SCHEDULE 5 Regulation 14

Medicated feedingstuffs and specified feed additives

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Signature

Explanatory Note

Scope and interpretation

1.—(1) This Schedule applies in relation to the following (referred to in this Schedule as "specified feed additives") when used as feed additives—

(a) coccidiostats;

(b) histomonostats; and

(c) all other zootechnical additives except—

(i) digestibility enhancers;

(ii) gut flora stabilisers; and

(iii) substances incorporated with the intention of favourably affecting the environment.

(2) It also applies in relation to the manufacture and placing on the market of feedingstuffs containing a veterinary medicinal product.

(3) In this Schedule—

"premixture" means a mixture of a veterinary medicinal product or a specified feed additive with feed materials, intended for further mixing with feedingstuffs before being fed to animals;

"zootechnical additive" means any additive used to maintain animals in good health or favourably affect their performance.

Enforcement of Regulation (EC) No. 178/2002

2.—(1) For the purposes of Council Regulation (EC) No. 178/2002 (of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**1**)) the competent authority is the Secretary of State.

(2) Any person who contravenes any of the following provisions of that Regulation is guilty of an offence—

(a) Article 11 (requirements relating to imports);

(b) Article 12 (requirements relating to exports);

(c) Article 15(1) (prohibition on the placing on the market or feeding unsafe feed);

(d) Article 16 so far as it prohibits misleading labelling, advertising or presentation of feed;

(e) Article 18(2) and (3) (requirements of traceability) in so far as it relates to feed business operators; and

(f) Article 20 (responsibilities of feed business operators).

Enforcement of Regulation (EC) No. 1831/2003

3.—(1) For the purposes of Regulation (EC) No. 1831/2003 (of the European Parliament and the Council on additives for use in animal nutrition(**2**)) the competent authority is the Secretary of State.

(2) When she grants an authorisation under Article 3(2) of that Regulation the authorisation shall be in writing.

(3) Any person who contravenes any of the following provisions of that Regulation is guilty of an offence—

(a) Article 3(1) or Article 3(3) (the authorisation, conditions of use and labelling of specified feed additives);

(b) Article 12(1) or (2) (conditions relating to specified feed additives);

(c) Article 16(1) (labelling);

(d) Article 16(3) (additional labelling requirement);

(e) Article 16(4) (premixtures containing specified feed additives);

(f) Article 16(5) (packaging).

Enforcement of Regulation (EC) No. 882/2004

4. For the purposes of Regulation (EC) No. 882/2004 (of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules(**3**)) the competent authority is the Secretary of State.

(**1**) OJ No. L 31, 1.2.2002, p. 1.
(**2**) OJ No. L 268, 18.10.2003, p. 29.
(**3**) Corrected version at OJ No. L 191, 28.5.2004, p. 1.

Enforcement of Regulation (EC) No. 183/2005

5.—(1) For the purposes of Regulation (EC) No. 183/2005 (of the European Parliament and of the Council laying down requirements for feed hygiene(**4**)) the competent authority is the Secretary of State.

(2) Any person who contravenes any of the following provisions of that Regulation is guilty of an offence—

(a) Article 5 (2), (5) and (6) (specific obligations);

(b) Article 6(1) as read with (2) and (3) (HACCP system);

(c) Article 7(1) (documents concerning the HACCP system);

(d) Article 9(2) (official controls, notification and registration);

(e) Article 11 (prohibition on operating without approval or registration);

(f) Article 17(2) (exemption from on-site visits);

(g) Article 18(3) (declaration of compliance);

(h) Article 23(1) (conditions relating to imports);

(i) Article 25 (feed produced for export to third countries).

(3) In accordance with Article 10(2) of that Regulation—

(a) a manufacturer incorporating a veterinary medicinal product into feedingstuffs, and

(b) any person acting as a distributor of feedingstuffs containing a veterinary medicinal product,

must be approved in the same way as a manufacturer incorporating specified feed additives or distributor of feedingstuffs containing specified feed additives.

