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—

[[F1]"animal keeper" means any natural or legal person responsible for animals, whether on a permanent or a temporary basis;

"batch" means an identifiable quantity of feed determined to have common characteristics whether in relation to origin, variety, type of packaging, packer, consignor or labelling and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units when produced in continuous order and stored together;

"cross-contamination" means contamination of a non-target feed with an active substance originating from the previous use of the relevant facilities or equipment;

"distributor" means a feed business operator distributing specified feed additives, intermediate feedingstuff or complete feed containing specified feed additives, or intermediate feedingstuff or complete feed containing medicinal premixes;

"feed business" means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on their own holding;

"feed business operator" means any person responsible for ensuring that the requirements of this Schedule are met within the feed business under that person's control;

"non-target feed" means feed, whether medicated or not which is not intended to contain a specific active substance;

"premises" means any unit of a feed business;**]**

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

Textual Amendments

F1 Words in Sch. 5 para. 1(3) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **128(b)**

F2 Words in Sch. 5 para. 1(3) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **128(a)**

Enforcement of Regulation (EC) No 178/2002

2.—(1) For the purposes of **[**F3Regulation (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

F3 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 **[**F4Regulation (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 **[**F5an intermediate feedingstuff**]** 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 **[**F6another**]** 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

F4 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)**

F5 Words in Sch. 5 para. 3(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **129**

F6 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 **[**[F158]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

E25 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

F158 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 [F7Regulation (EU) 2017/625] E+W+S

4. For the purposes of **[**[F8] 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

F7 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)**

F8 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)**

[F159Enforcement 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

E26 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

F159 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 **[**F9Regulation (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

F9 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.

[F10Authorisation] of manufacturers and distributors of feedingstuffs containing [F11medicinal premixes] E+W+S

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 [F12medicinal premix] into [F13an intermediate feedingstuff] or feedingstuff, or act as a distributor of [F14intermediate feedingstuffs] or feedingstuffs containing a [F12medicinal premix], without being [F15authorised] to do so by the Secretary of State.

(3) The conditions which govern [F16authorisation] of feed business [F17premises] under Regulation (EC) No 183/2005 laying down requirements for feed hygiene(**2**) also govern [F16authorisation] of manufacturers and distributors under sub-paragraph (2).

(4) The Secretary of State shall conduct inspections of manufacturers and distributors [F18authorised] 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.

[F19(5) A manufacturer must ensure that, so far as is reasonably practical the medicinal premix is evenly incorporated and homogeneously dispersed throughout the feedingstuffs, taking into account the specific properties of the medicinal premix and the mixing technology employed.]

(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 [F20medicinal premix] annually for that purpose.

(7) In the case of the refusal, suspension or revocation of an [F21authorisation] under this paragraph the appeals procedure relating to a manufacturing authorisation in regulation 30 applies.

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

F10 Word in Sch. 5 para. 7 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(g)(i)**

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

F11 Words in Sch. 5 para. 7 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(g)(ii)**
F12 Words in Sch. 5 para. 7(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(a)(i)**
F13 Words in Sch. 5 para. 7(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(a)(ii)**
F14 Words in Sch. 5 para. 7(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(a)(iii)**
F15 Word in Sch. 5 para. 7(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(a)(iv)**
F16 Word in Sch. 5 para. 7(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(b)(i)**
F17 Word in Sch. 5 para. 7(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(b)(ii)**
F18 Word in Sch. 5 para. 7(4) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(c)**
F19 Sch. 5 para. 7(5) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(d)**
F20 Words in Sch. 5 para. 7(6) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(e)**
F21 Word in Sch. 5 para. 7(7) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **130(f)**

Approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products N.I.

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).

(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.

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

Extent Information

E27 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Incorporation of a [F22medicinal premix into an intermediate feedingstuff] E+W+S

8. Any person who incorporates a **[**F23medicinal premix**]** into **[**F24an intermediate feedingstuff**]**—

(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 **[**F23medicinal premix**]** does not contain the same active substance as any other additive.

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

F22 Words in Sch. 5 para. 8 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **131(c)**

F23 Words in Sch. 5 para. 8 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **131(a)**

F24 Words in Sch. 5 para. 8 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **131(b)**

Incorporation of a veterinary medicinal product into a premixture N.I.

