of the delivery. In case where the testing is performed on the outgoing product, the proof that the product has been analysed shall be the analytical report.

Any delivery of products concerned by the carrying out of a representative analysis for a maximum tonnage (2000 or 5000 tonnes depending on the case) shall be accompanied by a proof that these products are in compliance with the requirements. If required, the proof of analysis that include the batch or batches delivered must be consigned to the consignee when the operator receives the analysis from the authorised laboratories.

14.2.4.1. Feed business operators processing crude vegetable fats and oils

| Outgoing products | Frequency | Maximum batch size |
|--|--------------------|--------------------|
| Products derived from oils and fats of vegetable origin except for glycerine,, lecithin, gums, acid oils from chemical refining, soap stocks, used filter aids and used bleaching earth) | All batches (100%) | 1000 tonnes |

The incoming and outgoing products not concerned by this specific monitoring, are subject to a monitoring put in place as part of the HACCP analysis (cf. documents 'AT-04 : Practical realisation of the HACCP Plan' and 'AT-05 : Monitoring').

14.2.4.2. Feed business operators producing animal fat including animal fat processors,

| Outgoing products | Frequency |
|---|--|
| Animal fats from an approved food business establishment | 1 representative analysis per 5000 tonnes with a minimum of one representative analysis per year |
| Animal fats and products derived from Category 3 material | 1 representative analysis per 5000 tonnes with a minimum of one representative analysis per year |

The incoming and outgoing products not concerned by this specific monitoring, are subject to a monitoring put in place as part of the HACCP analysis (cf. documents 'AT-04 : Practical realisation of the HACCP Plan' and 'AT-05 : Monitoring').

14.2.4.3. Feed business operators producing fish oil

| Incoming products | Frequency | Maximum batch size |
|-------------------|-----------|--------------------|
|-------------------|-----------|--------------------|

| Incoming products | Frequency | Maximum batch size |
|--|--------------------|--------------------|
| Fish oil produced from: <ul style="list-style-type: none"> - Products derived from fish oil other than refined fish oil; - Fisheries with no monitoring history, of unspecified origin or from the Baltic Sea; - Fish by-products from establishments manufacturing fish for human consumption that are not EU approved; - Blue whiting or menhaden. | All batches (100%) | 1000 tonnes |

| Outgoing products | Frequency | Maximum batch size |
|--|--|--------------------|
| Fish oil produced from: <ul style="list-style-type: none"> - Products derived from fish oil other than refined fish oil; - Fisheries with no monitoring history, of unspecified origin or from the Baltic Sea; - Fish by-products, from establishments manufacturing fish for human consumption, that are not EU approved; - Blue whiting or menhaden. | All batches (100%) | 1000 tonnes |
| Fish oil (not referred to in the previous point) | 1 representative analysis per 2000 tonnes | |
| Products derived from crude fish oil (other than refined fish oil) | All batches (100%) | 1000 tonnes |
| Fish oil decontaminated by an officially approved treatment (within the meaning of Regulation (EC) No 767/2009 - Art20 §1 and Annex VIII) | Company monitoring based on his HACCP plan | |

The incoming and outgoing products not concerned by this specific monitoring, are subject to a monitoring put in place as part of the HACCP analysis (cf. documents 'AT-04 : Practical realisation of the HACCP Plan' and 'AT-05 : Monitoring').

14.2.4.4. Oleochemical industry placing feed on the market

| Incoming products | Frequency | Maximum batch size |
|---|--------------------|--------------------|
| Animal fats (other than those controlled by producers of animal fats (cf. 14.2.4.2) or by the importers (cf. 14.2.4.8)) | All batches (100%) | 1000 tonnes |

| Incoming products | Frequency | Maximum batch size |
|--|--------------------|--------------------|
| Fish oils (other than those controlled by operators of fish oil (cf. 14.2.4.3) or by the importers (cf. 14.2.4.8) ² | All batches (100%) | 1000 tonnes |
| Oils and fats recovered from food business operators | All batches (100%) | 1000 tonnes |
| Blended fats and oils intended for use in animal feed | All batches (100%) | 1000 tonnes |

| Outgoing products | Frequency | Maximum batch size |
|--|--------------------|--------------------|
| Products derived from oils and fats (other than <ul style="list-style-type: none"> - glycerine, - pure distilled fatty acids from splitting, - crude fatty acids from splitting, - fatty acids esterified with glycerol, - mono and diglycerides of fatty acids, - salts of fatty acids) | All batches (100%) | 1000 tonnes |

The incoming and outgoing products not concerned by this specific monitoring, are subject to a monitoring put in place as part of the HACCP analysis (cf. documents 'AT-04 : Practical realisation of the HACCP Plan' and 'AT-05 : Monitoring').



