Draft Legislation

of the Federal Ministry of Agriculture, Food and Community

Fifty-seventh Regulation amending the Feed Regulation

A. Problem and objective

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, requires an adjustment to the German Feed Regulation (Futtermittelverordnung, FMV). Regulation (EU) 2019/4 lays down specific provisions for medicated feed and intermediate products. While medicated feed was designated as a medicated feed prior to the entry into force of Regulation (EU) 2019/4 and Regulation (EU) 2019/6 on veterinary medicinal products on 28 January 2019 and was therefore a medicinal product under national law, it is now considered to be a feed in the EU as defined in Article 3(2)(a) of Regulation (EU) 2019/4. In order to take account of the requirements of the Regulation, national procedural rules will be adapted and issued. In addition, in order to penalise infringements of the requirements and prohibitions laid down in the Regulation, additions to the Feed Regulation are necessary. Furthermore, a national sanction for an infringement of Regulation (EC) no. 999/2001 is to be supplemented in order to close a gap in criminal liability.

Finally, references to EU legal acts are to be updated.

B. Solution

Amendment of the Feed Regulation with the necessary provisions and adoption of sanctions regulations.

C. Alternatives

None. The directly applicable EU legislation requires a corresponding amendment of the Feed Regulation.

D. Budget expenditure without compliance costs

The Federal Government, Länder and municipalities will not incur any budget expenditure

E. Compliance costs

E.1 Compliance costs for citizens

None.

E.2 Compliance costs for businesses

An information obligation for the economy is created.

The economy incurs bureaucratic costs each year from information obligations in the amount of approximately EUR 6 300. The ongoing compliance costs result entirely from EU law and are not relevant for the Federal Government's 'one in, one out' rule. Furthermore, one-off costs of around EUR 271 000 arise from one-off information obligations.

E.3 Compliance costs for the authorities

An annual compliance cost of EUR 3 600 is incurred for the administration of the Länder (including municipalities). One-off compliance costs at the Land level (including municipalities) amount to approximately EUR 140 000. There are no compliance costs at the federal level.

F. Other costs

The draft Regulation provides that infringements of Regulation (EC) no. 999/2001, Annex IV, Chapter III, Section B, subparagraph 1, shall in future also be considered a criminal offence (see Section 39(2)). As only five relevant infringements were detected by authorities in 2022 and, in addition, only eight criminal proceedings were initiated in respect of infringements detected during official feed monitoring (c/f. BMEL, 2022 annual statistics on official feed monitoring in Germany (long version), pp. 5 and 86), the additional burden on investigating authorities and courts is negligible.

Additional impacts, particularly on unit prices and price levels, are not to be expected.

Draft Legislation of the Federal Ministry of Agriculture, Food and Community

Fifty-seventh Regulation amending the Feed Regulation[1]

Dated ...

The Federal Ministry of Agriculture, Food and Community hereby issues the following regulations, respectively in conjunction with Section 1(2) of the Competence Adjustment Regulation of 16 August 2002 (BGBI. I, p. 3165), amended by Article 7 of the Act of 31 August 2015 (BGBl. I p. 1474) and the Organisational Order of 6 May 2025 (BGBI. 2025 I no. 131), on the basis of:

- Section 4(2), subparagraph 2, Section 46(2), first sentence, subparagraph 1(c)(aa), Section 62(1), Section 65, first sentence, subparagraph 2, and Section 70(6) of the German Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch, LFGB), in the version published on 15 September 2021 (BGBl. I p. 4253; 2022 I p. 28), which was last amended by Article 11 of the Act of 6 May 2024 (BGBl. 2024 I no. 149), and

- Section 37(1) of the Food and Feed Code in the version published on 15 September 2021 (BGBl. I p. 4253; 2022 I p. 28), which was last amended by Article 11 of the Act of 6 May 2024 (BGBl. 2024 I no. 149), in agreement with the Federal Ministry for Economic Affairs and Energy:

Artikel 1

Amendment to the Feed Regulation

The Feed Regulation in the version published on 29 August 2016 (BGBI. I p. 2004), as last amended by Article 30 of the Act of 6 May 2024 (BGBl. 2024 I no. 149) is amended as follows:

1. Section 1 is amended as follows:

   a) In the entry before subparagraph 1, the entry ‘are:’ is replaced by the entry ‘is or are:’.

   b) Subparagraphs 1 to 8 are replaced by the following subparagraphs 1 to 11:

      1. ‘non-food producing animal’ means a non-food producing animal as defined in Article 3(2)(d) of Regulation (EC) no. 767/2009, as amended on 5 December 2018,

      2. Pet: Pet as defined in Article 3(2)(f) of Regulation (EC) no. 767/2009 as amended on 5 December 2018;

      3. Supplementary feed: Supplementary feed as defined in Article 3(2)(j) of Regulation (EC) no. 767/2009 as amended on 5 December 2018;

[1] Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17/9/2015, p. 1).

4. Feed intended for particular nutritional purposes: Feed intended for particular nutritional purposes as defined in Article 3(2)(o) of Regulation (EC) no. 767/2009 as amended on 5 December 2018;

5. Medicated feed: Medicated feed within the meaning of Article 3(2)(a) of Regulation (EU) 2019/4 as amended on 11 December 2018;

6. Intermediate product: Intermediate product within the meaning of Article 3(2)(b) of Regulation (EU) 2019/4 in the version of 11 December 2018,

7. Content: Substances - other than feed additives, intermediate residues and undesirable substances - which are contained in a feed material or compound feed and influence its feed value, unless this influence is only negligible,

8. Pesticide residues: Pesticide residues as defined in Article 3(2)(c) of Regulation (EC) no. 396/2005, as amended on 27 March 2025;

9. Mobile mixer: Mobile mixer as defined in Article 3(2)(f) of Regulation (EU) 2019/4, as amended on 11 December 2018,

10. EC Authorisation Regulation: Regulation of the European Community or of the European Union in accordance with

    a) Article 3, 9g (5), Article 9h(3) or Article 9i(3) of Directive 70/524/EEC, as amended on 23 September 2002,

    b) Article 3(1)(a) of Regulation (EC) no. 1831/2003, as amended on 20 June 2019,

11. Import: Release for free circulation within the meaning of Article 201 of Regulation (EU) no. 952/2013, as amended on 23 November 2022'.

c) The previous subparagraphs 9 to 13 become subparagraphs 12 to 16.

2. In Section 5(1) and (2) and Section 6(2), the words 'Regulation (EC) no. 767/2009' are replaced by 'Regulation (EC) no. 767/2009 in the version of 5 December 2018'.

3. Section 7 is replaced by the following Section 7:

'Section 7

Labelling

Supplementary feed for which no maximum levels of undesirable substances are set in Annex I to Directive 2002/32/EC in the version of 7 November 2019 may be placed on the market if the maximum levels set for corresponding complete feed are exceeded, only with the statement indicating the share of the supplementary feed in the daily ration, compliance with which shall not exceed the maximum levels set for a corresponding complete feed in Annex I to Directive 2002/32/EC in the version of 7 November 2019.'

4. In Section 8(1) and (2) and Section 9, the words 'Directive 2002/32/EC' are replaced by the words 'Directive 2002/32/EC as amended on 7 November 2019'.