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.

Extent Information

E28 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

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 [F25medicinal premix] into feedingstuffs E+W+S

10. Any person who incorporates a **[**F26medicinal premix**]** (or **[**F27an intermediate feedingstuff**]**) 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 **[**F26medicinal premix**]** does not contain the same active substance as any other additive;

(c) must ensure that the **[**F26medicinal premix**]** is incorporated in accordance with its marketing authorisation (unless it has been prescribed under the cascade) and the **[**F28medicated feedingstuff prescription**]**;

(d) must ensure that the daily dose of the **[**F26medicinal premix**]** 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.

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

F25 Words in Sch. 5 para. 10 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **132(d)**

F26 Words in Sch. 5 para. 10 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **132(a)**

F27 Words in Sch. 5 para. 10 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **132(b)**

F28 Words in Sch. 5 para. 10(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **132(c)**

Incorporation of a veterinary medicinal product into feedingstuffs N.I.

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.

Extent Information

E29 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Additional record keeping requirements relating to [F29medicinal premixes] E+W+S

11.—(1) Any person who—

(a) incorporates a [F30medicinal premix] into [F31an intermediate feedingstuff];

(b) incorporates [F32an intermediate feedingstuff] containing a [F33medicinal premix] into feedingstuffs; or

(c) incorporates a [F34medicinal premix] into feedingstuffs,

must make a daily record of—

(d) the types and quantities of all [F35medicinal premixes] (and specified feed additives, if any) and [F36intermediate feedingstuffs] used in the manufacturing process; and

(e) the quantity of feedingstuffs and [F37intermediate feedingstuffs] containing [F38medicinal premix] manufactured that day.

(2) An [F39authorised] distributor must make a daily record of—

(a) the types and quantities of all [F40intermediate feedingstuffs] and feedingstuffs containing [F41medicinal premixes] 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 [F42intermediate feedingstuffs] supplied;

(d) the quantity;

(e) the type of [F43medicinal premix] incorporated into the feedingstuffs; F44...

(f) the expiry date [F45; and

(g) the batch number.]

(4) Records must be kept for five years.

Textual Amendments

F29 Words in Sch. 5 para. 11 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(d)**

F30 Words in Sch. 5 para. 11(1)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(i)(aa)**

F31 Words in Sch. 5 para. 11(1)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(i)(bb)**

F32 Words in Sch. 5 para. 11(1)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(ii)(aa)**

F33 Words in Sch. 5 para. 11(1)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(ii)(bb)**
F34 Words in Sch. 5 para. 11(1)(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(iii)**
F35 Words in Sch. 5 para. 11(1)(d) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(iv)(aa)**
F36 Words in Sch. 5 para. 11(1)(d) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(iv)(bb)**
F37 Words in Sch. 5 para. 11(1)(e) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(v)(aa)**
F38 Words in Sch. 5 para. 11(1)(e) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(v)(bb)**
F39 Word in Sch. 5 para. 11(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(b)(i)**
F40 Words in Sch. 5 para. 11(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(b)(ii)**
F41 Words in Sch. 5 para. 11(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(b)(iii)**
F42 Words in Sch. 5 para. 11(3)(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(c)(i)**
F43 Words in Sch. 5 para. 11(3)(e) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(c)(ii)**
F44 Word in Sch. 5 para. 11(3) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(c)(iii)**
F45 Sch. 5 para. 11(3)(g) and word inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(c)(iv)**

Additional record keeping requirements relating to veterinary medicinal products N.I.