Production of additives and specific monitoring

Chemical establishments that produce additives from incoming products listed in the table below, are concerned by this specific monitoring.

Given the definition 'products derived from oils and fats', feed additives should not be considered as such. The specific monitoring related to products derived from oils and fats (outgoing products) shall therefore not apply.

14.2.4.5. Biodiesel industry placing feed on the market

| Incoming products | Frequency | Maximum batch size |
|--|--------------------|--------------------|
| Animal fats (other than those controlled by producers of fats (cf. 14.2.4.2) or by the importers (cf. 14.2.4.8)) | all batches (100%) | 1000 tonnes |

² Not applicable to refined oils originating from European establishments that are subject to monitoring.

| Incoming products | Frequency | Maximum batch size |
|--|--------------------|--------------------|
| Fish oil (other than those controlled by producers of fish oil (cf. 14.2.4.3) or by the importers (cf. 14.2.4.8)) ³ | all batches (100%) | 1000 tonnes |
| Oils and fats recovered from food business operators | all batches (100%) | 1000 tonnes |
| Blended fats and oils intended for use in feed | all batches (100%) | 1000 tonnes |

| Outgoing products | Frequency | Maximum batch size |
|---|--------------------|--------------------|
| Products derived from oils and facts (except for : <ul style="list-style-type: none"> - glycerine, - lecithin, - gums, - acid oils from chemical refining, - soap stocks) | all batches (100%) | 1000 tonnes |

The incoming and outgoing products not concerned by this specific monitoring, are subject to a monitoring put in place as part of the HACCP analysis (cf. documents 'AT-04 : Practical realisation of the HACCP Plan' and 'AT-05 : Monitoring').

14.2.4.6. Fat blending establishments

| Incoming products | Frequency | Maximum batch size |
|--|--------------------|--------------------|
| Crude coconut oil | All batches (100%) | 1000 tonnes |
| Products derived from oils and fats (except for <ul style="list-style-type: none"> - glycerine, - lecithin - gums, - acid oils from chemical refining - filter aids, - bleaching earth, - soap stocks) | All batches (100%) | 1000 tonnes |
| Animal fats (other than those controlled by the producers of fats (cf. 14.2.4.2) or by the importers (cf. 14.2.4.8)) | All batches (100%) | 1000 tonnes |
| Fish oils (other than those controlled by producers of fish oil (cf. 14.2.4.3) or by the | All batches (100%) | 1000 tonnes |

³ Refined oils originating from European establishments subject to monitoring are not affected.

| Incoming products | Frequency | Maximum batch size |
|--|--------------------|--------------------|
| importers (cf. 14.2.4.8)) ³ | | |
| Oils and fats recovered from food business operators | All batches (100%) | 1000 tonnes |
| Blended fats and oils intended for use in feed | All batches (100%) | 1000 tonnes |

| Outgoing products | Frequency | Maximum batch size |
|---|--------------------|--------------------|
| Blended fats and oils intended for use in animal feed | All batches (100%) | 1000 tonnes |

Fat blending establishments may choose the monitoring of:

- either incoming products; **or**
- either outgoing products.

The choice must be formalized in a written procedure, and communicated to the competent authority, in charge of the control of approved establishments (in Belgium the FASFC). The company may, only after notifying the competent authority, change the inspection strategy.

The incoming and outgoing products not concerned by this specific monitoring, are subject to a monitoring put in place as part of the HACCP analysis (cf. documents 'AT-04 : Practical realisation of the HACCP Plan' and 'AT-05 : Monitoring').

14.2.4.7. Producers of compound feed for food producing animals

| Incoming products | Frequency | Maximum batch size |
|---|--------------------|--------------------|
| Crude coconut oil | All batches (100%) | 1000 tonnes |
| Products derived from oils and fats (other than: <ul style="list-style-type: none"> - glycerine, - lecithin, - gums, - acid oils from chemical refining, - crude fatty acids from splitting, - pure distilled fatty acids from splitting, - filter aids, - bleaching earth, - soap stocks) | All batches (100%) | 1000 tonnes |
| Animal fats (other than those controlled by the producers of fats (cf. 14.2.4.2) or by the | All batches (100%) | 1000 tonnes |

| Incoming products | Frequency | Maximum batch size |
|--|--------------------|--------------------|
| importers (cf. 14.2.4.8)) | | |
| Fish oils (other than those controlled by producers of fish oil (cf. 14.2.4.3) or by the importers) ³ | All batches (100%) | 1000 tonnes |
| Oils and fats recovered from food business operators | All batches (100%) | 1000 tonnes |
| Blended fats and oils intended for use in feed | All batches (100%) | 1000 tonnes |