5. Section 10(1) is replaced by the following paragraph (1):

(1) ' By way of derogation from

1. Article 18(1) of Regulation (EC) no. 396/2005, as amended on 27 March 2025; and

2. the prohibition laid down in Section 21(3), first sentence, subparagraph 3 of the Food and Feed Code;

Feed referred to in column 2 of Annex VII to Regulation (EC) no. 396/2005 in the version of 27 March 2025 which has been treated as a post-harvest fumigant with an active substance referred to in column 1 of Annex VII to Regulation (EC) no. 396/2005 in the version of 27 March 2025 and whose content of one of these active substances therefore exceeds the maximum residue limit set for the active substance in accordance with Regulation (EC) no. 396/2005 in the version of 27 March 2025 may be delivered to a farm referred to in the second sentence. The establishment to which a feed within the meaning of the first sentence may be supplied shall treat or manufacture the feed in such a way that, when the feed so treated or produced is supplied to the end-user, the content of the active substance does not exceed the maximum residue level laid down in accordance with Regulation (EC) no. 396/2005, as amended on 27 March 2025.'

6. In Sections11 and 12(1) and (2), the words 'Regulation (EC) no. 767/2009' are replaced by the words 'Regulation (EC) no. 767/2009 in the version of 5 December 2018'.

7. According to Section 12, the following subsection 3 is added:

'Subsection 3

Medicated feed and intermediate products

Section 13

Notification obligations

(1) For mobile mixers that are authorised in another Member State and where placement of the medicated feed on the market in Germany is intended, this must be notified electronically to the competent authority under Land law in accordance with sentence 2 immediately after receipt of an order for the production of a medicated feed and before the start of production. The notification must contain the following:

1. Name, address and approval number of the mobile mixer,

2. Place and start of manufacture of the medicated feed; and

3. Vehicle registration number of the mobile mixer.

(2) Anyone wishing to place medicated feed for pets on the market as a retailer must notify this in writing or electronically to the competent authority under Land law, stating the retailer's name and address as well as the address of the permanent establishment, prior to the first placing on the market. The first sentence also applies to retailers supplying medicated feed in ready-to-sell packaging.

(3) Any person who, as a keeper of fur animals within the meaning of Article 3(2) (e) of Regulation (EC) no. 767/2009, as amended on 5 December 2018, intends to feed them with medicated feed, must notify this in writing or electronically to the competent authority under Land law, in accordance with the second sentence, before feeding begins. The notification must contain the following:

1. The name and address of the holder of the fur animal and the establishment in which the fur animals for which the medicated feed is intended are kept; and

2. A copy of the veterinary prescription for medicated feed as defined in Article 3(2) (h) of Regulation (EU) 2019/4, as amended on 11 December 2018.'

8. The previous subsection 3 becomes subsection 4.

9. In Section 14, first and second sentences, the words 'Directive 2002/32/EC' are replaced by the words 'Directive 2002/32/EC as amended on 7 November 2019'.

10. In Section 15, the words 'of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (ABl. 147, 31.5.2001, p. 1), as last amended by Regulation (EU) 2017/893 (ABl. 138, 25.5.2017, p. 92)' are replaced by 'in the version dated 19 February 2025'.

11. The previous subsection 4 is replaced by the following subsection 5:

'Subsection 5

Participation of the Federal Office for Consumer Protection and Food Safety

Section 16

Collaboration

(1) The Federal Office participates in:

1. The inclusion of a feed material in the Annex to Regulation (EU) no. 68/2013;

2. The examination of guidelines for good practice in the feed sector in accordance with Articles 20 and 22 of Regulation (EC) no. 183/2005, as amended on 20 June 2019.

(2) The Federal Office also participates in the coordination of the preparation

1. Control plans pursuant to Regulation (EU) 2017/625, as amended on 27 November 2024;

2. Other investigation and survey programmes in the animal feed sector to be carried out by the Member States in accordance with Community or Union legislation.'

12. The previous subsection 5 becomes subsection 6.

13. Section 17 is amended as follows:

a) In paragraph (3), second sentence, subparagraph 2 , the words 'of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (ABl. 35, 8.2.2005, p. 1, L 50, 23.2.2008, p. 71), as last amended by Regulation (EU) 2015/1905 (ABl. 278, 23.10.2015, p. 5)' are replaced by the words 'as amended on 20 June 2019'.

b) In paragraph (4), second sentence, subparagraph 2, the words ‘of the Council of 22 December 1995 laying down the conditions and arrangements for the approval and registration of certain establishments and intermediaries in the feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC (ABl. 332, 30.12.1995, p. 15, L 168, 3.7.1999, p. 35, L 138, 9.6.2000, p. 31), as last amended by Regulation (EC) no. 806/2003 (ABl. 122, 16.5.2003, p. 1)’ are replaced by the words ‘as amended on 14 April 2003’.

c) In paragraph (5), the words ‘of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (ABl. 35, 8.2.2005, p. 1, L 50, 23.2.2008, p. 71), as amended’ are deleted.

14. In Section 18(8), first sentence, subparagraph 2, the words ‘Regulation (EC) no. 183/2005’ are replaced by the words ‘Regulation (EC) no. 183/2005 as amended on 20 June 2019’.

15. In Section 19, first sentence, the words ‘Directive 2002/32/EC’ are replaced by the words ‘Directive 2002/32/EC in the version of 7 November 2019’.

16. Section 22(4) is replaced by the following paragraph (4):

'(4) Paragraphs (1) and (3) only applies to the extent that an establishment designated therein is not subject to an approval or registration requirement under Regulation (EC) no. 183/2005, as amended on 20 June 2019. Paragraph (1) does not apply to feed business operators within the meaning of Article 13(1) of Regulation (EU) 2019/4 as amended on 11 December 2018.’

17. Section 25 is amended as follows:

a) Paragraph (1) , first sentence, subparagraphs 1 and 2 are replaced by the following subparagraphs 1 to 2a:

‘1. The approval of establishments referred to in Article 10 of Regulation (EC) no. 183/2005, as amended on 20 June 2019,

2. The registration of establishments in accordance with Article 9 of Regulation (EC) no. 183/2005, as amended on 20 June 2019,

2a. The approval of establishments in accordance with Article 13 of Regulation (EU) 2019/4, as amended on 11 December 2018,’;

b) In paragraph (2), the words ‘Regulation (EC) no. 183/2005’ are replaced by the words ‘Regulation (EC) no. 183/2005, as amended on 20 June 2019’;

18. In Section 28, first sentence, the words ‘Regulation (EU) 2017/625’ are replaced by the words ‘Regulation (EU) 2017/625 as amended on 27 November 2024’.

19. In Section 30(2), the words ‘Regulation (EC) no. 183/2005’ are replaced by the words ‘Regulation (EC) no. 183/2005 as amended on 20 June 2019’.

20. Section 39 is amended as follows:

a) The indication referred to in subparagraph 1 is replaced by the indication ‘In accordance with Section 58(3), (4) to (6) of the Food and Feed Code, any person who commits an infringement of Regulation (EC) no. 999/2001, as amended on 25 March 2024, intentionally or negligently’ shall be punished.

b) After subparagraph 1, the following subparagraph 2 is added:

‘2. Contrary to subparagraph 1 of Section B of Chapter III or subparagraph 1 or 2 of Section C of Chapter V of Annex IV, produces a compound feed referred to therein,’.

c) The previous subparagraph 2 becomes subparagraph 3 and ‘stores’ is replaced by: ‘stores or’.

d) The previous subparagraph 3 is deleted.

21. Section 40(1) is amended as follows:

a) The previous subparagraphs 2 to 9 have become subparagraphs 1 to 8.

b) After subparagraph 8, the following subparagraph 9 is added:

‘9. Contrary to Section 13(1), first sentence, (2), first sentence, also in conjunction with the second sentence, or (3), first sentence, fails to make a notification, fails to do so correctly, fails to do so in full, fails to do so in the prescribed manner or fails to do so in good time,’.

