AT-13

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Procedure for the use of a fine dosing device

Feed Chain Alliance
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DOCUMENT HISTORY

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AT-13 : Procedure for the use of a fine dosing device

1. Legal basis

Conforming annex III, III 2, c) of the Belgian Royal Decree of February 21, 2006, laying down rules as regards approval and authorization of establishments active in the feed sector (see 'AT-01: Legislation'), and laying down additional provisions regarding the manufacturing of medicated feed.

2. Objective

This document aims at determining the procedure in view of administrating medication to farmed animals, based on the veterinary's prescription, through a medicated pre-mix, which is incorporated by means of a fine dosing device, upon delivery of the compound feed to the stock farmer, as provided in 4.2 of "Council Directive No. 90/167/EEC of March 26, 1990 laying down rules governing the preparation, placing on the market, and use of medicated feeding stuffs". In Belgium this fine dosing device may only be used as a part, and under the responsibility of an establishment, approved for the manufacturing of medicated feed, as laid down in the Belgian Royal Decree of January 16, 2006 'laying down detailed rules recognition, approval and prior registrations issued by the Federal Agency for the Safety of the Food Chain facility

3. Application scope

The application of a fine dosing device should be considered as an alternative to the production of medicated compound feedingstuffs within the compound feed unit of the company, always falling under the responsibility of the manufacturer of medicated feed. Here, the rights and obligations are applicable to the manufacturer of medicated feed, to the veterinary and to the breeder, as laid down in the Royal Decree of 21 December 2006 "laying down rules governing the preparation, placing on the market, and use of medicated feeding stuffs". The compound feed manufacturer must be in possession of an approval for manufacturing medicated feed, issued by the (in Belgium- FASFC approval (Royal Decree of January 16, 2006)); the combination(s) truck – fine dosing device must be identified (in the approval), via the truck's registration plate, as well as the brand and unique identification number of the fine dosing device. The specific conditions governing the approval of feed companies "for the approval establishments active in the animal feed sector" manufacturing medicated feed, are listed in the Royal Decree of February 21, 2006 "laying down rules as regards approval and authorization of establishments active in the animal feed sector".

4. The procedure to be followed by the establishment (animal feed sector)

4.1. Medicated pre-mixture

a. In Belgium, only registered medicated pre-mixtures are authorized, conforming article 3 of the Royal Decree of December 21, 2006 "laying down rules governing the preparation, the placing on the market, and use of medicated feed";
b. In accordance with the specifications of annex III to Royal Decree of February 21, 2006 "laying down the rules as regards the approval and authorization of establishments active in the animal feed sector", a sample of 50 g. is taken from each batch of medicated pre-mixtures.

4.2. Procedure

a. Compound feed to which, upon delivery, medicated pre-mixtures have been added, is loaded into a given cell of the truck; which is defined by the production manager (or delegate), in the management computer of the fine dosing device;
b. The production manager (or his delegate) will determine, based on the veterinary's prescription, the required quantity of medicated pre-mixture;
c. the production manager (or his delegate), will put the medicated pre-mixture, in a quantity determined based on the previous item, into a portable storage vessel, which is then closed and sealed by digital recognition (e.g. bar code). The storage vessel is designed in such a manner, that it can only be opened by the production manager (or his delegate), if opened by a third party, it could not be resealed by this third party;
d. Several storage vessels can be transported per trip, enabling the specific mixing with the compound feed, stored in various cells of the truck. The production manager (or his delegate) will organize the sequence of the stops.
e. The production manager (or his delegate), must affix a unique identification code to each storage vessel. This unique identification code is linked to the abovementioned cell of the truck, containing the compound feed, the batch number, the medicated pre-mixture, the weight of the compound feed and medicated pre-mixture, and the place of delivery.
f. Labeling and delivery is performed in the same way as for medicated feed (article 4 of the Belgian Royal Decree of December 21, 2006 "laying down rules governing the preparation, placing on the market, and use of medicated feeding stuffs");
g. Upon delivery to the farm, the driver will install the storage vessel (with digital recognition of the identification code) on the fine dosing device.
h. The fine dosing device can only be activated if the identification code corresponds to the data in the control computer;
i. After each use, the driver must visually inspect the fine dosing device, for the presence of pre-mixture and compound feed residues, if necessary, he must perform an appropriate cleaning so that the risk of residue formation, as a result of cross-contamination is negligible. Residues originating from cleaning, may be considered as waste and thus treated as such. These residues may under no circumstances be re-incorporated into feed.
j. In case of problems, the production manager (or his delegate) must be present on-site.
k. Barrels (containers) must be cleaned between each use.