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 [F46an intermediate feedingstuff] containing a [F47medicinal premix] E+W+S

12.—(1) **[**F48An intermediate feedingstuff**]** containing a **[**F49medicinal premix**]** must be clearly and legibly labelled with the following—

(a) the words "**[**F50INTERMEDIATE FEEDINGSTUFF**]**" (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 **[**F51medicinal premix**]** and the authorisation number;

(c) the name and amount of the active substance (mg/kg) in the **[**F52intermediate feedingstuff**]**;

(d) the range of acceptable inclusion rates of the **[**F53intermediate feedingstuff**]** into the final feedingstuffs, the range of acceptable levels of the active ingredients in the final feedingstuffs and the words "refer to the **[**F54medicated feedingstuffs prescription**]** for the exact inclusion rate" or equivalent wording;

(e) warnings and contra-indications;

[F55(ea) a statement that the product must be used in accordance with its summary of product characteristics;

(eb) the contact details (including a free helpline number) for the supplier of the product;

(ec) the words "inappropriate disposal of this product poses a serious threat to the environment";

(ed) in the case of a product containing an antibiotic, the words "inappropriate disposal of this product may contribute to antimicrobial resistance";**]**

(f) the withdrawal period, and a statement that, if the **[**F56medicated feedingstuffs prescription**]** requires a longer withdrawal period, that is the one that applies;

(g) the expiry date;

(h) any special storage instructions **[**F57required by the marketing authorisation**]**;

(i) where a **[**F58medicated feedingstuffs prescription**]** is required, a statement to this effect.

(2) If there is more than one **[**F59medicinal premix**]** used, the longest withdrawal period must be shown on the label.

(3) If the **[**F60intermediate feedingstuff**]** 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**).

(4) No person may supply such **[**F61an intermediate feedingstuff**]** unless it is labelled in accordance with this paragraph.

(**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.)

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

F46 Words in Sch. 5 para. 12 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(e)(i)** (with reg. 205)

F47 Words in Sch. 5 para. 12 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(e)(ii)** (with reg. 205)

F48 Words in Sch. 5 para. 12(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(i)(aa)** (with reg. 205)

F49 Words in Sch. 5 para. 12(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(i)(bb)** (with reg. 205)

F50 Words in Sch. 5 para. 12(1)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(ii)** (with reg. 205)

F51 Words in Sch. 5 para. 12(1)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(iii)** (with reg. 205)

F52 Words in Sch. 5 para. 12(1)(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(iv)** (with reg. 205)

F53 Words in Sch. 5 para. 12(1)(d) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(v)(aa)** (with reg. 205)

F54 Words in Sch. 5 para. 12(1)(d) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(v)(bb)** (with reg. 205)

F55 Sch. 5 para. 12(1)(ea)-(ed) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(vi)** (with reg. 205)

F56 Words in Sch. 5 para. 12(1)(f) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(vii)** (with reg. 205)

F57 Words in Sch. 5 para. 12(1)(h) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(viii)** (with reg. 205)

F58 Words in Sch. 5 para. 12(1)(i) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(a)(ix)** (with reg. 205)

F59 Words in Sch. 5 para. 12(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(b)** (with reg. 205)

F60 Words in Sch. 5 para. 12(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(c)** (with reg. 205)

F61 Words in Sch. 5 para. 12(4) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **134(d)** (with reg. 205)

Labelling a premixture containing a veterinary medicinal product N.I.

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;

(**3**) OJ No L86, 6.4.1979, p. 30.

(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**).

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

Extent Information

E30 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

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 [F62medicinal premix] E+W+S

14.—(1) Feedingstuffs containing a **[**F63medicinal premix**]** 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 **[**F63medicinal premix**]** 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;

[F64(ea) the contact details (including a free helpline number) for the supplier of the product;

(eb) the words "inappropriate disposal of this product poses a serious threat to the environment";

(ec) in the case of a product containing an antibiotic, the words "inappropriate disposal of this product may contribute to antimicrobial resistance";**]**

(**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.)

(f) the withdrawal period, and a statement that, if the **[**[F65]medicated feedingstuffs prescription**]** requires a longer withdrawal period, that is the one that applies;

[[F66](fa) the batch number;**]**

(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 **[**[F67]medicated feedingstuffs prescription**]**;

(j) the name and **[**[F68]authorisation**]** number of the manufacturer or the distributor.

(2) If there is more than one **[**[F69]medicinal premix**]** 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 **[**[F70]containing a medicinal premix**]** unless they are labelled in accordance with this paragraph.