22. In Section 40a, the indication ‘of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (ABl. 147, 31.5.2001, p. 1), as last amended by Regulation (EU) 2017/893 (ABl. (L 138, 25.5.2017, p. 92),’ is replaced by the words ‘as amended on 19 February 2025’.

23. In Section 41(1), the words ‘of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (ABl. 268, 18.10.2003, p. 29, L 192, 29.5.2004, p. 34, L 98, 13.4.2007, p. 29), as last amended by Regulation (EU) 2015/2294 (ABl. 324, 10.12.2015, p. 3)’ are replaced by the words ‘asamended on 20 June 2019’.

24. In Section 42 the words ‘of the European Parliament and of the Council of 12 January 2005 laying down rules on feed hygiene (ABl. 35, 8.2.2005, p. 1, L 50, 23.2.2008, p. 71), as last amended by Regulation (EU) 2015/1905 (ABl. (L 278, 23.10.2015, p. 5),’ is replaced by the words ‘as amended on 20 June 2019’.

25. Section 44 is amended as follows:

a) In paragraph (1) the words ‘of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending Regulation (EC) no. 1831/2003 of the European Parliament and of the Council and repealing Council Directives 79/373/EEC, 80/511/EEC, 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (ABl. L 229, 1.9.2009, p. 1, L 192, 22.7.2001, p. 71), as last amended by Regulation (EU) 2017/2279 (ABl. (L 328, 12.12.2017, p. 3),’ is replaced by the words ‘as amended on 5 December 2018’.

b) In paragraph (2), the words ‘Regulation (EC) no. 767/2009’ are replaced by the words ‘Regulation (EC) no. 767/2009 as amended on 5 December 2018’.

26. In Section 46a, the words ‘of 19 May 2015 laying down criteria for the admissibility of detoxification processes applied to products intended for animal feed pursuant to Directive 2002/32/EC of the European Parliament and of the Council (ABl. 125, 21.5.2015, p. 10)’ are replaced by the words ‘as amended on 19 May 2015’.

27. Section 47 is replaced by the following Section 47:

'Section 47

Administrative offences for certain infringements of Regulation (EU) 2019/4

An administrative offence within the meaning of Section 60(4)(2)(a) of the Food and Feed Code is deemed to have been committed by any person who infringes upon Regulation (EU) 2019/4, as amended on 11 December 2018, by intentionally or negligently:

1. if a feed business operator, contrary to Article 5(1), manufactures a medicated feed or an intermediate product that is not authorised in accordance with Article 5(1) of Regulation (EU) 2019/6 as amended on 23 November 2022;

2. contrary to Article 5(2)(a), (b) or (c), fails to ensure a requirement referred to therein;

3. fails to ensure that the medicated feed complies with the prescription referred to in Article 16(1)(a), first clause, contrary to Article 5(3);

4. supplies a medicated feed or intermediate product to an animal keeper contrary to Article 8, first sentence;

5. promotes a medicated feed or intermediate product contrary to Article 11(1), first sentence;

6. distributes medicated feed contrary to Article 11(3) or (4);

7. contrary to Article 13(1), does not ensure that an establishment referred to therein is approved;

8. uses, contrary to Article 17(1), (2), first sentence, first clause or (3), a medicated feed referred to therein in animals within the meaning of Section 1, subparagraph 1;

9. fails to ensure, contrary to Article 17(2), first sentence, second clause, that a medicated feed is only fed to an animal referred to therein;

10. fails to ensure that a medicated feed referred to therein is not used, contrary to the second sentence of Article 17(2);

11. contrary to Article 17(6), does not ensure that the prescribed waiting period is complied with;

12. fails to keep the book, does not keep it correctly or does not keep it in full, contrary to Article 17(7), first sentence;

13. contrary to Article 17(7)(2), failing to keep a record or to do so for at least five years,

14. contrary to Section 6(1) of Annex I in conjunction with paragraph (2), first sentence, does not record the data referred to therein, does not record them correctly or does not record them in full,

15. contrary to the Section 8(1) of Annex I, does not carry a document referred to therein; or

16. uses a vehicle in contravention of Section 8(3) of Annex I.

(2) An administrative offence within the meaning of Section 60(4)(2)(b) of the Food and Feed Code is deemed to have been committed by any person who, intentionally or negligently, fails to ensure, contrary to Article 12(2) of Regulation (EU) 2019/4, as amended on 11 December 2018, that a veterinary medicinal product authorised in accordance with Article 5(1) of Regulation (EU) 2019/6, as amended on 23 November 2022, is used.'

28. In Section 47a, the words 'the Commission of 4 March 2020 establishing a list of intended uses of feed for particular nutritional purposes and repealing Directive 2008/38/EC (ABl. 67, 5.3.2020, p. 1)' are replaced by the words 'as amended on 20 November 2024'.

29. In footnotes 2 and 3 of Appendix 2, the words 'Regulation (EC) no. 152/2009' are replaced by the words 'Regulation (EC) no. 152/2009 as amended on 23 April 2025'.

30. In the first sentence of subparagraph 3 of Annex 4, the words 'Directive 2002/32/EC' are replaced by the words 'Directive 2002/32/EC in the version of 7 November 2019' and the words 'Regulation (EC) no. 178/2002' by the words 'Regulation (EC) no. 178/2002 in the version of 17 January 2024'.

Artikel 2

Entry into force

This Decree enters into force on 1 January 2026.

The Bundesrat has granted approval.

EU legal acts:

1. Council Directive of 23 November 1970 concerning additives in feedstuffs (70/524/EEC) (ABl. 270, 14.12.1970, p. 1), repealed by Regulation (EC) 767/2009 (ABl. 229, 1.9.2009, p. 1)

2. Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries in the feed sector and amending Directives 70/524/EEC, 74/63/EEC 79/373/EEC and 82/471/EEC (ABl. 332, 30.12.1995, p. 15), repealed by Regulation (EC) no. 183/2005 of 12 January 2005 (ABl. 35, 8.5.2005, p. 1)

3. Regulation (EC) no. 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (ABl. 147, 31.5.2001, p. 1), as last amended by Implementing Regulation (EU) 2025/328 of 19 February 2025 (ABl. 2025/328, 20.2.2025).

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 (ABl. 31, 1.2.2002, p. 1), as last amended by Delegated Regulation (EU) 2024/908 of 17 January 2024 (ABl. 2024/908, 20.3.2024)

5. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (ABl. 140, 30.5.2002, p. 10), as last amended by Regulation (EU) 2019/1869 of 7 November 2019 (ABl. 289, 8.11.2019, p. 32).

6. Regulation (EC) no. 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (ABl. 268, 18.10.2003, p. 29), as last amended by Regulation (EU) 2019/1381 of 20 June 2019 (ABl. 231, 6.9.2019, p. 1)

7. Regulation (EC) no. 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (ABl. 35, 8.2.2005, p. 1), as last amended by Regulation (EU) 2019/1243 of 20 June 2019 (ABl. 198, 25.7.2019, p. 241).

8. Regulation (EC) no. 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (ABl. 70, 16.3.2005, p. 1), as last amended by Regulation (EU) 2025/581 of 27 March 2025 (ABl. 2025/581, 28.3.2025).