4.3. Registration

a. Records for each medicated pre-mixture and medicated feed, must be kept conforming the specifications laid down in annex III to the Belgian Royal Decree of February 21, 2006 "laying down rules as regards approval and authorization of establishments active in the animal feed sector";
b. The records are updated per trip, on a daily basis, by indicating the identification number of the truck (registration plate), the fine dosing device (identification number), and the installed storage vessels (affixed unique identification code). These records must be kept for 5 years.

4.4. Monitoring, analysis and periodic determination of dosing accuracy

a. The driver shall, for each delivery of medicated feed, take a representative sample of 500g upon unloading the bulk truck. The production manager (or his delegate) will provide a suitable recipient containing all required information along with the transport, conforming the specifications laid down in annex III to the Belgian Royal Decree of February 21, 2006, "laying down rules as regards approval and authorization of establishments active in the animal feed sector";

b. Upon returning to the plant, the sample is handed over to the production manager (or his delegate), and the compound feed manufacturer will preserve this sample for a period of at least 4 months, conforming the specifications laid down in annex III to the Belgian Royal Decree of February 21, 2006, *"laying down rules as regards approval and authorization of establishments active in the animal feed sector"*;
c. According to the specifications indicated in annex III to the Belgian Royal Decree of February 21, 2006 *"laying down rules as regards approval and authorization of establishments active in the animal feed sector"*. For each medicated pre-mixture used, an analysis, per 100 ton of manufactured medicated feed, is performed (or at least every six months) to verify the level of the active substance;
d. Based on the available analyses, performed on manufactured medicated compound feed, dosing accuracy of the fine dosing device is determined on a yearly basis. The annually obtained accuracy should be at least 90% (measurement uncertainty not included). At the back of this document, an example is given of the annual determination accuracy.
e. At least every 6 months, a complete homogeneity control should take place, by means of a calculation based on information on the unloading process of the bulk product, as well as information on dosing the medicated pre-mixture, stored in the data base. A test, for complete homogeneity of manufactured medicated feed, must be performed at least every 3 years.
f. The production manager, must take into account the data obtained from previous items, ensuring compliance of each medicated feed batch, with the prescribed content of active substance(s) (taking the analysis uncertainty into account). The minimum authorized dosing accuracy of 90 % does not involve a relaxation of the guarantee(s) on the content(s) of active substance(s).

5. Criteria which a fine dosing device must satisfy

It is the responsibility of the manufacturer of the fine dosing device, to demonstrate compliance with the criteria mentioned below. He will issue a certificate stating the criteria and operating instructions, with the exception of the in item 5.1 mentioned calibration (for which a separate certificate is provided).

5.1. Calibration

Initially the weighing equipment is calibrated after assembling. After which, the fine dosing device is re-calibrated at least annually (in accordance with the specifications given by the manufacturer). Re-calibration is also required, following repairs to the fine dosing device, and after its removal to another truck (in latter case, a modification to the agreement is necessary). This re-calibration is done by the manufacturer of the fine dosing device, or by a competent body, approved by the manufacturer, who must ensure that the medicated pre-mixture can be dosed and injected with great precision upon unloading the compound feed.

If the fine dosing device is calibrated, the body/manufacturer, in charge of the calibration, will issue a separate attestation, indicating the following data as a minimum: name of body/manufacturer performing the calibration, truck registration number, brand of the fine dosing device, unique identification number of the fine dosing device, and date of calibration and of previous calibration.

5.2. Monitoring

The fine dosing device should allow, the taking of a representative sample upon unloading of the medicated feed, conforming the description indicated in point 4.4.

5.3. Dosing accuracy of the fine dosing device (initial adjustment)

The fine dosing device should allow the uniform distribution of the pre-mixture on compound feed. The manufacturer of the fine dosing device, must perform a dosing accuracy test, using a reference device per type of compound feed (meal, crumb, grain), and per type of medicated premixture. The obtained accuracy must be at least 90% (measurement uncertainty not included).