| Outgoing products | Frequency |
|--|-------------------|
| Compound feed containing following products ; <ul style="list-style-type: none"> - crude coconut oil - products derived from oils and fats (other than glycerine, lecithin, gums) - Animal fats (other than those controlled by the producers of fats (cf. 14.2.4.2) or by the importers (cf. 14.2.4.8)) - Fish oils (other than those controlled by producers of fish oil (cf. 14.2.4.3) or by the importers) - Oils and fats recovered from food business operators - Blended fats and oils intended for use in feed - Acid oils from chemical refining - Crude fatty acids from splitting - Pure distilled fatty acids from splitting - Filter aids - Bleaching earth - Soap stocks | 1% of the batches |

The monitoring modalities as described in point 14.2.4.7 are not related to blended fats complying with the definition of compound feed. These blended fats must be analyzed in compliance with point 14.2.4.6.

The production of compound feed for pet animals is not affected by such specific monitoring.

The incoming and outgoing products not concerned by this specific monitoring are subject to a monitoring put in place as part of the HACCP analysis (cf. documents 'AT-04 : Practical realisation of the HACCP Plan' and 'AT-05 : Monitoring').

14.2.4.8. Importers placing the following feed on the market

| Imported products | Frequency | Maximum batch size |
|--|--------------------|--------------------|
| Crude coconut oil | all batches (100%) | 1000 tonnes |
| Products derived from oils and fats (other than : <ul style="list-style-type: none"> - glycerine, - lecithin, - gums, - acid oils from chemical refining, - crude fatty acids from splitting, - pure distilled fatty acids from splitting, - soap stocks | all batches (100%) | 1000 tonnes |
| Animal fats | all batches (100%) | 1000 tonnes |
| Fish oils | all batches (100%) | 1000 tonnes |
| Oils and fats recovered from food business operators | all batches (100%) | 1000 tonnes |
| Blended fats and oils | all batches (100%) | 1000 tonnes |
| Tocopherols extracted from vegetable oil and tocopheryl acetate made thereof | all batches (100%) | 1000 tonnes |

The imported products not concerned by this specific monitoring, are subject to a monitoring put in place as part of the HACCP analysis (cf. documents 'AT-04 : Practical realisation of the HACCP Plan' and 'AT-05 : Monitoring').

14.2.5. Sampling

The sampling can be done by an operator or by an independent third (f.i. independent accredited body).

A Belgian operator applying the monitoring described in points 14.2.2 and 14.2.4, must satisfy the following specific requirements^{4 5}:

- To have an inspection body accredited ISO 17020 collect on the premises of his exploitation site a representative sample in three specimen of 500 grams of the animal feed in question. The monitoring may also be performed by an ISO 17025 accredited laboratory in charge of the analysis. The sample must be kept in storage conditions excluding any abnormal composition or alteration;
- To entrust the first specimen to a laboratory, approved by the FASFC, or to a laboratory accredited for ISO 17025;
- To have the laboratory determine the levels of dioxins and dioxin-like PCBs, conforming methods laid down in the European legislation (cf AT-01: Legislation);
- To report, any exceeding of standards and intervention thresholds for undesirable substances, to the FASFC, and keep the batch in question available for relevant control;

⁴ Annex V of the Royal Decree of 21/02/2006 laying down the conditions for approval and authorization for feed business operators.

⁵ These specific requirements for monitoring shall not apply to feed business operators, placing feed materials of animal origin on the market, exclusively intended for pet animals.

- To keep a second specimen for traceability reasons (available for a subsequent control) and a third specimen for possible defense rights, and this for a period of 6 months following the date of the placing on the market of the batch in question.

Belgian feed business operators may obtain a derogation in connection with the obligation to have the sampling performed by an inspection body accredited ISO 17020, or by a laboratory accredited for 17025, as described above.

Subject to a prior agreement with the FASFC, these companies may proceed themselves with the sampling of 3 specimen of 500 grams of produced feed if satisfying the following requirements:

- 1) The feed business operator shall be responsible for all production steps of the following feed:
 - Products derived from vegetable oils, other than refined oil, glycerol, lecithin and gums and manufactured by establishments processing crude vegetable oils, covered in point 14.2.4.1;
 - Products derived from vegetable oils, other than refined oil, glycerol, lecithin and gums, manufactured by the oleochemical and biodiesel industry, covered in point 14.2.4.4 and 14.2.4.5 ;
 - Animal fats and products derived from Category 3 material, manufactured by producers of animal fats, covered in point 14.2.4.2;
 - Fish oils and products derived from crude fish oils, manufactured by operators of fish oil, covered in point 14.2.4.3;
 - Fat mixtures produced by fat blending establishments, covered in point 14.2.4.6;
 - Compound feed for food producing animals covered in 14.2.4.7;
- 2) The company must demonstrate its ability to collect a representative sample of feed, produced in accordance with a written procedure established in the Auto-control system inherent to the company;
- 3) The operator must have his Auto-control system validated for the production activity in question, an must not have been the subject of a suspension during the past 2 years;
- 4) Finally the company, for the past two years, should not have been the subject of a sanction, related to a non-conformity such as Auto-control, notification required or traceability.