9. Commission Regulation (EC) no. 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (ABl. 54, 26.2.2009, p. 1), as last amended by Implementing Regulation (EU) 2025/782 of 23 April 2025 (ABl. 2025/782, 24.4.2025)

10. 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 Regulation (EC) no. 1831/2003 of the European Parliament and of the Council and repealing Council Directives 79/373/EEC, 80/551/EEC, 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EEC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1), as last amended by Regulation (EU) 2018/1903 of 5 December 2018 (OJ L 310, 6.12.2018, p. 22)

11. Commission Regulation (EU) no. 68/2013 of 16 January 2013 on the catalogue of feed materials (ABl. 29, 30.1.2013, p. 1), as last amended by Regulation (EU) 2022/1104 of 1 July 2022 (ABl. 177, 4.7.2022, p. 4).

12. Regulation (EU) no. 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (ABl. 269, 10.10.2013, p. 1), as last amended by Regulation (EU) 2022/2399 of 23 November 2022 (ABl. 317, 9.12.2022, p. 1).

13. Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council (ABI. L 125 dated 21.5.2015, p. 10)

14. 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 Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC of the Council 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) (ABI. L 95, 7.4.2017, p. 1), as last amended by Regulation (EU) 2024/3115 of 27 November 2024 (ABI. L 2024/3115, 16.12.2024)

15. 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 (ABI. L 4, 7.1.2019, p. 1)

16. 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 (ABl. 4, 7.1.2019, p. 43), as last amended by Delegated Regulation (EU) 2023/183 of 23 November 2023 (ABl. 26, 30.1.2023, p. 7).

17. Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed for particular nutritional purposes and repealing Directive 2008/38/EC (ABl. 67, 5.3.2020, p. 1), as amended by Regulation (EU) 2024/2899 of 20 November 2024 (ABl. 2024/2899, 21.11.2024)

Justification

A. General part

I. Objective of and need for the provisions

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, requires an adjustment to the Feed Regulation. Regulation (EU) 2019/4 lays down specific provisions for medicated feed and intermediate products. While medicated feed was designated as a medicated feed prior to the entry into force of Regulation (EU) 2019/4 and Regulation (EU) 2019/6 on veterinary medicinal products on 28 January 2019 and was therefore a medicinal product under national law, it is now considered to be a feed in the EU as defined in Article 3(2)(a) of Regulation (EU) 2019/4. In order to take account of the requirements of the Regulation, national procedural rules will be adapted and issued. The rules on the authorisation and registration of feed business operators are directly derived from Article 13 of Regulation (EU) 2019/4 and from Regulation (EC) 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene and therefore do not need to be included in the Regulation. In addition, in order to penalise infringements of the requirements and prohibitions laid down in the Regulation, additions to the Feed Regulation are necessary. Furthermore, a national sanction for an infringement of Regulation (EC) no. 999/2001 is to be supplemented in order to close a gap in criminal liability. Finally, references to EU regulations are to be updated.

II. Main content of the draft

The draft regulation lays down notification obligations for certain undertakings producing and distributing medicated feed. These include mobile mixers licensed abroad and retailers selling medicated feed for pets. The notification obligation is necessary in order for the monitoring authorities to be aware of the activities of the establishments and to be able to fulfil their monitoring task. In addition, in Article 13(5) of Regulation (EU) 2019/4, the EU legislature calls for the establishment of corresponding national procedures. Infringements of the reporting obligations are punishable as an administrative offence.

In order to protect against the spread of transmissible spongiform encephalopathies, a national penalty for non-compliance with subparagraph 1 of Section B of Chapter III of Annex IV to Regulation (EC) no. 999/2001 is to be added. In this way, manufacturers are encouraged to produce compound feed intended for the feeding of farmed animals other than ruminants in accordance with the requirements laid down in subparagraph 1 of Section B of Chapter III of Annex IV to Regulation (EC) no. 999/2001. This includes, in particular, production in an establishment which does not produce compound feed for ruminants and which is approved by the competent authority. This fills a gap in the sanctioning of infringements at the production level.

Furthermore, infringements of Regulation (EU) 2019/4 are subject to comprehensive sanctions. Article 22(1) of Regulation 2019/4 obliges Member States to lay down rules on penalties for infringements of this Regulation. Sanctioning is also necessary due to the potential risks to humans and animals associated with medicated feed and intermediate products. For example, incorrect dosages in the manufacture and feeding of medicated feed may affect the health and well-being of the animals. Residues of veterinary medicinal products used in the manufacture of medicated feed in the food of animal origin obtained

may be harmful to human health. Residues of antibiotic active substances may lead to the development and spread of antimicrobial resistance.

III. Alternatives

The regulations are necessary for the implementation of Union law. In this respect, there are no alternatives.

IV. Regulatory competence

The regulatory competence of the Federal Ministry of Agriculture, Food and Community is derived from Section 37(1) of the Food and Feed Code, in agreement with the Federal Ministry of Economic Affairs and Energy, Section 46(2), first sentence, subparagraph 1(c) (aa), Section 62(1), Section 65, first sentence, subparagraph 2, and Section 70(6) of the Food and Feed Code.

V. Compatibility with European Union law and international treaties

The draft Regulation is compatible with European Union legislation and treaties under international law concluded by the Federal Republic of Germany.

VI. Consequences of the legislation

The draft regulation provides legal clarity for the undertakings concerned and the authorities in the authorisation and registration of medicated feed establishments.

The new Section 13 establishes legal clarity as to how the notification of the activity of mobile mixers to the competent authority specified in accordance with Article 13(4) of Regulation (EU) 2019/4 must be made. Section 13 also establishes the national procedure required by Article 13(5) of Regulation (EU) 2019/4 to ensure knowledge of the activities of retail establishments of medicated feed for pets by the competent authorities.

By adopting the penalty standards, establishments are required to comply with the requirements of Regulation (EU) 2019/4. The proposed penalty for non-compliance with Annex IV, Chapter III, Section B subparagraph 1 to Regulation (EC) 999/2001 also serves the purpose of compliance.

1. Legal and administrative simplification

The draft Regulation does not imply any legal or administrative simplification.

2. Sustainability aspects

A sustainability assessment has been carried out in accordance with the Section 44(1), fourth sentence, of the Joint Rules of Procedure of the Federal Ministries (Gemeinsamen Geschäftsordnung, GGO). The regulations are sustainable in the sense of the German Sustainability Strategy, as they serve the safe use of medicated feed in live animals and thus promote the achievement of sustainability goal 3 ‘Ensure a healthy life for all people of all ages and promote their well-being’ with indicator 3.1a/b ‘Health and nutrition, live healthier for longer’. In addition, the principle of sustainable development no. 3 ‘Preserving natural resources’ is taken into account, as the safe use of medicated feed avoids hazards and unacceptable risks to human health, such as the development of resistance to antimicrobial active substances.

3. Budget expenditure without compliance costs

None.

4. Compliance costs

The economy incurs bureaucratic costs each year from information obligations in the amount of approximately EUR 6 300. The ongoing compliance costs result entirely from EU law and are not relevant for the 'one in, one out' regulation of the Federal Government. Furthermore, a one-off compliance cost of around EUR 271 000 arises from one-off information obligations.

Section 13 creates information obligations for the business community.

The obligation to provide information under Section 13(1) relates to the mobile mixers referred to in Article 13(4) of Regulation (EU) 2019/4. They must notify their respective activities to the competent authority under Land law.

Change in annual compliance costs:

Falling number	Time expenditure per case (in minutes)	Hourly wage (in EUR)	Material costs per case (in EUR)	Personnel costs (in thousands of EUR)	Material costs (in thousands of EUR)
100	10	45.80	0	0.76	0
Change in compliance costs (in thousands of thousand)				0.76	

Section 13(2) also lays down an obligation to provide information for retail establishments wishing to distribute medicated feed for pet animals. This is a one-time notification requirement. Typically, animal keepers obtain veterinary medicinal products through the veterinarians treating them. The previous regulation on medicated feed was of very little importance in Germany. It is assumed that in future, livestock farmers will obtain medicated feed predominantly from veterinarians.