Extent Information

E7 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

F62 Words in Sch. 5 para. 14 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **135(d)** (with reg. 205)

F63 Words in Sch. 5 para. 14(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **135(a)(i)** (with reg. 205)

F64 Sch. 5 para. 14(1)(ea)-(ec) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **135(a)(ii)** (with reg. 205)

F65 Words in Sch. 5 para. 14(1)(f) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **135(a)(iii)** (with reg. 205)

F66 Sch. 5 para. 14(1)(fa) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **135(a)(iv)** (with reg. 205)

F67 Words in Sch. 5 para. 14(1)(i) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **135(a)(v)** (with reg. 205)

F68 Word in Sch. 5 para. 14(1)(j) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **135(a)(vi)** (with reg. 205)

F69 Words in Sch. 5 para. 14(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **135(b)** (with reg. 205)

F70 Words in Sch. 5 para. 14(4) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **135(c)** (with reg. 205)

Labelling of feedingstuffs containing a veterinary medicinal product N.I.

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.

Extent Information

E31 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply of specified feed additives E+W+S

15.—(1) No person other than the person who manufactured a specified feed additive or an **[**F71authorised**]** distributor may supply a specified feed additive.

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

(a) an **[**F71authorised**]** distributor;

(b) an **[**F71authorised**][**F72intermediate feedingstuff**]** manufacturer or an **[**F71authorised**]** complementary feedingstuffs manufacturer; or

(c) a feedingstuff manufacturer **[**F71authorised**]** to mix a specified feed additive directly into feedingstuff.

(3) An **[**F71authorised**]** distributor may only supply it to—

(a) another **[**F71authorised**]** distributor;

(b) an **[**F71authorised**][**F73intermediate feedingstuff**]** manufacturer or an **[**F71authorised**]** complementary feedingstuffs manufacturer; or

(c) a feedingstuff manufacturer **[**F71authorised**]** to mix a specified feed additive directly into feedingstuff.

Extent Information

E8 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

F71 Word in Sch. 5 para. 15 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **136(a)**

F72 Words in Sch. 5 para. 15(2)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **136(b)**

F73 Words in Sch. 5 para. 15(3)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **136(c)**

Supply of specified feed additives N.I.

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.

Extent Information

E32 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply of [F74intermediate feedingstuff or specified feed additive] E+W+S

16.—(1) No person other than the person who manufactured **[**F75an intermediate feedingstuff or specified feed additive**]** or an **[**F76authorised**]** distributor may supply **[**F75an intermediate feedingstuff or specified feed additive**]**.

(2) The person who manufactured the **[**F77intermediate feedingstuff or specified feed additive**]** may only supply it to—

(a) an **[**F76authorised**]** distributor; or

(b) a feedingstuff manufacturer **[**F76authorised**]** to incorporate that **[**F77intermediate feedingstuff or specified feed additive**]**.

(3) An **[**F76authorised**]** distributor may only supply it to—

(a) another **[**F76authorised**]** distributor; or

(b) a feedingstuff manufacturer **[**F76authorised**]** to incorporate that **[**F78intermediate feedingstuff or specified feed additive**]**.

Extent Information

E9 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

F74 Words in Sch. 5 para. 16 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **137(e)**

F75 Words in Sch. 5 para. 16(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **137(b)**

F76 Word in Sch. 5 para. 16 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **137(a)**

F77 Words in Sch. 5 para. 16(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **137(c)**

F78 Words in Sch. 5 para. 16(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **137(d)**

Supply of premixture N.I.

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.

Extent Information

E33 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply of a complementary feedingstuff E+W+S

17.—(1) No person other than—

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

(b) an **[**F79authorised**]** 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 **[**F79authorised**]** distributor; or

(b) a feedingstuff manufacturer registered to incorporate that complementary feedingstuff or **[**F79authorised**]** to incorporate **[**F80an intermediate feedingstuff**]**.

(3) An **[**F79authorised**]** distributor may only supply it to—

(a) another **[**F79authorised**]** distributor, or

(b) a feedingstuff manufacturer registered to incorporate that complementary feedingstuff or **[**F79authorised**]** to incorporate **[**F81an intermediate feedingstuff**]**.

F82(4) . . . . . .