(4) A manufacturer must ensure that, so far as is reasonably practicable, the active ingredient is evenly incorporated throughout the feedingstuffs and failure to do so is an offence.

(5) In the case of the refusal, suspension or revocation of an approval under the Regulation the representations procedure relating to a manufacturing authorisation in paragraph 6 of Schedule 2 shall apply.

Incorporation of a veterinary medicinal product into premixtures

6.—(1) Any person who incorporates a veterinary medicinal product into a premixture—

(a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there; and

(b) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive.

(2) It is an offence to fail to comply with this paragraph.

Incorporation of a veterinary medicinal product into feedingstuffs

7.—(1) Any person who incorporates a veterinary medicinal product (or a premixture containing a veterinary medicinal product) into feedingstuffs—

(a) must ensure that the feedingstuff has been prescribed in writing by a person authorised to prescribe the veterinary medicinal product;

(b) must incorporate in accordance with the summary of product characteristics, and must take account of any interactions listed there;

(**4**) OJ No. L35, 8.2.2005, p. 1.

(c) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive;

(d) must ensure that the veterinary medicinal product is incorporated in accordance with its marketing authorisation (unless it has been prescribed under the cascade) and the prescription, if any;

(e) must ensure that the daily dose of the veterinary medicinal product is contained in a quantity of medicated feedingstuffs corresponding to at least half the daily feed ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirements of non-mineral supplementary feedingstuffs.

(2) It is an offence to fail to comply with this paragraph.

Additional record keeping requirements relating to veterinary medicinal products

8.—(1) Any person who—

(a) incorporates a veterinary medicinal product into a premixture;

(b) incorporates a premixture containing a veterinary medicinal product into feedingstuffs; or

(c) incorporates a veterinary medicinal product into feedingstuffs,

shall maintain a daily record of—

(i) the types and quantities of all veterinary medicinal products (and specified feed additives, if any) and premixtures used in the manufacturing process;

(ii) the quantity of feedingstuffs and premixtures containing veterinary medicinal product manufactured that day;

(iii) the quantity held;

(iv) the quantity despatched;

(v) the name and address of the distributor, if there is one.

(2) Manufacturers who supply feedingstuffs incorporating a veterinary medicinal product shall record the names and addresses of persons supplied and keep a copy of the prescription.

(3) An approved distributor shall record daily—

(a) the types and quantities of all premixtures and feedingstuffs containing veterinary medicinal products bought and sold that day;

(b) the quantity held.

(4) He shall also record, in relation to each consignment supplied—

(a) the date of delivery;

(b) the name and address of each consignee;

(c) the type of feedingstuff or premixture supplied;

(d) the quantity;

(e) the type of veterinary medicinal product incorporated into the feedingstuff; and

(f) the expiry date.

(5) Records and prescriptions must be kept for five years.

(6) It is an offence to fail to comply with this paragraph.

Additional labelling requirement for premixtures containing a veterinary medicinal product

9. A label on a premixture containing a veterinary medicinal product must contain the information required under Article 16 of Regulation (EC) No. 1831/2003 and, in addition, the following——

(a) the words "medicated premixture";

(b) the proprietary name of the veterinary medicinal product and the authorisation number;

(c) the strength;

(d) the inclusion rate of the premixture into the feedingstuff;

(e) the level of the active ingredient in the final feed;

(f) warnings and contra-indications;

(g) withdrawal period;

(h) the expiry date;

(i) any special storage instructions;

(j) where a prescription is required, a statement to this effect;

and any person who supplies such a premixture not labelled in this way is guilty of an offence.

Labelling of feedingstuffs containing specified feed additives

10.—(1) Feedingstuffs containing a specified feed additive or a premixture containing a specified feed additive must be clearly and legibly labelled with the following—

(a) the name of the specified feed additive;

(b) the name of the active substance and the level incorporated in the feedingstuff;

(c) the withdrawal period if one is specified in the authorisation;

(d) the expiry date (if there are several additives with different expiry dates, the expiry date given must be the earliest expiry date);

(e) the name and approval number of the manufacturer or the distributor;

(f) any particulars concerning the proper use of the feedingstuffs specified in the authorisation of the specified feed additive.