Retailers with zoological needs and live animals:

Change in annual compliance costs:

Falling number	Time expenditure per case (in minutes)	Hourly wage (in EUR)	Material costs per case (in EUR)	Personnel costs (in thousands of EUR)	Material costs (in thousands of EUR)
128	20	62.40	2	2	0.3
Change in compliance costs (in thousands of EUR)				2.92	

One-off compliance costs:

Falling number	Time expenditure per case (in minutes)	Hourly wage (in EUR)	Material costs per case (in EUR)	Personnel costs (in thousands of EUR)	Material costs (in thousands of EUR)
512	20	62.40	2	10.6	1
Compliance costs (in thousands of EUR)				11.7	

Veterinarians:

Change in annual compliance costs:

Falling number	Time expenditure per case (in minutes)	Hourly wage (in EUR)	Material costs per case (in EUR)	Personnel costs (in thousands of EUR)	Material costs (in thousands of EUR)
114	20	62.00	2	2.4	0.2
Change in compliance costs (in thousands of EUR)				2.6	

One-off compliance costs:

Falling number	Time expenditure per case (in minutes)	Hourly wage (in EUR)	Material costs per case (in EUR)	Personnel costs (in thousands of EUR)	Material costs (in thousands of EUR)
11 437	20	62.00	2	236	23
Compliance costs (in thousands of thousand)				259	

In accordance with Section 13(3), holders of fur animals feeding animals with medicated feed are also affected. The regulation of fur farming in Germany was amended by the Animal Products Trade Prohibition Act of 30 June 2017. Since then, fur farming in Germany has been subject to a statutory prohibition subject to authorisation. The legal requirements are so high that there are currently no commercial fur farms in Germany. These were therefore not taken into account in the calculation of the implementation costs.

The administration of the Länder (including municipalities) incurs an annual implementation cost of around EUR 4 000. One-off compliance costs at the Land level (including municipalities) amount to approximately EUR 140 000. The amount of the respective compliance costs results from the receipt of the notifications. There are no compliance costs at the federal level.

Receipt of the display of mobile mixers:

Change in annual compliance costs of the Länder:

Falling number	Time expenditure per case (in minutes)	Hourly wage (in EUR)	Material costs per case (in EUR)	Personnel costs (in EUR EUR)	Material costs (in thousands of EUR)
100	10	46.70	0	0.8	0
Change in compliance costs (in thousands of EUR)				0.8	

Receiving notification from retailers of medicated feed for pet animals:

Change in annual compliance costs of the Länder:

Falling number	Time expenditure per case (in minutes)	Hourly wage (in EUR)	Material costs per case (in EUR)	Personnel costs (in thousands of EUR)	Material costs (in thousands of EUR)
128	20	62.40	2	2.7	0.3
Change in compliance costs (in thousands of EUR)				2.92	

One-off compliance costs of the Länder:

Falling number	Time expenditure per case (in minutes)	Hourly wage (in EUR)	Material costs per case (in EUR)	Personnel costs (in thousands of EUR)	Material costs (in thousands of EUR)
11 949	15	46.70	0	140	0
Compliance costs (in thousands of EUR)				140	

The new Section 47 FuttMV provides for the sanctioning of infringements of Regulation (EU) 2019/4. This creates the legal basis for the competent enforcement authorities of the Länder to penalise infringements of EU law.

As no data are available on the number of current infringements and it is difficult to differentiate between the individual offences, one compliance cost per case is reported. Overall, a small number of cases is assumed.

The time required for the enforcement authorities of the Länder is estimated on average at two hours per case, with the estimate based on experience from other re-measured administrative offence proceedings.

The wage rate corresponds to the average of the wage costs for the categories at the administrative level of the Länder (EUR 46.70).

Material costs in the amount of EUR 1 postage per case are incurred for the dispatch of the penalty notice.

The annual compliance costs for the monitoring of the newly regulated administrative offences amount to around EUR 80 per case or penalty of an administrative offence.

5. Other costs

The draft Regulation provides that, in future, infringements of Regulation (EC) no. 999/2001, Annex IV, Chapter III, Section B, subparagraph 1, shall also be regarded as criminal offences (c/f. Section 39(2) of the FuttMV). As only five relevant infringements were detected by authorities in 2022 and, in addition, only eight criminal proceedings were initiated in respect of infringements detected during official feed monitoring (c/f. BMEL, 2022 annual statistics on official feed monitoring in Germany (long version), pp. 5 and 86), the additional burden on investigating authorities and courts is negligible. There are no additional costs to businesses. No impact is anticipated on unit prices or price levels, in particular on consumer price levels.

6. Further regulatory consequences

The rules contribute to the safety of feed and thus also benefit animal health and consumers by improving the safety of food of animal origin. Equality policy and demographic concerns are not affected.

The Regulation has no negative impact on consumers.

The amendments envisaged have been reviewed for their relevance to gender equality. There are no indications that genders were affected differently.

From a demographic point of view, the draft regulation is also not expected to have any impact. The same applies to effects on the requirement of equivalent living conditions.

In accordance with the Guidelines on implementing ‘equivalence checks’ for draft federal legislation of 20 April 2020, it has been examined whether and what impact the draft federal legislation would have on the equivalence of people’s living conditions in Germany. Although the Regulation imposes a small financial burden on municipalities, it is expected to have a positive impact on the ‘natural livelihoods’ factor mentioned in the guidelines.

VII. Limitation; evaluation

The Regulation implements Union law of indefinite duration and is therefore of indefinite duration.

VIII. Section 43(1), subparagraph 13 GGO

Appointed third parties have not contributed to the content of the draft law.

B. Specific part

Re Artikel 1 (Amendment to the Feed Regulation)

Re Nummer 1

Re Buchstabe a and b

Re subparagraph 1:

Regulation (EC) no. 767/2009, cited in Section 1(1) of the Feed Regulation (FuttMV), was last amended by Regulation (EU) 2018/1903. This requires an update of the quotation in Section 1(1) FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re subparagraph 2:

Regulation (EC) no. 767/2009, cited in Section 1, subparagraph 2 of the FuttMV, was last amended by Regulation (EU) 2018/1903. This requires an update of the quotation in Section 1, subparagraph 2 FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re subparagraph 3:

Regulation (EC) no. 767/2009, cited in Section 1, subparagraph 3 of the FuttMV, was last amended by Regulation (EU) 2018/1903. This requires an update of the quotation in Section 1, subparagraph 3 FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re subparagraph 4:

Regulation (EC) no. 767/2009, cited in Section 1, subparagraph 4 of the FuttMV, was last amended by Regulation (EU) 2018/1903. This requires an update of the quotation in Section 1, subparagraph 4 FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re subparagraph 5:

There is a need for a definition of the term ‘medicated feed’.

The regulation is based on Section 4(2), subparagraph 2 of the LFGB.

Re subparagraph 6:

There is a need for a definition of the term ‘intermediate products’.

The regulation is based on Section 4(2), subparagraph 2 of the LFGB.

Re subparagraph 7:

Consequential amendment to subparagraph 5 and subparagraph 6.

Re subparagraph 8:

Regulation (EC) no. 396/2005, cited in Section 1, subparagraph 8 of the FuttMV, was last amended by Regulation (EU) 2025/581. This requires an update of the quotation in Section 1, subparagraph 8 FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re subparagraph 9:

There is a need for a definition of the term ‘mobile mixer’.