Extent Information

E10 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

F79 Word in Sch. 5 para. 17 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **138(a)**

F80 Words in Sch. 5 para. 17(2)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **138(b)**

F81 Words in Sch. 5 para. 17(3)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **138(c)**

F82 Sch. 5 para. 17(4) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **138(d)**

Supply of a complementary feedingstuff N.I.

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.

Extent Information

E34 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply of feedingstuffs containing a [F83medicinal premix] E+W+S

18.—(1) No person other than the person who manufactured the feedingstuffs or an **[**F84authorised**]** distributor may supply feedingstuffs containing a **[**F85medicinal premix**]**.

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

(a) an **[**F84authorised**]** distributor; or

(b) **[**F86an animal keeper**]** for feeding to those animals.

(3) A distributor may only supply it to—

(a) another **[**F84authorised**]** distributor; or

(b) **[**F87an animal keeper**]** for feeding to those animals.

(4) Supply to **[**F88an animal keeper**]** must be in accordance with a written **[**F89medicated feedingstuff prescription**]** as specified in the following paragraph.

(5) If a **[**F90medicated feedingstuff 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 **[**F91medicated feedingstuff prescription**]** for five years.

[F92(8) Nothing in this paragraph prevents a commercial feed manufacturer from incorporating a medicinal premix with a feedingstuff in advance of receiving a written prescription for that feedingstuff.**]**

Extent Information

E11 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

F83 Words in Sch. 5 para. 18 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **139(i)**

F84 Word in Sch. 5 para. 18 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **139(a)**

F85 Words in Sch. 5 para. 18(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **139(b)**

F86 Words in Sch. 5 para. 18(2)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **139(c)**

F87 Words in Sch. 5 para. 18(3)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **139(d)**

F88 Words in Sch. 5 para. 18(4) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **139(e)(i)**

F89 Words in Sch. 5 para. 18(4) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **139(e)(ii)**

F90 Words in Sch. 5 para. 18(5) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **139(f)**

F91 Words in Sch. 5 para. 18(7) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **139(g)**

F92 Sch. 5 para. 18(8) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **139(h)**

Supply of feedingstuffs containing a veterinary medicinal product N.I.

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.

Extent Information

E35 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F93Medicated feedingstuff prescriptions] for feedingstuffs containing a [F94medicinal premix] E+W+S

19.—(1) A **[**F95medicated feedingstuff prescription**]** for feedingstuffs containing a **[**F96medicinal premix**]** 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;

[F97(ea) the diagnosed disease to be treated or prevented (in the case of immunological veterinary medicinal products or antiparasitics without antimicrobial effects);**]**

(f) the date of the prescription;

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

[F98(h) the name, active substance, amount of the product prescribed and inclusion rate of the medicinal premix and resulting inclusion rate of the active substance;**]**

(i) the dosage and administration instructions;

(j) any necessary warnings;

[F99(ja) a statement that the prescription may not be re-used;**]**

(k) the withdrawal period;

(l) the manufacturer or the distributor of the feedingstuffs (who must be **[**F100authorised**]** for the purpose) **[**F101, whichever is the supplier to the end user**]**;

(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;

[F102(na) the overall amount of feedingstuff to be supplied under the prescription;**]**

F103(o) . . . . . .

(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 **[**F104medicated feedingstuff prescription**]**.

[F105(2A) In the case of a prescription to which sub-paragraph (1) applies which relates to an antibiotic, the time between a prescription being issued and the course of treatment starting must be no more than five working days.

(2B) Subject to paragraph 7A in Schedule 3, a prescription for a medicated feedingstuff containing a medicinal premix which includes an antibiotic may not be issued for prophylactic purposes.**]**

[F106(3) In relation to food-producing animals a medicated feedingstuffs prescription may not confer authority for more than one course of treatment.**]**

Extent Information

E12 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

F93 Words in Sch. 5 para. 19 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(e)(i)** (with reg. 206)

F94 Words in Sch. 5 para. 19 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(e)(ii)** (with reg. 206)

F95 Words in Sch. 5 para. 19(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(i)** (with reg. 206)

F96 Words in Sch. 5 para. 19(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(ii)** (with reg. 206)

