Requirements for handling of medicated feedingstuffs[1]

Regulation No. 150 of the Minister of Agriculture of 10 December 2007

RTL[2], 20.12.07, 98, 1641

Entered into force 01.01.08

The Regulation is established on the basis of subsection 13 (4) of the Feedingstuffs Act.

§ 1. Requirements for manufacture of medicated feedingstuffs

(1) Enterprises engaged in the manufacture of feedingstuffs shall have approval for the manufacture of feedingstuffs pursuant to the Feedingstuffs Act.

(2) Medicated feedingstuffs may only be manufactured from those pre-mixes for medicated feedingstuffs concerning which the State Agency of Medicines has issued marketing authorisation for a veterinary medicinal product and which have been registered at the State Agency of Medicines as veterinary medicinal products (hereinafter authorised pre-mix) and on the basis of a prescription for medicated feedingstuffs issued by a veterinarian in accordance with Regulation No 21 of the Minister of Agriculture of 23 February 2005 "Conditions and procedure for the use of medicinal products and medicated feedingstuffs for the prevention and treatment of animal disease".

(3) A person engaged in the manufacture of medicated feedingstuffs (hereinafter manufacturer) shall ensure that:

1) good manufacturing practice is adhered to in the enterprise;

2) upon manufacture of medicated feedingstuffs only feedingstuffs or mix of feedingstuffs conforming to the requirements and authorised pre-mixes are used under the conditions of authorisation for use issued on the basis of the Medicinal Products Act;

3) the manufactured medicated feedingstuff forms a homogeneous and stable mix;

4) the undesirable combined effect of the different ingredients of the medicated feedingstuff is precluded;

5) the storability of the medicated feedingstuff conforms to the published conditions;

6) the feedingstuff used in the manufacture of manufacture of the medicated feedingstuffs does not contain the same coccidiostat as the one used as an active substance in the manufactured medicated feedingstuffs ;

7) the daily dose of active substance of the medicinal product is contained in a quantity of feedingstuffs corresponding to at least half of the daily feed ration of the animals treated or, in the case of ruminants, corresponding to at least half of the daily requirement of nonmineral complementary feedingstuffs.

(4) A sample shall be taken from each lot of medicated feedingstuffs in order to verify the conformity, homogeneity, stability and storability of the medicated feedinstuffs. The samples shall be preserved in the enterprise for six months as of the date of manufacture of the feedingstuffs.

§ 2. Requirements for packaging and labelling of medicated feedingstuffs

(1) Medicated feedingstuffs may be placed on the market only in properly sealed packages or containers. A packaging shall be closed in such a way that it is damaged upon opening and the package cannot be reused. A container shall be sealed in such a way that upon the existence of a seal it is damaged when the container is opened.

(2) Upon placing on the market of medicated feedingstuffs, the word "medicated feedingstuffs", the instructions for the use of the medicated feedingstuffs, indication to the storage time and withdrawal period shall be set out on the labelling of the packaging in addition to the labelling of complete and complementary feedingstuffs. Upon carriage of feedingstuffs in a container, the abovementioned information shall be indicated on the document accompanying the lot.

§ 3. Requirements for storage and issue of medicated feedingstuffs

(1) Medicated feedingstuffs and the authorised pre-mix used in the manufacture thereof shall be stored in separate and firmly closable premises or in hermetically sealed containers prescribed for such products.

(2) Only persons with appropriate training may engage in the storage and issue of medicated feedingstuffs.

(3) The medicated feedinstuffs issued shall be packaged and labelled in compliance with the requirements of § 2.

(4) Medicated feedingstuffs shall only be issued to a person engaged in the retail or wholesale of medicinal products (hereinafter distributor), a veterinarian or a stockfarmer who holds an activity licence issued on the basis of the Medicinal Products Act.

(5) Both, the manufacturer and the distributor shall issue to a stockfarmer a copy of the prescription for medicated feedingstuffs together with the date of issue marked on the prescription, whereas the original copy shall be kept by the manufacturer.

(6) A manufacturer or distributor shall issue medicated feedingstuffs directly to a stockfarmer on the basis of prescription and in the prescribed quantity.

(7) As an exception, a veterinarian may send a prescription for medicated feedingstuffs to the manufacturer or distributor by fax. In such case, the manufacturer or distributor shall verify the correctness of the prescription for medicated feedingstuffs by contacting the veterinarian. The veterinarian shall send one original copy of the prescription for medicated feedingstuffs to the manufacturer or distributor within the following week. The distributor shall forward the original copy of the prescription sent thereto to the manufacturer.

§ 4. Requirements for placing medicated feedingstuffs on market

(1) Only medicated feedingstuffs packaged and labelled in conformity with the requirements specified in § 2 may be placed on the market.

(2) It is prohibited to repackage medicated feedingstuffs upon placing on the market.

(3) Medicated feedingstuffs may be placed on the market only by distributors.

(4) The container used upon placing medicated feedingstuffs on the market shall be cleaned before reuse in order to prevent cross contamination or undesirable combined effect of substances.

§ 5. Requirements for imported medicated feedingstuffs

(1) Medicated feedingstuffs may be imported only by a person holding an activity licence for wholesale trade in medicinal products issued by the State Agency of Medicines.

(2) The pre-mix used in the imported medicated feedingstuffs shall have marketing authorisation issued by the State Agency of Medicines and the pre-mix shall be registered in the State Agency of Medicines or the imported medicated feedingstuffs or the pre-mix thereof shall have a single import permit or authorisation for use issued by the State Agency of Medicines.

(3) Imported medicated feedingstuffs shall be accompanied by a document issued by a competent supervisory authority of the country of origin which shall set out:

1) the name, address of residence or seat of the manufacturer or distributor;

2) the name and quantity of the medicated feedingstuff;

3) the type of animal for which the medicated feedingstuff is intended;

4) the name and composition of the authorized medicated pre-mix;

5) the dosage of the medicated pre-mix authorized in the medicated feeding stuff;

6) the name, address of residence or seat of the recipient of medicated feedingstuff;

7) the text "It is hereby certified that the medicated feedingstuff has been manufactured by an approved enterprise in accordance with the requirements of European Union Directive 90/167/EEC";

8) the place and date of preparation of the document;

9) the stamp of the competent supervisory authority;

10) the name, title and signature of the person who prepared the document;

(4) The documents concerning the information listed in subsection (3) shall be preserved in the enterprise for at least three years as of the date of receipt of the documents.

§ 6. Keeping account of medicated feedingstuffs manufactured and placed on the market

(1) The manufacturer shall maintain a register on the authorised pre-mixes used upon manufacture and the manufactured, stored and issued medicated feedingstuffs. The following information shall be entered in the register:

1) the name and quantity of the authorised pre-mix used upon manufacture and the feedingstuff;

2) the name, quantity and lot number of the manufactured medicated feedingstuff;

3) the period and conditions of storage of the medicated feedingstuff;

4) the name, personal identification or registry code, address of the residence or seat, and telephone number of the person to whom the medicated feedingstuff was issued;

5) if necessary, the name and postal address of the veterinarian who prescribed the medicated feedingstuff;

6) the results of self-check carried out upon manufacture.

(2) Distributors shall keep record of their activities which shall set out the information specified in clauses (1) 2) - 5).

(3) The register of the information listed in subsection (1) and (2) shall be preserved in the enterprise for at least three years from the date of the last entry.

§ 7. Entry into force of Regulation

This Regulation enters into force on 1 January 2008.

[1]Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ L 92, 07.04.1990, pp. 42–48)

[2] RTL = *Riigi Teataja Lisa = Appendix to the State Gazette*