The regulation is based on Section 4(2), subparagraph 2 of the LFGB.

Re subparagraph 10:

Re subparagraph 10(a):

Directive 70/524/EEC, cited in Section 1, subparagraph 7 of the FuttMV, was repealed by Regulations (EC) no. 767/2009 and no. 1831/2003. This requires an update of the quotation in Section 1, subparagraph 10(a) of the FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

On subparagraph 10(b):

Regulation (EC) no. 1831/2003, cited in Section 1, subparagraph 10(b) of the FuttMV, was last amended by Regulation (EU) 2019/1381. This requires an update of the quotation in Section 1, subparagraph 10(b) FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re subparagraph 11:

Regulation (EU) no. 952/2013, cited in Section 1, subparagraph 11 of the FuttMV, was last amended by Regulation (EU) 2022/2399. This requires an update of the quotation in Section 1, subparagraph 11 FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Buchstabe c

Consequential amendment to subparagraph 1(a)

Re Nummer 2

Regulation (EC) no. 767/2009, cited in Section 5, subparagraph 1 and 2 and Section 6(2) of the FuttMV, was last amended by Regulation (EU) 2018/1903. This requires an update of the respective citation in Section 5, subparagraph 1 and 2 and Section 6(2) of the FuttMV, which has so far referred to another older amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 3

Directive 2002/32/EC, cited in Section 7 of the FuttMV, was last amended by Regulation (EU) 2019/1869. This requires an update of the quotation in Section 7 FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 4

Directive 2002/32/EC, cited in Section 8(1) and (2) and Section 9 of the FuttMV, was last amended by Regulation (EU) 2019/1869. This requires an update of the respective quotations in Section 8(1) and (2) and Section 9 of the FuttMV, which so far refers to other earlier amending regulations. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 5

Regulation (EC) no. 396/2005, cited in Section 10(1), first sentence of the FuttMV, was last amended by Regulation (EU) 2025/581. This requires an update of the quotation in Section 10(1), first sentence of the FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 6

Regulation (EC) no. 767/2009, cited in Sections 11 and 12, subparagraphs 1 and 2 of the FuttMV, was last amended by Regulation (EU) 2018/1903. This requires an update of the respective citation in Sections 11 and 12, subparagraph 1 of the FuttMV, which has so far referred to another older amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 7

The new subsection 3 lays down procedural rules for the implementation of Regulation (EU) 2019/4.

The newly inserted Section 13 contains various notification obligations.

Paragraph (1) concerns mobile mixers. Pursuant to Article 13(4) of Regulation (EU) 2019/4, mobile mixers placing medicated feed on the market in a Member State other than that in which they were authorised must notify the competent authority of this activity. Section 13 defines this requirement as a duty of notification. The obligation is necessary in order for the supervisory authorities to be aware of the activities of the establishments and to fulfil their supervisory role.

The provision is based on Section 46(2), first sentence, subparagraph 1(c)(aa) LFGB.

Paragraphs (2) and (3) are intended to implement Article 13(5) of Regulation (EU) 2019/4. According to this, Member States have national procedures in place to ensure that relevant information on the respective activity is available to the competent authorities.

Paragraph (2) concerns retailers of medicated feed for pet animals. This paragraph also applies to veterinarians. Veterinarians are sometimes subject to derogations (e.g. in veterinary medicinal products legislation), but Regulation (EU) 2019/4 does not provide for exemptions for veterinarians when distributing medicated feed.

The provision is based on Section 46(2), first sentence, subparagraph 1(c)(aa) LFGB.

Section 3 contains a corresponding notification obligation for keepers of fur animals feeding medicated feed. In Germany, fur farming was re-regulated by law by amending the Animal Products Trade Prohibition Act of 30 June 2017. Since then, fur farming in Germany has been subject to a statutory prohibition subject to authorisation. The legal requirements are so high that there are currently no commercial fur farms in Germany.

The provision is based on Section 46(2), first sentence, subparagraph 1(c)(aa) LFGB.

Re Nummer 8

This is a follow-up editorial amendment to subparagraph 7.

Re Nummer 9

Directive 2002/32/EC, cited in Section 14, first and second sentences of the FuttMV, was last amended by Regulation (EU) 2019/1869. This requires an update of the relevant quotation in Section 14, first and second sentences of the FuttMV, which so far refers to another older amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 10

Regulation (EC) no. 999/2001, cited in Section 15 of the FuttMV, was last amended by Implementing Regulation (EU) 2025/328. This requires an update of the quotation in Section 15 FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 11

This is a follow-up editorial amendment to subparagraph 7.

Re Nummer 12

This is a follow-up editorial amendment to subparagraph 7.

Re Nummer 13

Re Buchstabe a

Regulation (EC) no. 183/2005, cited in Section 17(3), subparagraph 2 of the FuttMV, was last amended by Regulation (EU) 2019/1243. This requires an update of the quote in Section 17(3), subparagraph 2 of the FuttMV, which has so far referred to another earlier amending Regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Buchstabe b

The citation of the Directive referred to in Section 17(4), second sentence, subparagraph 2, of the FuttMV is merely legally adapted.

Re Buchstabe c

The citation of the Regulation cited in Section 17(5) of the FuttMV is merely legally adapted.

Re Nummer 14

Regulation (EC) no. 183/2005, cited in Section 18(8), first sentence, subparagraph 2 of the FuttMV, was last amended by Regulation (EU) 2019/1243. This requires an update of

the quote in Section 18(8), first sentence, subparagraph 2 of the FuttMV, which has so far referred to another older amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 15

Directive 2002/32/EC, cited in Section 19, first sentence of the FuttMV, was last amended by Regulation (EU) 2019/1869. This requires an update of the quotation in Section 19, first sentence of the FuttMV, which so far refers to another older amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 16

Consequential amendment to subparagraph 7.

Section 22(1) of the FuttMV lays down a notification obligation for establishments wishing to place feed for pet animals on the market. Since establishments that commercially place medicated feed for pet animals on the market are approved by the competent authority pursuant to Article 13(1) of Regulation (EU) 2019/4, the new Section 22(4), second sentence of the FuttMV provides for an exception to the notification obligation pursuant to Section 22(1) of the FutMV in this case. This means that there is no unnecessary additional notification for these holdings.

The provision is based on Section 46(2), first sentence, subparagraph 1(c)(aa) LFGB.

Re Nummer 17

Re Buchstabe a

Regulation (EC) no. 183/2005, cited in Section 25(1), first sentence, subparagraphs 1 and 2 of the FuttMV, was last amended by Regulation (EU) 2019/1243. This requires an update of the respective citation in Section 25(1), first sentence, subparagraphs 1 and 2 of the FuttMV, which has so far referred to another older amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

An obligation to notify the approval pursuant to Article 13 of Regulation (EU) no. 2019/4 of the competent authority under Land law to the Federal Office of Consumer Protection and Food Safety is required. This notification is necessary in order to comply with Article 14 of Regulation (EU) 2019/4. Accordingly, the establishments approved in accordance with Article 13(1) of that Regulation shall be entered in a national list referred to in Article 19(2) of Regulation (EC) no. 183/2005 with an individual identification number.

Under Section 4, second sentence of the Act on the Establishment of a Federal Office for Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVLG), regulations based on the Food and Feed Code provide that the Federal Ministry’s competence for announcements pursuant to Section 4, first sentence 4 of the BVLG may be transferred, in whole or in part, to the Federal Office. Section 25(1) of the FuttMV transferred the notice from the Federal Ministry of Agriculture, Food and Community to the BVL. In order to be able to perform this task, the authorities competent under Land law must communicate the necessary data to the BVL.