(2) It is an offence to supply feedingstuffs not labelled in accordance with this paragraph.

Labelling of feedingstuffs containing a veterinary medicinal product

11.—(1) A feedingstuff containing a veterinary medicinal product must be clearly and legibly labelled with the following—

(a) the words "Medicated Feedingstuff";

(b) the proprietary name, authorisation number and inclusion rate (kg/t or mg/kg) of the veterinary medicinal product incorporated into the feed;

(c) the name and amount of the active substance (mg/kg) in the feed;

(d) the species of animal for which the feed is intended;

(e) warnings and contra-indications required by the marketing authorisation for the veterinary medicinal product;

(f) the withdrawal period;

(g) the expiry date;

(h) any special storage instructions required by the marketing authorisation;

(i) a statement to the effect that the feed must only be fed in accordance with a prescription written by a veterinary surgeon, where a prescription is required;

(j) the name and approval number of the manufacturer or the distributor.

(2) It is an offence to supply feedingstuffs not labelled in accordance with this paragraph.

Supply of specified feed additives

12.—(1) A manufacturer of specified feed additives may only supply them to a person approved to hold them in accordance with this Schedule.

(2) It is an offence to fail to comply with this paragraph.

Supply of premixture

13.—(1) A manufacturer of a premixture may only supply it to a person approved to hold it in accordance with this Schedule.

(2) It is an offence to fail to comply with this paragraph.

Supply of feedingstuffs containing a veterinary medicinal product

14.—(1) A manufacturer or distributor of feedingstuffs containing a veterinary medicinal product may only supply to—

(a) a person approved to hold them in accordance with this Schedule, or

(b) a person who keeps animals.

(2) If the veterinary medicinal product requires a prescription, the manufacturer or distributor may supply to another manufacturer or a distributor without a prescription, but may only supply to a person who keeps animals in accordance with a prescription.

(3) It is an offence to fail to comply with this paragraph.

Possession

15.—(1) It is an offence for any person other than a person holding the appropriate approval under this Schedule to be in possession of any—

(a) specified feed additive or veterinary medicinal product to which this Schedule applies;

(b) premixtures containing such an additive or a veterinary medicinal product; or

(c) feedingstuff containing a veterinary medicinal product unless supplied under these Regulations.

(2) It is an offence for any person other than a manufacturer or distributor to be in possession of a feedingstuff incorporating a veterinary medicinal product unless it has been supplied under a prescription.

Sampling and analysis

16.—(1) If any enforcement action is taken under this Schedule based on a sample, that sample must have been taken and analysed in accordance with Council Directive 76/371/EEC (establishing Community methods of sampling for the official control of feedingstuffs(**5**)).

(2) Unless otherwise specified in the marketing authorisation, it is a defence if the active substance in the sample is within the following tolerances—

(**5**) OJ No. L102, 15.4.76, p. 1.

(a) not exceeding 50 mg/kg of active ingredient: +/− 50%;

(b) exceeding 50 mg/kg but not exceeding 500 mg/kg: +/− 40%;

(c) exceeding 500 mg/kg but not exceeding 5g/kg: +/− 30%;

(d) exceeding 5g/kg but not exceeding 50g/kg: +/− 20%;

(e) exceeding 50g/kg: +/− 10%.

Storage

17.—(1) Any person who stores veterinary medicinal products intended for incorporation into feedingstuffs, or premixtures or feedingstuffs containing such veterinary medicinal products shall do so in a suitable storage area that is locked when not in use or in hermetic containers designed to store those products.

(2) It is an offence to fail to comply with this paragraph.

Packages and other containers

18.—(1) Any person placing feedingstuffs containing a veterinary medicinal product on the market in packages or containers must ensure that they are sealed in such a way that, when the package or container is opened, the seal is damaged.

