SCHEDULE 5

Regulation 14

Medicated feedingstuffs and specified feed additives

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.

Enforcement of Regulation (EC) No 178/2002

2.—(1) For the purposes of **[**[F1]Regulation (EC) No 178/2002**]** the competent authority is the Secretary of State.

(2) No person may fail to comply with any of the following provisions of that Regulation—

(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).

Textual Amendments

F1 Words in Sch. 5 para. 2(1) substituted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(4)(a)**

Enforcement of Regulation (EC) No 1831/2003 E+W+S

3.—(1) For the purposes of **[**[F2]Regulation (EC) No 1831/2003**]** the competent authority is the Secretary of State.

(2) An authorisation under Article 3(2) of that Regulation must be in writing.

(3) No person may possess 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 **[**[F3]another**]** country.

(4) No person may fail to comply with any of the following provisions of that Regulation—

(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).

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F2 Words in Sch. 5 para. 3(1) substituted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(4)(b)**

F3 Word in Sch. 5 para. 3(3) substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(35)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Enforcement of Regulation (EC) No 1831/2003 N.I.

3.—(1) For the purposes of **[**[F18]Regulation (EC) No 1831/2003**]** the competent authority is the Secretary of State.

(2) An authorisation under Article 3(2) of that Regulation must be in writing.

(3) No person may possess 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) No person may fail to comply with any of the following provisions of that Regulation—

(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).

Extent Information

E7 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F18 Words in Sch. 5 para. 3(1) substituted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(4)(b)**

Enforcement of [[F4]Regulation (EU) 2017/625] E+W+S

4. For the purposes of **[**[F5] Regulation (EU) 2017/625**]** the competent authority is the Secretary of State.

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F4 Words in Sch. 5 para. 4 heading substituted (E.) (14.12.2019) by The Official Controls (Animals, Feed and Food, Plant Health Fees etc.) Regulations 2019 (S.I. 2019/1488), regs. 1(1), 27(d)(ii); and said words substituted (W.) (31.1.2020) by The Official Controls (Animals, Feed and Food, Plant Health Fees etc.) (Wales) Regulations 2020 (S.I. 2020/44), regs. 1(2), **24(1)(d)(ii)**; and said words substituted (S.N.I.) (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) (No. 2) Regulations 2020 (S.I. 2020/1631), regs. 1(2), **3(4)(b)**

F5 Words in Sch. 5 para. 4 substituted (E.) (14.12.2019) by The Official Controls (Animals, Feed and Food, Plant Health Fees etc.) Regulations 2019 (S.I. 2019/1488), regs. 1(1), 27(d)(ii); and said words substituted (W.) (31.1.2020) by The Official Controls (Animals, Feed and Food, Plant Health Fees etc.) (Wales) Regulations 2020 (S.I. 2020/44), regs. 1(2), **24(1)(d)(i)**; and said words substituted (S.N.I.) (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) (No. 2) Regulations 2020 (S.I. 2020/1631), regs. 1(2), **3(4)(b)**

[[F19]Enforcement of Regulation (EU) 2017/625 N.I.

4. For the purposes of Regulation (EU) 2017/625 the competent authority is the Secretary of State.**]**

Extent Information

E8 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F19 Sch. 5 para. 4 substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(15)(b)**

Enforcement of Regulation (EC) No 183/2005

5.—(1) For the purposes of **[**[F6]Regulation (EC) No 183/2005**]** the competent authority is the Secretary of State.

(2) No person may fail to comply with any of the following provisions of that Regulation—

(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 10(1) (approval of feed business establishments);

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

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

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

(i) Article 23(1) (conditions relating to imports from third countries);

(j) 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.

(4) In the case of the refusal, suspension or revocation of an approval under the Regulation the appeals procedure relating to a manufacturing authorisation in regulation 30 applies.

Textual Amendments

F6 Words in Sch. 5 para. 5(1) substituted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(4)(d)**

Enforcement of Regulation (EC) No 767/2009

6. No person may contravene Article 8 of Regulation (EC) No 767/2009 of the European Parliament and of the Council in relation to feedingstuffs containing specified feed additives.

Approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products

7.—(1) For the purposes of Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community(**1**) the competent authority is the Secretary of State.

(2) No person may incorporate a veterinary medicinal product into a premixture or feedingstuff, or act as a distributor of premixtures or feedingstuffs containing a veterinary medicinal product, without being approved to do so by the Secretary of State.

(3) The conditions which govern approval of feed business establishments under Regulation (EC) No 183/2005 laying down requirements for feed hygiene(**2**) also govern approval of manufacturers and distributors under sub-paragraph (2).

(**1**) OJ No L 92, 7.4.1990, p. 42.
(**2**) OJ No L 35, 8.2.2005, p. 1.

(4) The Secretary of State shall conduct inspections of manufacturers and distributors approved under sub-paragraph (2) basing the frequency of inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

(5) A manufacturer must ensure that, so far as is reasonably practical, the veterinary medicinal product is evenly incorporated throughout the feedingstuffs.

(6) The provisions of this paragraph do not apply in relation to any person breeding or selling ornamental fish not intended for human consumption provided that the person does not use more than a total of 1kg of veterinary medicinal product annually for that purpose.

(7) In the case of the refusal, suspension or revocation of an approval under this paragraph the appeals procedure relating to a manufacturing authorisation in regulation 30 applies.

Incorporation of a veterinary medicinal product into a premixture

8. 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.

Top dressing

9. No person may promote or label any veterinary medicinal product, or anything containing a veterinary medicinal product, as being suitable for top dressing (that is, sprinkling it on to feedingstuffs without thoroughly incorporating it) unless the summary of product characteristics specifically permits this use.

Incorporation of a veterinary medicinal product into feedingstuffs

10. 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 complementary feedingstuffs.

Additional record keeping requirements relating to veterinary medicinal products

11.—(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—

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

(e) 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; and

(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.

Labelling a premixture containing a veterinary medicinal product

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

(a) the words "MEDICATED PREMIXTURE" (or, if it is to be labelled as "complementary feedingstuffs" under legislation implementing Council Directive 79/373/EEC on the marketing of compound feedingstuffs(**3**), "MEDICATED COMPLEMENTARY FEEDINGSTUFFS") 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 range of acceptable inclusion rates of the premixture into the final feedingstuffs, the range of acceptable levels of the active ingredients in the final feedingstuffs and the words "refer to the prescription for the exact inclusion rate" or equivalent wording;

(e) warnings and contra-indications;

(f) the withdrawal period, and a statement that, if the prescription requires a longer withdrawal period, that is the one that applies;

(g) the expiry date;

(h) any special storage instructions;

(i) where a prescription is required, a statement to this effect.

(2) If there is more than one veterinary medicinal product used, the longest withdrawal period must be shown on the label.

(3) 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(**4**).

(**3**) OJ No L86, 6.4.1979, p. 30.
(**4**) OJ No L268, 18.10.2003, p. 29. Regulation (EC) no 1831/2003 was last amended by Article 29 of Regulation (EC) No 767/2009 (OJ No L229, 1.9.2009, p. 1.)

(4) No person may supply such a premixture unless it is labelled in accordance with this paragraph.

Labelling of feedingstuffs containing a specified feed additive

13. No person may contravene the labelling requirements of Article 15 and Article 17 of Regulation (EC) No 767/2009 of the European Parliament and of the Council.

Labelling of feedingstuffs containing a veterinary medicinal product

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

(a) the words "MEDICATED COMPLETE FEED" in upper case letters, or where feedingstuffs are to be labelled as a complementary feedingstuff and intended to be fed to animals without further mixing with feed materials, the words "MEDICATED COMPLEMENTARY FEEDINGSTUFF";

(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, and a statement that, if the prescription requires a longer withdrawal period, that is the one that applies;

(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) If there is more than one veterinary medicinal product used, the longest withdrawal period must be shown on the label.

(3) If the feedingstuff also contains a specified feed additive to which this Schedule applies it must also contain the information required by Articles 15 and 17 of Regulation (EC) No 767/2009 of the European Parliament and of the Council.