The regulation is based on Section 65, first sentence, subparagraph 2 of the LFGB.

Re Buchstabe b

Regulation (EC) no. 183/2005, cited in Section 25(2) of the FuttMV, was last amended by Regulation (EU) 2019/1243. This requires an update of the quotation in Section 25(2)

FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 18

Regulation (EC) no. 2017/625, cited in Section 28, first sentence of the FuttMV, was last amended by Regulation (EU) 2024/3115. This requires an update of the quotation in Section 28, first sentence of the FuttMV, which so far refers to another older amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 19

Regulation (EC) no. 183/2005, cited in Section 30(2) of the FuttMV, was last amended by Regulation (EU) 2019/1243. This requires an update of the quotation in Section 30(2) FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 20

Re Buchstabe a

Regulation (EC) no. 999/2001, cited in Section 39 FuttMV, was last amended by Regulation (EU) 2024/918. This requires an update of the quotation in Section 39 FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Buchstabe b

The addition of subparagraph 2 to Section 39 of the FuttMV creates a new criminal offence. The aim is to close a criminal liability gap with regard to the requirements for the production plant of compound feed set out in subparagraph 1 of Section B of Chapter III of Annex IV to Regulation (EC) no. 999/2001. This supplement is intended to encourage manufacturers to produce compound feed intended for the feeding of farmed animals other than ruminants containing feed materials listed in subparagraphs 1(a) to (c) of Section B of Chapter III of Annex IV in establishments which do not produce compound feed for ruminants and which are approved by the competent authority, in accordance with the provisions of Regulation (EC) no. 999/2001.

The provision is based on Section 62(1), subparagraph 1 of the LFGB in conjunction with Section 58(3), subparagraph 2, Section 58(1), subparagraph 18 and Section 22 of the LFGB.

Re Buchstabe c

Subsequent amendment to point b

Re Buchstabe d

Subsequent amendment to point b

Re Nummer 21

Re Buchstabe a

Amendment to point b

Re Buchstabe b

The new subparagraph 9 in Section 40 penalises violations of the notification obligation laid down in the new Section 13.

For the national authority responsible for the inspection, knowledge of mobile mixers authorised in another Member State which carry out their activities in the respective area of competence in Germany is required. The mobile mixers are required by the sanctioning to comply properly with the notification obligation.

The sanctioning of retailers and keepers of fur animals is also necessary for the reasons set out above.

The provision is based on Section 62(1) subparagraph 2(a) of the LFGB in conjunction with Section 60(4) subparagraph 2(a), Section 60(2) subparagraph 26(a), Section 46(2), first sentence, subparagraph 1(c)(aa) of the LFGB.

Re Nummer 22

Regulation (EC) no. 999/2001, cited in Section 40a of the FuttMV, was last amended by Regulation (EU) 2024/918. This requires an update of the quotation in Section 40a FuttMV, which has so far referred to another older amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 23

Regulation (EC) no. 1831/2003, cited in Section 41(1) of the FuttMV, was last amended by Regulation (EU) 2019/1381. This requires an update of the quotation in Section 41(1) FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 24

Regulation (EC) no. 183/2005, cited in Section 42 FuttMV, was last amended by Regulation (EU) 2019/1243. This requires an update of the quotation in Section 42 FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 25

Re Buchstabe a

Regulation (EC) no. 1831/2003, cited in Section 44(1) of the FuttMV, was last amended by Regulation (EU) 2019/1381. This requires an update of the quotation in Section 44(1) FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Buchstabe b

Regulation (EC) no. 767/2009, cited in Section 44(2) of the FuttMV, was last amended by Regulation (EU) 2018/1903. This requires an update of the quotation in Section 44(2) FuttMV, which so far refers to another earlier amending regulation. The reference adjustment is based on Section 70(6) of the LFGB.

Re Nummer 26

The citation of the regulation cited in Section 46a of the FuttMV is merely legally adapted.

Re Nummer 27

The new Section 47 FuttMV provides for the necessary sanctioning of infringements of Regulation (EU) 2019/4. Recital 35 of Regulation (EU) 2019/4 calls on Member States to lay down rules on penalties applicable to infringements of that Regulation and to take all measures necessary to ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

Re subparagraph 1:

The purpose of sanctioning the infringement of Article 5(1) of Regulation (EU) 2019/4 is to ensure the safety of medicated feed and intermediate products. Medicated feed and intermediate products shall only be manufactured from veterinary medicinal products authorised for the manufacture of medicated feed in accordance with Article 5(1) of Regulation (EU) 2019/6. The aim is to ensure safe and effective treatment of animals in order to prevent adverse effects on animal health and the safety of food of animal origin.

The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 23a, subparagraph 8(b) LFGB.

Re subparagraph 2:

The sanctioning of non-compliance with Article 5(2)(a) of Regulation (EU) 2019/4 is also intended to ensure the safety of medicated feed and intermediate products. The medicated feed or intermediate product shall be manufactured in accordance with the relevant conditions of the veterinary prescription for medicated feed or, in the cases referred to in Article 8 of Regulation (EU) 2019/4, in accordance with the relevant conditions of the summary of product characteristics for the veterinary medicinal products to be incorporated into the feed.

The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 23a, subparagraph 8(b) LFGB.

The purpose of sanctioning the infringement of Article 5(2)(b) of Regulation (EU) 2019/4 is to ensure the safe use of medicated feed and intermediate products.

A feed additive authorised as a coccidiostat or histomonostat for which a maximum content has been set in the relevant authorisation act shall not be incorporated in the medicated feed or intermediate product if it is already used as an active substance in the veterinary medicinal product. The relevant authorisation acts are available on EUR-Lex.

The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4) subparagraph 2(a), Section 60(2) subparagraph 26(a) and Section 23a subparagraph 8(a) LFGB.

The sanctioning of non-compliance with Article 5(2)(c) of Regulation (EU) 2019/4 also serves to ensure the safe use of medicated feed and intermediate products.

In cases where the active substance of the veterinary medicinal product is identical to a substance contained in a feed additive of the feed concerned, the total content of that active substance in the medicated feed shall not exceed the maximum content laid down in the veterinary prescription for medicated feed or, in the cases referred to in Article 8 of Regulation 2019/4, the maximum content laid down in the summary of product characteristics.

The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 23a, subparagraph 8(b) LFGB.

Re subparagraph 3:

The purpose of sanctioning the infringement of Article 5(3) is to ensure that the medicated feed supplied by the feed business operator to the animal keeper complies with the prescription referred to in Article 16(1)(a) of Regulation 2019/4. This serves to avoid errors in the supply and use of medicated feed, thereby protecting the health and welfare of animals and ensuring the safety of food of animal origin.

The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 23a, subparagraph 8(b) LFGB.

Re subparagraph 4:

The purpose of sanctioning the infringement of the first sentence of Article 8 of Regulation (EU) 2019/4 is to ensure that medicated feed or intermediate products are only used in animals where this is necessary from a veterinary point of view. Misuse or unnecessary administration to an animal should be prevented. This serves to protect the health and well-being of animals, to ensure the safety of food of animal origin and, in particular, to prevent the development of antimicrobial resistance.

Except for on-farm mixers and mobile mixers, medicated feed and intermediate products shall not be supplied to the animal keeper before the relevant veterinary prescription is presented in accordance with Article 16 of Regulation (EU) 2019/4.

The provision is based on Section 62(1), subparagraph 2(a) of the LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 23a, subparagraph 8(b) of the LFGB.

