SCHEDULE 5 Regulation 14

MEDICATED FEEDINGSTUFFS AND SPECIFIED FEED ADDITIVES

CONTENTS

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 feedingstuffs 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.

Commencement Information

I1 Sch. 5 para. 1 in force at 1.10.2006, see **reg. 1**

Enforcement of Regulation (EC) No. 178/2002

2.—(1) For the purposes of 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 feedingstuffs);

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

(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).

Commencement Information

I2 Sch. 5 para. 2 in force at 1.10.2006, see **reg. 1**

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

(3) It is an offence to be in possession of a specified feed additive, or a premixture or feedingstuffs containing a specified feed additive, unless the specified feed additive has been authorised under Regulation (EC) No. 1831/2003 or is for export to a third country.

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

(**1**) OJ No. L 31, 1.2.2002, p. 1.
(**2**) OJ No. L 268, 18.10.2003, p. 29.

(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).

Commencement Information

I3 Sch. 5 para. 3 in force at 1.10.2006, see **reg. 1**

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.

Commencement Information

I4 Sch. 5 para. 4 in force at 1.10.2006, see **reg. 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) or (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 from third countries);

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

(3) 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.

(4) 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 applies.

(**3**) Corrected version at OJ No. L 191, 28.5.2004, p. 1.
(**4**) OJ No. L 35, 8.2.2005, p. 1.

Commencement Information

I5 Sch. 5 para. 5 in force at 1.10.2006, see **reg. 1**

Approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products

6.—(1) It is an offence to incorporate a veterinary medicinal product into a premixture or feedingstuffs, or to act as a distributor of premixtures or feedingstuffs containing a veterinary medicinal product, without being approved to do so by the Secretary of State.

(2) The requirements of this paragraph do not apply in relation to a person who incorporates a veterinary medicinal product into feedingstuffs in domestic premises for feeding, on those premises—

(a) non-food-producing animals, or

(b) food-producing animals kept purely for domestic consumption.

(3) The provisions of Regulation (EC) No. 183/2005 apply to those producers and distributors in the same way as to persons approved under Article 9 of that Regulation.

(4) A manufacturer must ensure that, so far as is reasonably practicable, the veterinary medicinal product 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 this paragraph the representations procedure relating to a manufacturing authorisation in paragraph 6 of Schedule 2 applies.

Commencement Information

I6 Sch. 5 para. 6 in force at 1.10.2006, see **reg. 1**

Incorporation of a veterinary medicinal product into a premixture

7.—(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.

Commencement Information

I7 Sch. 5 para. 7 in force at 1.10.2006, see **reg. 1**

Incorporation of a veterinary medicinal product into feedingstuffs

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

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

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

(c) 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;

(d) 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 feedingstuffs 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.

Commencement Information

I8 Sch. 5 para. 8 in force at 1.10.2006, see **reg. 1**

Additional record keeping requirements relating to veterinary medicinal products

9.—(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,

must make a daily record of—

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

(ii) the quantity of feedingstuffs and premixture containing veterinary medicinal product manufactured that day.

(2) An approved distributor must make a daily record of—

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

(b) the quantity held.

(3) A manufacturer and distributor must also record, as soon as reasonably practicable, for each consignment supplied—

(a) the date of delivery;

(b) the name and address of each consignee (or, in the case of a manufacturer supplying to a distributor, the name and address of the distributor);

(c) the type of feedingstuffs or premixture supplied;

(d) the quantity;

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

(f) the expiry date.

(4) Records must be kept for five years.

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

Commencement Information

I9 Sch. 5 para. 9 in force at 1.10.2006, see **reg. 1**

Labelling a premixture containing a veterinary medicinal product

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

(a) the words "MEDICATED PREMIXTURE" in upper case letters;

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

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

(d) the inclusion rate into the feedingstuffs (or, where liquid is to be incorporated into the final feedingstuffs, the words "typical inclusion rate but refer to the prescription for the exact inclusion rate" or equivalent wording);

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

(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.

(2) If the premixture also contains a specified feed additive to which this Schedule applies it must also contain the information required under Article 16 of Regulation (EC) No. 1831/2003.

(3) It is an offence to supply such a premixture not labelled in accordance with this paragraph.

Commencement Information

I10 Sch. 5 para. 10 in force at 1.10.2006, see **reg. 1**

Labelling of feedingstuffs containing a specified feed additive

11.—(1) Feedingstuffs 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 and amount of the active substance (mg/kg) in the feedingstuffs;

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

(d) the 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 such feedingstuffs not labelled in accordance with this paragraph.