(4) No person may supply feedingstuffs unless they are labelled in accordance with this paragraph.

Supply of specified feed additives

15.—(1) No person other than the person who manufactured a specified feed additive or an approved distributor may supply a specified feed additive.

(2) The person who manufactured the specified feed additive may only supply it to—

(a) an approved distributor;

(b) an approved premixture manufacturer or an approved complementary feedingstuffs manufacturer; or

(c) a feedingstuff manufacturer approved to mix a specified feed additive directly into feedingstuff.

(3) An approved distributor may only supply it to—

(a) another approved distributor;

(b) an approved premixture manufacturer or an approved complementary feedingstuffs manufacturer; or

(c) a feedingstuff manufacturer approved to mix a specified feed additive directly into feedingstuff.

Supply of premixture

16.—(1) No person other than the person who manufactured a premixture or an approved distributor may supply a premixture.

(2) The person who manufactured the premixture may only supply it to—

(a) an approved distributor; or

(b) a feedingstuff manufacturer approved to incorporate that premixture.

(3) An approved distributor may only supply it to—

(a) another approved distributor; or

(b) a feedingstuff manufacturer approved to incorporate that premixture.

Supply of a complementary feedingstuff

17.—(1) No person other than—

(a) the person who manufactured a complementary feedingstuff containing a specified feed additive; or

(b) an approved distributor

may supply a complementary feedingstuff containing a specified feed additive.

(2) The person who manufactured such complementary feedingstuff may only supply it to—

(a) an approved distributor; or

(b) a feedingstuff manufacturer registered to incorporate that complementary feedingstuff or approved to incorporate a premixture.

(3) An approved distributor may only supply it to—

(a) another approved distributor, or

(b) a feedingstuff manufacturer registered to incorporate that complementary feedingstuff or approved to incorporate a premixture.

(4) In this paragraph "complementary feedingstuff" has the meaning given in Article 3 of Regulation EC No 767/2009.

Supply of feedingstuffs containing a veterinary medicinal product

18.—(1) No person other than the person who manufactured the feedingstuffs or an approved distributor may supply feedingstuffs containing a veterinary medicinal product.

(2) The person who manufactured the feedingstuff may only supply it to—

(a) an approved distributor; or

(b) a person who keeps animals for feeding to those animals.

(3) A distributor may only supply it to—

(a) another approved distributor; or

(b) a person who keeps animals for feeding to those animals.

(4) Supply to a person who keeps animals must be in accordance with a written prescription as specified in the following paragraph.

(5) If a 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.

(6) No manufacturer or distributor may supply a feedingstuff to anyone not specified in this paragraph, or otherwise than in accordance with this paragraph.

(7) The person supplying the feedingstuff must keep the prescription for five years.

Prescriptions for feedingstuffs containing a veterinary medicinal product

19.—(1) A prescription for feedingstuffs containing a veterinary medicinal product 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 keeper of the animals to be treated;

(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 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) if the validity exceeds one month, a statement that 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;

(q) the percentage of the prescribed feedingstuffs to be added to the daily ration; and

(r) if it is prescribed under the cascade, a statement to that effect.

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

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

Writing the prescription

20.—(1) 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.

(2) The person 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.

[[F7](3) The person must prescribe a veterinary medicinal product authorised for incorporation in feedingstuffs but may, if there is no veterinary medicinal product authorised for a condition in a particular species—

(a) prescribe a veterinary medicinal product authorised for another species or for another condition in the same species, and

(b) prescribe more than one veterinary medicinal product,

provided all veterinary medicinal products prescribed are authorised for incorporation in feedingstuffs.**]**

Textual Amendments

F7 Sch. 5 para. 20(3) substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **3(2)**

Possession

21.—(1) No person other than a person holding the appropriate approval under this Schedule may 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 or complementary feedingstuffs containing such an additive or a veterinary medicinal product unless supplied under these Regulations.