F97 Sch. 5 para. 19(1)(ea) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(iii)** (with reg. 206)

F98 Sch. 5 para. 19(1)(h) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(iv)** (with reg. 206)

F99 Sch. 5 para. 19(1)(ja) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(v)** (with reg. 206)

F100 Word in Sch. 5 para. 19(1)(l) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(vi)(aa)** (with reg. 206)

F101 Words in Sch. 5 para. 19(1)(l) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(vi)(bb)** (with reg. 206)

F102 Sch. 5 para. 19(1)(na) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(vii)** (with reg. 206)
F103 Sch. 5 para. 19(1)(o) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(viii)** (with reg. 206)
F104 Words in Sch. 5 para. 19(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(b)** (with reg. 206)
F105 Sch. 5 para. 19(2A)(2B) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(c)** (with reg. 206)
F106 Sch. 5 para. 19(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(d)** (with reg. 206)

Prescriptions for feedingstuffs containing a veterinary medicinal product N.I.

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.

Extent Information
E36 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Writing the [F107medicated feedingstuff prescription] E+W+S

20.—(1) The person who writes the [F108medicated feedingstuff prescription] must—

(a) give a copy to the person incorporating the [F109medicinal premix] into the feedingstuffs or to the distributor of the feedingstuffs [F110, whichever is the supplier to the end user];

(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 [F111medicinal premix] and any feed additive used in the feedingstuffs; and

(b) the active substance of the [F111medicinal premix] is not the same as an active substance in any feed additive used in the feedingstuffs.

[F112(3) The person must prescribe a [F113medicinal premix] authorised for incorporation in feedingstuffs but may, if there is no [F113medicinal premix] authorised for a condition in a particular species—

(a) prescribe a [F113medicinal premix] authorised for another species or for another condition in the same species, and

(b) prescribe more than one [F113medicinal premix],

provided all [F114medicinal premixes] prescribed are authorised for incorporation in feedingstuffs.]

Extent Information

E13 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

F107 Words in Sch. 5 para. 20 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **141(d)**

F108 Words in Sch. 5 para. 20(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **141(a)(i)**

F109 Words in Sch. 5 para. 20(1)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **141(a)(ii)(aa)**

F110 Words in Sch. 5 para. 20(1)(a) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **141(a)(ii)(bb)**

F111 Words in Sch. 5 para. 20(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **141(b)**

F112 Sch. 5 para. 20(3) substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **3(2)**

F113 Words in Sch. 5 para. 20(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **141(c)(i)**

F114 Words in Sch. 5 para. 20(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **141(c)(ii)**

Writing the prescription N.I.

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.

[F160(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.**]**

Extent Information

E37 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

F160 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 E+W+S

21.—(1) No person other than a person holding the appropriate **[**F115authorisation**]** under this Schedule may be in possession of any—

(a) specified feed additive or **[**F116medicinal premix**]** to which this Schedule applies;

(b) **[**F117intermediate feedingstuffs**]** containing such an additive or a **[**F118medicinal premix**]**; or

(c) feedingstuffs or complementary feedingstuffs containing **[**F119a medicinal premix**]** unless supplied under these Regulations.

(2) No person other than a manufacturer or distributor may be in possession of feedingstuffs incorporating a **[**F120medicinal premix**]** unless it has been supplied under a **[**F121medicated feedingstuffs prescription**]**.

Extent Information

E14 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

F115 Word in Sch. 5 para. 21(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **142(a)(i)**

F116 Words in Sch. 5 para. 21(1)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **142(a)(ii)**
F117 Words in Sch. 5 para. 21(1)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **142(a)(iii)(aa)**
F118 Words in Sch. 5 para. 21(1)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **142(a)(iii)(bb)**
F119 Words in Sch. 5 para. 21(1)(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **142(a)(iv)**
F120 Words in Sch. 5 para. 21(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **142(b)(i)**
F121 Words in Sch. 5 para. 21(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **142(b)(ii)**

Possession N.I.

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.

Extent Information
E38 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Sampling and analysis E+W+S

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 **[**[F122]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—

[[F123]**Tolerance table for medicated feedingstuff**

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

Extent Information

E15 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

F122 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)**

F123 Sch. 5 para. 22(2) Table substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **143** (with reg. 207)

Sampling and analysis N.I.