5.4. Cleanliness - Cleaning

The fine dosing device must be designed in a way, that residue formation as a result of cross-contamination, is negligible.

The storage vessels must be designed in a way as to make cleaning easier.

5.5. Security

The security system is designed in a way that:

a. Each fine dosing device must be provided with a unique engraved identification number.
b. Each storage vessel, when filling in the establishment, must receive a unique identification code, and must be closed by the production manager (or his delegate), in a non re-closable way.
c. The storage vessel can only be opened if correctly installed on the fine dosing device;
d. The storage vessel cannot be removed from the fine dosing device, until the feed is complete unloaded;
e. The fine dosing device can only be activated, if the correct storage vessel is installed and connected to the previously indicated compound feed cell;
f. The fine dosing device can only be activated if the weight in the compound feed cell and in the storage vessel correspond to the indicated dosage;
g. Each use of the fine dosing device is logged in a data base. This data can be consulted on the company computer. It contains information relating to the company, time period, cell, pre-mixture, identification number of the storage vessel, time period for possible cleaning of the fine dosing device, location, silo number, weight of compound feed and of medicated pre-mixture, course of the unloading process, ...;
h. If there are no medicated feed deliveries, then use of the fine dosing device is excluded.

6. Training

The driver performing deliveries, using the fine dosing device, must have received an appropriate training. This training will include taking representative samples, handling the fine dosing device, and other information listed in this procedure as regards the delivery itself. This training must be recorded.

7. Identification of the combination truck – fine dosing device, in the approval for the manufacture of medicated animal feed

For the incorporation of the combination(s) truck – fine dosing device, in the approval for the manufacture of medicated animal feed, the compound feed manufacturer must submit the following additional documents/data to his Provincial control unit (PCE/UPC).

a. Certificate by the manufacturer of the fine dosing device indicating the necessary criteria and operating instructions as referred to in point 5 of this procedure.
b. Calibration certificate.

c. A signed statement by the person responsible for the production of medicated feed, certifying that he will follow this procedure when using the fine dosing device for the incorporation of medicated pre-mixtures in the compound feed (stockbreeder).
d. A signed statement by the person responsible for the production of medicated feed, certifying that the drivers, who will be performing deliveries using the fine dosing device, have received an appropriate training.

The combination(s) concerned must be specified in the approval act.

In Belgium, changes in connection with used, or no longer used combination(s) truck - fine dosing device, must be communicated by the company producing the medicated feed, to its Provincial control unit. After which an amendment to the approval act will take place.

8. Document to accompany at all times the lorry with the fine dosage apparatus

a. A copy of the approval act of the medicated feed manufacturer, mentioning the combination lorry – fine dosage apparatus;
b. Certificate by the manufacturer of the fine dosage apparatus, mentioning the necessary criteria and operating instructions referred to in point 5 of this procedure;
c. The calibration certificate, referred to in point 5.1.

Example of the yearly determination of the accuracy of the device:
Use of 2 medicated pre-mixtures (A and B) in the year 20XX;

Manufacture of a quantity of medicated compound feed, prescribed by a veterinary (active substance **dose** prescribed);

For each medicated pre-mixture, an **analysis** is conducted per100 tons of medicated compound feed manufactured (or at least every 6 months) for determining the amount of active substance;

% = (**analysis** (ppm) / **dose** (ppm)) * 100

% deviation compared to 100 % = absolute value of (100 - **%**)

Periodical accuracy 20XX = 100 – (∑ **% deviation compared to 100 %** / number of analyses)

Example :

Year 20XX	**Pre-mixture A**				**Pre-mixture B**			
	Dose (ppm)	Analysis (ppm)	%	% deviation compared to 100%	Dose (ppm)	Analysis (ppm)	%	% deviation compared to 100%
100 tons	100	90	90	**10**	200	200	100	**0**
100 tons	150	145	97	**3**	200	210	105	**5**

100 tons	200	205	103	**3**	200	205	103	**3**
∑ % deviation compared to 100%								**24%**
Periodical precision 20XX =								**96%**