(2) No person other than a manufacturer or distributor may be in possession of feedingstuffs incorporating a veterinary medicinal product unless it has been supplied under a prescription.

Sampling and analysis

22.—(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 **[**[F8]Regulation (EC) No 152/2009 laying down methods of sampling and analysis for the official control of feedingstuffs.**]**

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

Tolerance table for medicated feedingstuff

Level of active ingredient specified on the label	*Tolerance*
≤50 mg/kg	± 50%
>50 mg/kg ≤ 500 mg/kg	± 40%
>500 mg/kg ≤ 5g/kg	± 30%
>5g/kg ≤50g/kg	± 20%
>50g/kg	± 10%

(3) Unless otherwise specified in the Commission Regulation authorising the specified feed additive in question, it is a defence if the active ingredient of a specified feed additive in a feedingstuff sample is within the tolerances set out in Articles 11(5) and paragraph 2(e) of Annex IV to Regulation (EC) No 767/2009 of the European Parliament and of the Council.

Textual Amendments

F8 Words in Sch. 5 para. 22(1) substituted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(4)(e)**

Storage

23. No person may store a veterinary medicinal product intended for incorporation into feedingstuffs, or a premixture or feedingstuffs containing a veterinary medicinal product, except in—

(a) a suitable storage area that is locked when not in use; or

(b) a hermetic container designed to store those products.

Packages and other containers

24. No person may place on the market feedingstuffs containing a veterinary medicinal product except in packages or containers that are sealed in such a way that, when the package or container is opened, the seal is damaged.

Transport

25.—(1) No person may transport feedingstuffs by road tankers or in bulk unless the labelling requirements are set out in a document accompanying the feedingstuffs, and the transporter must hand over details when delivering 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 the transporter 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.

Possession, placing on the market and use of feedingstuffs

26.—(1) No person may 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) No person may feed to any animal, or buy, possess or supply for the purpose of feeding to any animal, any feedingstuff containing a veterinary medicinal product or specified feed additive unless—

(a) that veterinary medicinal product or specified feed additive is authorised for that species of animal and for the purpose for which it is used; or

(b) in the case of a veterinary medicinal product, it was prescribed for that animal.

(3) This paragraph does 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.

Imports from third countries E+W+S

[F9]**27.** . . . . . .

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F9 Sch. 5 para. 27 omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(35)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Imports from third countries N.I.

27. No person may import a feedingstuff containing a veterinary medicinal product from a third country.

Extent Information

E9 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Trade between [[F10]countries] E+W+S

28. No person may bring in from another **[**[F11]country**]** a feedingstuff containing a veterinary medicinal product unless—

[F12](a) . . . . . .

(b) it only contains a veterinary medicinal product that has the same quantitative and qualitative composition as a veterinary medicinal product authorised in **[**[F13]Great Britain**]**.

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F10 Word in Sch. 5 para. 28 heading substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(35)(c)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F11 Word in Sch. 5 para. 28 substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(35)(c)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F12 Sch. 5 para. 28(a) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(35)(c)(iii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Words in Sch. 5 para. 28(b) substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461), regs. 1(2)(b), **4(9)**

Trade [F20with] member States N.I.

28. No person may bring in from **[**F21a**]** member State a feedingstuff containing a veterinary medicinal product unless—

(a) the feedingstuff 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(**5**)) and Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for food hygiene; and

(b) it only contains a veterinary medicinal product that has the same quantitative and qualitative composition as a veterinary medicinal product authorised in **[**F22Northern Ireland**]**.

Extent Information

E10 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F20 Word in Sch. 5 para. 28 heading substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(15)(c)(i)**

F21 Word in Sch. 5 para. 28 substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(15)(c)(ii)**

F22 Words in Sch. 5 para. 28(b) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(15)(c)(iii)**

Import for incorporation into premixture or feedingstuffs for export E+W+S

29.—[F14(1) A manufacturer of premixture or feedingstuffs who imports a veterinary medicinal product authorised in another F15... country for the purposes of incorporating it into premixture or feedingstuffs for export does not commit an offence under regulation 43(q) (importation of an unauthorised veterinary medicinal product) or regulation 43(r) (possession of an unauthorised veterinary medicinal product)**]**

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

(2) No person may place that premixture or feedingstuff on the market in the United Kingdom once the veterinary medicinal product has been incorporated into it.