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 **[**F161Regulation (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.

Extent Information

E39 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

F161 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)**

[F124Sampling for cross-contamination

22A.—(1) A feed business operator must ensure that cross-contamination of non-target feeds is as low as is reasonably achievable.

(2) A feed business operator must analyse samples of non-target feeds in order to determine whether cross-contamination into non-target feed has occurred.

(3) Where as a result of the process mentioned in sub-paragraph (2) it is determined that a cross-contamination rate has occurred which is 1% or more but less than 3% compared to the authorised maximum content, the feed business operator must make a record of this cross-contamination.

(4) Where as a result of the process mentioned in sub-paragraph (2) it is determined that a cross-contamination rate has occurred of 3% or more compared to the authorised maximum content, the feed business operator must conduct an investigation in order to discover the cause of the occurrence and make a record of the fact and any conclusions.

(5) The feed business operator must keep the records under sub-paragraphs (3) and (4) for at least five years.

(6) Upon request of the Secretary of State, the feed business operator must provide any information in the feed business operator's possession relating to the matters mentioned in this paragraph.**]**

Textual Amendments

F124 Sch. 5 para. 22A inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **144** (with reg. 208)

Storage E+W+S

23. No person may store a **[**[F125]medicinal premix**]** intended for incorporation into feedingstuffs, or **[**[F126]an intermediate feedingstuff**]** or feedingstuffs containing a **[**[F125]medicinal premix**]**, except in—

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

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

Extent Information

E16 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

F125 Words in Sch. 5 para. 23 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **145(a)**

F126 Words in Sch. 5 para. 23 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **145(b)**

Storage N.I.

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.

Extent Information

E40 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Packages and other containers E+W+S

24. No person may place on the market feedingstuffs containing a **[**F127medicinal premix**]** except in packages or containers that are sealed in such a way that, when the package or container is opened, the seal is damaged.

Extent Information

E17 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

F127 Words in Sch. 5 para. 24 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **146**

Packages and other containers N.I.

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.

Extent Information

E41 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Transport E+W+S

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 **[**F128medicinal premixes**]** 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 **[**F129medicinal premix or specified feed additive**]** the transporter must ensure that the vehicle is accompanied by documentation stating this.

(4) Any person operating an undertaking transporting feedingstuffs containing **[**F130medicinal premixes**]** 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.

Extent Information

E18 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

F128 Words in Sch. 5 para. 25(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **147(a)**

F129 Words in Sch. 5 para. 25(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **147(b)**

F130 Words in Sch. 5 para. 25(4) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **147(c)**

Transport N.I.

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.

Extent Information

E42 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Possession, placing on the market and use of feedingstuffs E+W+S

26.—(1) No person may possess, place on the market or feed to animals any feedingstuffs incorporating **[**F131medicinal premixes**]** 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 **[**F132medicinal premix**]** or specified feed additive unless—

(a) that **[**F132medicinal premix**]** 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 **[**F132medicinal premix**]**, it was prescribed for that animal.

[F133(2A) An animal keeper must ensure that any product to which this Schedule applies is appropriately stored in accordance with its authorisation.

(2B) An animal keeper must ensure in respect of any such product that—

(a) no cross-contamination occurs between products held by the keeper;

(b) no product contaminates any feedingstuff or feed material;

(c) no product escapes into the environment; and

(d) a product is administered only to correctly identified animals mentioned on the medicated feedingstuffs prescription.

(2C) An animal keeper must comply with the withdrawal period in relation to any such product.**]**

(3) This paragraph does not apply in relation to feedingstuffs if the **[**[F134]medicinal premix**]** has been incorporated in accordance with an animal test certificate or the feedingstuff has been imported in accordance with this Schedule.

Extent Information

E19 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

F131 Words in Sch. 5 para. 26(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **148(a)**

F132 Words in Sch. 5 para. 26(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **148(b)**

F133 Sch. 5 para. 26(2A)-(2C) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **148(c)**

F134 Words in Sch. 5 para. 26(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **148(d)**

Possession, placing on the market and use of feedingstuffs N.I.

