Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (Text with EEA relevance)

ANNEX I

SPECIFIC REQUIREMENTS FOR FEED BUSINESS OPERATORS IN ACCORDANCE WITH ARTICLE 4

SECTION 1

Facilities and equipment

1. Feed business operators shall ensure that facilities and equipment and...

2. Feed business operators shall ensure that access to all facilities...

SECTION 2

Personnel

1. An adequately trained person responsible for the manufacture, placing on...

2. With the exception of mobile mixers and on-farm mixers, the...

SECTION 3

Manufacture

1. Feed business operators shall take account of requirements under relevant...

2. Medicated feed and intermediate products shall be stored separately from...

3. Veterinary medicinal products shall be stored in a separate secured...

4. The material used for cleaning the production line after the...

SECTION 4

Quality control

1. A quality control plan shall be drawn up in writing...

2. Specific regular own checks as well as stability tests shall...

SECTION 5

Storage and transport

1. Medicated feed and intermediate products shall be stored in suitable...

2. Veterinary medicinal products shall be stored in separate, safe and...

3. Specific facilities shall be identified for the storage of expired,...

4. Containers in vehicles used for the transport of medicated feed...

SECTION 6

Record-keeping

1. Feed business operators manufacturing, storing, transporting or placing on the...

2. The record referred to in paragraph 1 of this Section...

SECTION 7

Complaints and product recall

1. Feed business operators placing medicated feed and intermediate products on...

2. Feed business operators shall put in place a system for...

SECTION 8

Additional requirements for mobile mixers

1. Mobile mixers shall have a copy of the following documents...

2. Mobile mixers shall take all the appropriate precautionary measures to...

3. Where vehicle registration plate numbers are available, mobile mixers shall...

ANNEX II

ANNEX III

SPECIFIC LABELLING REQUIREMENTS REFERRED TO IN ARTICLE 9(1)

The label of medicated feed and intermediate products shall include...
the expression ‘Medicated feed’ or ‘Intermediate product for the manufacturing...
Points 1 to 10 shall not apply to mobile mixers...

ANNEX IV

PERMITTED TOLERANCES FOR THE COMPOSITIONAL LABELLING OF MEDICATED FEED OR INTERMEDIATE PRODUCTS AS REFERRED TO IN ARTICLE 9(3)

The tolerances laid down in this Annex shall only include...
Where the composition of a medicated feed or an intermediate...
For the other active substances, the following tolerances shall apply:...

ANNEX V

INFORMATION TO BE INCLUDED IN THE VETERINARY PRESCRIPTION FOR MEDICATED FEED AS REFERRED TO IN ARTICLE 16(6)

VETERINARY PRESCRIPTION FOR MEDICATED FEED

1. Full name and contact details of the veterinarian including, if...
2. Issue date, unique number of prescription, expiry date of prescription...
3. Full name and contact details of the animal keeper, and...
4. Identification (including category, species and age) and number of animals...
5. Diagnosed disease to be treated. In the case of immunological...
6. Designation (name and marketing authorisation number) of the veterinary medicinal...
7. If the veterinary medicinal product is prescribed under Article 107(4),...
8. Inclusion rate of the veterinary medicinal product or products and...
9. Quantity of medicated feed.
10. Instructions for use for the animal keeper, including the duration...
11. Percentage of medicated feed in the daily ration or quantity...
12. For food-producing animals, withdrawal period, even if such period is...
13. Any warnings necessary to ensure the proper use including, where...
14. For food-producing animals and fur animals, the mention ‘This prescription...
15. The following mentions to be completed by the supplier of...
16. Signature of supplier to the animal keeper or of on-farm...

ANNEX VI

(**1**) OJ C 242, 23.7.2015, p. 54.

(**2**) Position of the European Parliament of 25 October 2018 (not yet published in the Official Journal) and decision of the Council of 26 November 2018.

(**3**) Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ L 92, 7.4.1990, p. 42).

(**4**) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

(**5**) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (see page 43 of this Official Journal).

(**6**) Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

(**7**) Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).

(**8**) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

(**9**) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

(**10**) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

(**11**) OJ L 123, 12.5.2016, p. 1.

(**12**) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/4 of the European Parliament and of the Council.