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F14 Sch. 5 para. 29(1) substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **3(3)**

F15 Words in Sch. 5 para. 29(1) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(35)(d)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Import for incorporation into premixture or feedingstuffs for export N.I.

29.—[[F23](1) A manufacturer of premixture or feedingstuffs who imports a veterinary medicinal product authorised in **[**[F24]a**]** Member State or third country for the purposes of incorporating it into premixture or feedingstuffs for export does not commit an offence under regulation 43(q) (importation of an unauthorised veterinary medicinal product) or regulation 43(r) (possession of an unauthorised veterinary medicinal product)**]**

(2) No person may place that premixture or feedingstuff on the market in **[**[F25]Northern Ireland**]** once the veterinary medicinal product has been incorporated into it.

Extent Information

E11 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F23 Sch. 5 para. 29(1) substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **3(3)**

F24 Word in Sch. 5 para. 29(1) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(15)(d)(i)**

F25 Words in Sch. 5 para. 29(2) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(15)(d)(ii)**

Animals on domestic premises

30.—(1) The requirements of paragraph 7 (approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal product) 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 provided that the animals or products from those animals are not sold or supplied commercially.

(2) Notwithstanding paragraphs 16 and 18 of this Schedule, a veterinary surgeon, a pharmacist or a suitably qualified person who is registered in accordance with paragraph 14 of Schedule 3 may be supplied with and may supply a premixture containing a veterinary medicinal product, or feedingstuffs containing a veterinary medicinal product, to such a producer.

(3) The requirement for a written prescription does not apply in relation to such supply, but the provisions of Schedule 3 relating to supply of a veterinary medicinal product apply in relation to the supply of premixture and feedingstuffs in the same way as they apply to a veterinary medicinal product.

Offences **E+W+S**

31. It is an offence to fail to comply with—

(a) paragraph 2(2);

(b) paragraph 3(3) or (4);

(c) paragraph 5(2) or (3);

(d) paragraph 6;

(e) paragraph 7(2) or (5);

(f) paragraph 8;

(g) paragraph 9;

(h) paragraph 10;

(i) paragraph 11;

(j) paragraph 12(4);

(k) paragraph 13;

(l) paragraph 14(4);

(m) paragraph 15;

(n) paragraph 16;

(o) paragraph 17;

(p) paragraph 18;

(q) paragraph **[**[F16]20**]** ;

(r) paragraph 21;

(s) paragraph 23;

(t) paragraph 24;

(u) paragraph 25;

(v) paragraph 26(1) or (2);

[F17](w) . . . . . .

(x) paragraph 28; or

(y) paragraph 29(2).

Extent Information

E6 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F16 Word in Sch. 5 para. 31(q) substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **3(4)**

F17 Sch. 5 para. 31(w) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(35)(e)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Offences N.I.

31. It is an offence to fail to comply with—

(a) paragraph 2(2);

(b) paragraph 3(3) or (4);

(c) paragraph 5(2) or (3);

(d) paragraph 6;

(e) paragraph 7(2) or (5);

(f) paragraph 8;

(g) paragraph 9;

(h) paragraph 10;

(i) paragraph 11;

(j) paragraph 12(4);

(k) paragraph 13;

(l) paragraph 14(4);

(m) paragraph 15;

(n) paragraph 16;

(o) paragraph 17;

(p) paragraph 18;

(q) paragraph **[**[F26]20**]** ;

(r) paragraph 21;

(s) paragraph 23;

(t) paragraph 24;

(u) paragraph 25;

(v) paragraph 26(1) or (2);

(w) paragraph 27;

(x) paragraph 28; or

(y) paragraph 29(2).

Extent Information

E12 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F26 Word in Sch. 5 para. 31(q) substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **3(4)**

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, SCHEDULE 5.