(2) It is an offence to fail to comply with this paragraph.

Transport

19.—(1) In the case of feedingstuffs distributed by road tankers or in bulk the labelling requirements must be given in a document accompanying the feedingstuffs, and the transporter must hand over details when he delivers the feedingstuff unless these have already been provided to the purchaser.

(2) Any person transporting feedingstuffs containing veterinary medicinal products or specified feed additives in road tankers or similar containers must ensure that the vehicle or container is cleaned before any re-use if this is necessary to prevent undesirable interaction or contamination.

(3) In the case of a feedingstuff containing a veterinary medicinal product he must ensure that the vehicle is accompanied by documentation stating this.

(4) Any person operating an undertaking transporting feedingstuffs containing veterinary medicinal products or specified feed additives must give written instructions to drivers on how to load and unload vehicles so as to avoid cross-contamination, and take reasonable steps to ensure that the driver complies with those instructions.

(5) It is an offence to fail to comply with this paragraph.

Possession, placing on the market and use of feedingstuffs

20.—(1) It is an offence for any person to possess, place on the market or feed to animals any feedingstuffs incorporating veterinary medicinal products or specified feed additives unless they have been incorporated in accordance with this Schedule.

(2) It is an offence to feed to any animal, or buy or possess for the purpose of feeding to any animal, any feedingstuff containing a veterinary medicinal product or specified feed additive unless that veterinary medicinal product or specified feed additive is authorised for that species of animal and for the purpose for which it is used (unless prescribed under the cascade).

(3) This paragraph shall not apply in relation to feedingstuffs if the veterinary medicinal product has been incorporated in accordance with an animal test certificate or the feedingstuff has been imported in accordance with this Schedule.

Prescriptions for feedingstuffs containing a veterinary medicinal product

21.—(1) It is an offence to supply feedingstuffs containing a veterinary medicinal product except in accordance with a written prescription that contains the following in addition to the information required by paragraph 6 of Schedule 3—

(a) the manufacturer or the distributor;

(b) a statement that, if the validity exceeds one month, only 31 days supply may be provided at any time;

(c) the name, type and quantity of feedingstuffs to be used;

(d) the inclusion rate of the veterinary medicinal product and the resulting inclusion rate of the active substance;

(e) any special instructions for the stockfarmer;

(f) the percentage of the prescribed feedingstuffs to be added to the daily ration.

(2) A prescription for feedingstuffs is valid for three months or such shorter period as may be specified in the prescription.

(3) The prescription must be sufficient for only one course of treatment.

(4) If the prescription is for a period of longer than one month, the supplier may not provide more than one month's supply at any one time.

(5) The person who writes the prescription must—

(a) give a copy to the person incorporating the veterinary medicinal product or to the distributor;

(b) give one copy to the keeper of the animals to be treated;

(c) keep a copy himself.

(6) The person who writes the prescription must be satisfied that—

(a) there is no undesirable interaction between the veterinary medicinal product and any feed additive used in the feedingstuffs; and

(b) the active substance of the veterinary medicinal product is not the same as an active substance in any feed additive used in the feedingstuffs.

(7) For the avoidance of doubt, a veterinary surgeon may prescribe either a veterinary medicinal product authorised for that species and condition, or under the cascade.

(8) It is an offence to fail to comply with this paragraph.

Imports from third countries

22. No person shall import feedingstuffs containing a veterinary medicinal product from a third country, and it is an offence to fail to comply with this paragraph.

Trade between member States

23.—(1) No person shall bring in feedingstuffs containing a veterinary medicinal product from another member State unless—

(a) it has been manufactured in accordance with the provisions of Council Directive 90/167/EEC (laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community(**6**)) and Regulation (EC) No. 183/2005; and

(b) it uses a veterinary medicinal product that has the same quantitative and qualitative composition as a veterinary medicinal product authorised in the United Kingdom.

(2) It is an offence to fail to comply with this paragraph.

(**6**) OJ No. L92, 7.4.90, p.42.