Re subparagraph 5:

The sanctioning of the infringement of the first sentence of Article 11(1) of Regulation (EU) 2019/4 is intended to result in compliance with the prohibition on advertising laid down therein.

Advertising of medicated feed and intermediate products is prohibited in accordance with the first sentence of Article 11(1) of Regulation (EU) 2019/4. According to recital 20 of Regulation (EU) 2019/4, corresponding advertising could have an impact on public and animal health and distort competition. Persons who therefore do not correctly assess the risk of use could, for example, overdose on medicated feed and intermediate products and use them differently from the prescription. An exception to the advertising ban exists for advertising aimed exclusively at veterinarians.

The provision is based on Section 62(1), subparagraph 2(a) of the LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a), Section 23a, subparagraph 12 of the LFGB.

Re subparagraph 6:

The sanctioning of the infringement of Article 11(3) and (4) of Regulation (EU) 2019/4 should lead to compliance with the relevant advertising bans.

Medicated feed shall not be distributed for advertising purposes, except in samples containing small quantities. Medicated feed containing antimicrobial veterinary medicinal products shall not be marketed as samples or in any other form for promotional purposes.

The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 23a, subparagraph 8(b) LFGB.

Re subparagraph 7:

The purpose of sanctioning the infringement of Article 13(1) of Regulation (EU) 2019/4 is to ensure that feed business operators comply with the authorisation requirement laid down therein.

Feed business operators manufacturing, storing, transporting or placing on the market medicated feed or intermediate products are to ensure that establishments under their control are approved by the competent authority. This ensures, among other things, that the establishments comply with feed safety requirements.

The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 37(1) LFGB; there is a need for agreement with the Federal Ministry of Economic Affairs and Energy.

Re subparagraph 8:

The purpose of sanctioning the infringement of Article 17(1), (2), first sentence, first clause, and (3) of Regulation (EU) 2019/4 is to prevent the abusive or unnecessary use of medicated feed in non-food-producing animals within the meaning of Section 1, subparagraph1 of the Feed Regulation by the animal keeper.

Thus, animal keepers may use the prescribed medicated feed only for animals for which a veterinary prescription for medicated feed has been issued. In addition, animal owners must comply with the requirements of the veterinary prescription when using medicated feed. In addition, animal keepers must ensure that expired medicated feed is not used. The ban on the prophylactic administration of medicated feed containing antimicrobial veterinary medicinal products is intended to reduce the risk to public health arising from antimicrobial resistance.

The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 23a, subparagraph 8(b) LFGB.

Re subparagraph 9:

The purpose of sanctioning the infringement of Article 17(2), first sentence, second clause of Regulation (EU) 2019/4 is to prevent the abusive or unnecessary feeding of medicated feed by the animal keeper. Thus, animal keepers may use the prescribed medicated feed only for animals for which a veterinary prescription for medicated feed has been issued. The abusive feeding of medicated feed by the keeper of food-producing animals is already sanctioned by Section 59(2), subparagraph 12(c) LFGB in conjunction with Section 4(1), subparagraph 1 LFGB. The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 23a, subparagraph 8(b) LFGB.

Re subparagraph 10:

The purpose of sanctioning the infringement of Article 17(2), second sentence of Regulation (EU) 2019/4 is to prevent the use of medicated feed by the animal keeper after the expiry of the shelf life.

In accordance with Article 17(2), second sentence of Regulation (EU) 2019/4, livestock owners must ensure that expired medicated feed is not used. The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 23a, subparagraph 8(b) LFGB.

Re subparagraph 11:

The purpose of sanctioning the infringement of Article 17(6) is to oblige animal keepers to respect the withdrawal periods. This serves to protect the health and well-being of animals, to ensure the safety of food of animal origin and, in particular, to avoid residues in food.

The provision is based on Section 62(1), subparagraph 2(a) LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a) and Section 23a, subparagraph 8(b) LFGB.

Re subparagraph 12:

The purpose of sanctioning the infringement of Article 17(7), first sentence of Regulation (EU) 2019/4 is to encourage keepers of food-producing animals to comply with the accounting requirements laid down in Article 108 of Regulation (EU) 2019/6. The keeper’s records are traceable both for the keeper and for the competent authorities.

The provision is based on Section 62(1), subparagraph 2(a) of the LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a), Section 46(2), first sentence, subparagraph1(a) of the LFGB.

Re subparagraph 13:

The purpose of sanctioning the infringement of Article 17(7), second sentence of Regulation (EU) 2019/4 is to encourage keepers of food-producing animals to keep the relevant records referred to in the first sentence for at least five years from the date of administration of medicated feed. This must also be done if the food-producing animal is slaughtered within five years. Retention over five years serves the purpose of traceability for both the animal keeper and the competent authorities.

The provision is based on Section 62(1), subparagraph 2(a) of the LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a), Section 46(2), first sentence, subparagraph 1(a), in conjunction with the second sentence, subparagraph 1, of the LFGB.

Re subparagraph 14:

The purpose of sanctioning the infringement of Section 6(1) of Annex I to Regulation (EU) 2019/4 is to ensure that the feed business operator complies with the recording obligations.

Feed business operators manufacturing, storing, transporting or placing on the market medicated feed and intermediate products shall keep a record of relevant data, including details of purchase, manufacture, storage, transport and placing on the market. This serves to ensure effective tracking from entry to exit, including export to the final destination.

The provision is based on Section 62(1), subparagraph 2(a) of the LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a), Section 46(2), first sentence, subparagraph1(a) of the LFGB.

Re subparagraph 15:

The purpose of sanctioning the infringement of Section 8(1) of Annex I to Regulation (EU) 2019/4 is to encourage mobile mixers to comply with the obligation to carry the documents referred to in points (a) to (e).

The provision is based on Section 62(1), subparagraph 2(a) of the LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a), Section 46(2), first sentence, subparagraph 1(d) of the LFGB.

Re subparagraph 16:

By sanctioning the infringement of Section 8(3) of Annex I to Regulation (EU) 2019/4, mobile mixers shall comply with the obligation, where vehicle registration plates are available, to use only those vehicles whose vehicle registration plates have been notified to the competent authority.

The provision is based on Section 62(1), subparagraph 2(a) of the LFGB in conjunction with Section 60(4), subparagraph 2(a), Section 60(2), subparagraph 26(a), Section 46(2), first sentence, subparagraph 1(e) of the LFGB.

Section 47(2) of the FuttMV is intended to ensure that feed business operators importing medicinal products or intermediate products into the Union comply with the provision laid down in Article 12(2) of Regulation (EU) 2019/4.

Unauthorised veterinary medicinal products have the risk of causing harm to both human health through the consumption of food of animal origin and animal health.

Feed business operators importing medicated feed or intermediate products into the Union shall ensure that the veterinary medicinal products used for the manufacture of the medicated feed or the intermediate products are authorised for use in the Member State of use in accordance with Article 5(1) of Regulation (EU) 2019/6.

The provision is based on Section 62(1), subparagraph 2(b) of the LFGB in conjunction with Section 60(4), subparagraph 2(b), Section 60(2), subparagraph 26(b), Section 56(1), first sentence, subparagraph 2(c), of the LFGB.

Re Nummer 28

The citation of the regulation cited in Section 47a of the FuttMV is merely legally adapted.

Re Nummer 29

The citation of the Regulation cited in Annex 2 to the FuttMV is merely legally adapted.

Re Nummer 30

The citation of the Regulation cited in Annex 4, subparagraph 3, first sentence to the FuttMV is merely legally adapted.

Re Artikel 2 (Entry into force)

Article 2 lays down the necessary provisions on entry into force.