Commencement Information

I11 Sch. 5 para. 11 in force at 1.10.2006, see **reg. 1**

Labelling of feedingstuffs containing a veterinary medicinal product

12.—(1) Feedingstuffs containing a veterinary medicinal product must be clearly and legibly labelled with the following—

(a) the words "MEDICATED FEEDINGSTUFFS" in upper case letters;

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

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

(d) the species of animal for which the feedingstuffs are intended;

(e) warnings and contra-indications;

(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 feedingstuffs must only be fed in accordance with its prescription;

(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.

Commencement Information
I12 Sch. 5 para. 12 in force at 1.10.2006, see **reg. 1**

Supply of specified feed additives

13.—(1) A manufacturer or distributor 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.

Commencement Information
I13 Sch. 5 para. 13 in force at 1.10.2006, see **reg. 1**

Supply of premixture

14.—(1) A manufacturer or distributor 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.

Commencement Information
I14 Sch. 5 para. 14 in force at 1.10.2006, see **reg. 1**

Supply of feedingstuffs containing a veterinary medicinal product

15.—(1) A manufacturer (if his approval so permits) or distributor of feedingstuffs containing a veterinary medicinal product may only supply those feedingstuffs to—

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

(b) in accordance with a prescription as specified in paragraph 22, a person who keeps animals.

(2) He must keep the prescription for five years.

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

Commencement Information
I15 Sch. 5 para. 15 in force at 1.10.2006, see **reg. 1**

Possession

16.—(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) feedingstuffs containing such an additive or 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 feedingstuffs incorporating a veterinary medicinal product unless it has been supplied under a prescription.

Commencement Information
I16 Sch. 5 para. 16 in force at 1.10.2006, see **reg. 1**

Sampling and analysis

17.—(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—

(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%.

Commencement Information
I17 Sch. 5 para. 17 in force at 1.10.2006, see **reg. 1**

Storage

18.—(1) Any person who stores veterinary medicinal products intended for incorporation into feedingstuffs, or a premixture or feedingstuffs containing such veterinary medicinal products, shall

(**5**) OJ No. L 102, 15.4.76, p. 1.

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.

Commencement Information
I18 Sch. 5 para. 18 in force at 1.10.2006, see **reg. 1**

Packages and other containers

19.—(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.

Commencement Information
I19 Sch. 5 para. 19 in force at 1.10.2006, see **reg. 1**

Transport

20.—(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 feedingstuffs 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 feedingstuffs 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.

Commencement Information
I20 Sch. 5 para. 20 in force at 1.10.2006, see **reg. 1**

Possession, placing on the market and use of feedingstuffs

21.—(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.

Commencement Information

I21 Sch. 5 para. 21 in force at 1.10.2006, see **reg. 1**

Prescriptions for feedingstuffs containing a veterinary medicinal product

22.—(1) A prescription for feedingstuffs containing a veterinary medicinal product must be in writing (notwithstanding the provisions of paragraph 5 of Schedule 3) and must contain the following—

(a) the name and address of the person prescribing the product;

(b) the qualifications enabling the person to prescribe the product;

(c) the name and address of the owner or keeper of the animal;

(d) the species of animal, identification and number of the animals;

(e) the premises at which the animals are kept if this is different from the address of the owner or keeper;

(f) the date of the prescription;

(g) the signature or other authentication of the person prescribing the product;

(h) the name and amount of the product prescribed;

(i) the dosage and administration instructions;

(j) any necessary warnings;

(k) the withdrawal period;

(l) the manufacturer or the distributor of the feedingstuffs (who must be approved for the purpose);

(m) a statement that, if the validity exceeds one month, not more than 31 days supply may be provided at any time;

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

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

(p) any special instructions for the stockfarmer; and

(q) 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 into the feedingstuffs or to the distributor of the feedingstuffs;

(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.

Commencement Information

I22 Sch. 5 para. 22 in force at 1.10.2006, see **reg. 1**

Imports from third countries

23. 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.

Commencement Information

I23 Sch. 5 para. 23 in force at 1.10.2006, see **reg. 1**

Trade between member States

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

(a) they have 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) they only contain 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.

Commencement Information

I24 Sch. 5 para. 24 in force at 1.10.2006, see **reg. 1**

(**6**) OJ No. L 92, 7.4.90, p. 42.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2006, SCHEDULE 5.