14.2.6. Register

A company located in Belgium shall also keep records of the following information:

Nature and quantity of produced or purchased feed;

Date of production or reception;

If applicable, number of batch or specifically defined production fraction in case of continuous production, and an accurate description of storage location (tank number, silo number, etc.) in case of bulk storage;

Name and address of customers to whom feed has been delivered, and number of batch or specifically defined production fraction in case of continuous production and an accurate description of storage location (tank number, silo number, etc.) in case of bulk storage.

15. The placing on the market of diet feed

15.1. Definitions

Particular nutritional purpose:

The aim is to satisfy the specific nutritional needs of animals whose process of assimilation, or absorption metabolism is temporarily or irreversibly impaired and, therefore, may benefit from the ingestion of feed adapted to their condition.

Animal feed with a particular nutritional purpose (or diet feed):

Animal feed, satisfying a particular nutritional purpose based on their specific composition, or on the procedure applied, and because of this, are clearly distinguished from regular animal feed.

15.2. Principles

Diet feed, are either feed materials or compound feed

This matter is regulated by two European Directives, a transposition into national legislation is therefore necessary.

In Belgium, the specific legislation as regards this type of animal feed included in the Royal Decree of 20 July 1995, laying down the list of destinations as regards the animal feed with a particular nutritional purpose (link to the consolidated text as regards this decision see AT-01: Legislation’).

The list regarding the particular nutritional purpose, is included in various texts. This list consist of 6 columns:

1. Particular nutritional purpose;
2. The essential nutritional characteristics expected in feed material, in order to satisfy the particular nutritional purpose (indicated in column 1);
3. The species or category of animals, for whom the particular nutritional purpose is intended;
4. The mandatory labeling requirement as regards animal feed with a particular nutritional purpose;
5. The specific recommended duration for use of this diet feed;
6. Other possible indications.

When a company decides upon indicating specific terms such as « diet » or « particular nutritional purpose », or one of the particular nutritional purposes listed above, mentioned on the label, all requirements will be applicable.

The specific requirements are included in part A of the annex to the Legal text.



Use of additives in animal feed with a particular nutritional purpose.

The level of additives in feed materials, may only exceed the authorized maximum level (see point 3) if use of this additive in that particular quantity is required in order to achieve the particular nutritional purpose.

All additives used in diet feed, should be authorized for both, animal feed as well as for animal species in question, to which the particular nutritional purpose is applicable.

For example, if aiming at a particular nutritional purpose for ruminants, an authorized additive for ruminants will be required. The use of an additive, which possibly may be of interest in achieving the intended target, but is only authorized for cats and dogs, must therefore not be used.

The use of additives, intended to satisfy a particular nutritional purpose, is not limited to this type of approval. It is however, important to note, that there are other restrictions, or prohibitions for using this type of animal feed. (e.g. feed materials of animal origin ('AT-11: Animal byproducts').

15.3. Specific approval

Manufacturers of diet feed should have a specific approval (equivalent to the approval required for the production of certain pre-mixtures), if exceeding the maximum levels as regards the following

additives (100 times or 5 times the maximum level for complete animal feed) for the following additives:

- Zootechnical additives:, as intended in annex I, point 4d) (other Zootechnical additives), Regulation (EC) No 1831/2003;
- All coccidiostats and histomonostats;
- All growth promoters;
- Vitamins A and D;
- Trace elements Cu and Se.

15.4. Labeling

The labeling as regards animal feed with a particular nutritional purpose is regulated by both the Regulation (EC) NO 767/2009, and by the specific legislation for this feed.

- Animal feed intended for a particular nutritional purpose such as compound feed or feed materials, must comply with the general labeling provisions (see point 10);
- The labeling of animal feed with a particular nutritional purpose also includes the qualification « diet » (diet feed, complete diet feed, supplementary diet feeds);
- According to the intended objective, the label must contain all specific indications in relation to this objective, and should be included in the list of destinations;
- The labeling should mention that before using the feed, or before any extension of the period for use, the advice of a nutritionist or veterinarian should be sought.

The company placing diet feed on the market, must pay particular attention to the claims included in the labeling (point 10).