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.

Extent Information

E43 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F135Unused and expired medicated feedingstuffs

26A. No person may feed medicated feedingstuffs which have passed their expiry date to an animal.**]**

Textual Amendments

F135 Sch. 5 para. 26A inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **149**

Imports from third countries E+W+S

F136**27.** . . . . . .

Extent Information

E20 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

F136 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

E44 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 [F137countries] E+W+S

28. No person may bring in from another **[**F138country**]** a feedingstuff containing a veterinary medicinal product unless—

F139(a) . . . . . .

(b) it only contains a veterinary medicinal product that has the same quantitative and qualitative composition as a **[**F140medicinal premix**]** authorised in **[**F141Great Britain**]**.

Extent Information

E21 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

F137 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)**

F138 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)**

F139 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)**

F140 Words in Sch. 5 para. 28(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **150**

F141 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 [F162with] member States N.I.

28. No person may bring in from **[**F163a**]** 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 **[**F164Northern Ireland**]**.

Extent Information

E45 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

F162 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)**

F163 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)**

F164 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)**

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

Import for incorporation into [F142intermediate feedingstuffs] or feedingstuffs for export E+W+S

29.—[F143(1) A manufacturer of [F144intermediate feedingstuffs] or feedingstuffs who imports a veterinary medicinal product authorised in another F145... country for the purposes of incorporating it into [F144intermediate feedingstuffs] 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 [F146intermediate feedingstuff] or feedingstuff on the market in the United Kingdom once the veterinary medicinal product has been incorporated into it.

Extent Information

E22 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

F142 Words in Sch. 5 para. 29 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **151(c)**

F143 Sch. 5 para. 29(1) substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **3(3)**

F144 Words in Sch. 5 para. 29(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **151(a)**

F145 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)**

F146 Words in Sch. 5 para. 29(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **151(b)**

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

29.—[F165(1) A manufacturer of premixture or feedingstuffs who imports a veterinary medicinal product authorised in [F166a] 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 [F167Northern Ireland] once the veterinary medicinal product has been incorporated into it.

Extent Information

E46 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

F165 Sch. 5 para. 29(1) substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **3(3)**

F166 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)**

F167 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 E+W+S

30.—(1) The requirements of paragraph 7 (**[**F147authorisation**]** of manufacturers and distributors of feedingstuffs containing **[**F148medicinal premix**]**) do not apply in relation to a person who incorporates a **[**F148medicinal premix**]** 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 **[**F149an intermediate feedingstuff**]** containing a **[**F150medicinal premix**]**, or feedingstuffs containing a **[**F150medicinal premix**]**, 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 **[**F151intermediate feedingstuffs**]** and feedingstuffs in the same way as they apply to a veterinary medicinal product.

Extent Information

E23 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

F147 Word in Sch. 5 para. 30(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **152(a)(i)**

F148 Words in Sch. 5 para. 30(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **152(a)(ii)**

F149 Words in Sch. 5 para. 30(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **152(b)(i)**

F150 Words in Sch. 5 para. 30(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **152(b)(ii)**

F151 Words in Sch. 5 para. 30(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **152(c)**

Animals on domestic premises N.I.

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.

Extent Information

E47 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

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;

[[F152](pa) paragraph 19;**]**

(q) paragraph **[**[F153]20**]**;

(r) paragraph 21;

[[F154](ra) paragraph 22A;**]**

(s) paragraph 23;

(t) paragraph 24;

(u) paragraph 25;

(v) paragraph 26(1) **[**[F155], (2), (2A), (2B) or (2C)**]**;

[F156(va) paragraph 26A;]

F157(w) . . . . . .

(x) paragraph 28; or

(y) paragraph 29(2).

Extent Information

E24 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

F152 Sch. 5 para. 31(pa) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **153(a)**

F153 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)**

F154 Sch. 5 para. 31(ra) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **153(b)**

F155 Words in Sch. 5 para. 31(v) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **153(c)**

F156 Sch. 5 para. 31(va) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **153(d)**

F157 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 **[**[F168]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

E48 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

F168 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)**

Status:
Point in time view as at 17/05/2024.

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