EUROPEAN
COMMISSION

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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

supplementing Regulation (EU) 2019/4 of the European Parliament and of the Council by establishing specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed and methods of analysis for these substances in feed

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION DELEGATED REGULATION (EU) …/...

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supplementing Regulation (EU) 2019/4 of the European Parliament and of the Council by establishing specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed and methods of analysis for these substances in feed

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 7(3) thereof,

Whereas:

(1) Regulation (EU) 2019/4 lays down specific provisions regarding medicated feed and intermediate products. Cross-contamination of non-target feed with antimicrobials has been identified as a core issue of the Union in the context of protecting animal health, human health and the environment, and should be avoided or kept as low as possible.

(2) In accordance with Article 7(3) of Regulation (EU) 2019/4, the Commission must adopt delegated acts to supplement that Regulation by establishing, as regards the 24 antimicrobial active substances listed in Annex II thereto ('the 24 antimicrobial active substances'), specific maximum levels of cross-contamination for active substances in non-target feed, and methods of analysis for these antimicrobial active substances in feed. Pursuant to Article 7(3) of that Regulation, those delegated acts which establish maximum levels of cross-contamination must be based on a scientific risk assessment carried out by the European Food Safety Authority ('the Authority').

(3) At the Commission's request, the Authority assessed, in cooperation with the European Medicines Agency ('EMA'), the specific concentrations of the 24 antimicrobial active substances resulting from cross-contamination in non-target feed for food-producing animals, below which there would be no effect on the emergence of, and/or selection for, resistance in antimicrobial active substances relevant for human and animal health ('antimicrobial resistance', 'AMR').

(4) The Authority was also requested by the Commission to assess the levels of the 24 antimicrobial active substances which could have a growth promotion or increased yield effect taking into account that the use of antibiotics other than coccidiostats or histomonostats used as feed additives, has been phased out as from 1 January 2006 in accordance with Article 11(2) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council[2]. The specific maximum level of each antimicrobial

[1] OJ L 4, 7.1.2019, p. 1.

[2] 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).

active substance in non-target feed should be below the level that causes a growth promotion or increased yield effect.

(5) In addition, the Commission requested the Reference Laboratory, set up pursuant to Regulation (EC) No 1831/2003 ('the Reference Laboratory'), to recommend methods of analysis for the 24 antimicrobial active substances in feed.

(6) In its 13 Opinions of 15 September 2021 on maximum levels of cross-contamination for the 24 antimicrobial active substances in non-target feed[3] ('Opinions of 15 September 2021'), the Authority could only establish specific concentrations concerning AMR for six of the 24 antimicrobial active substances and not for all relevant animal species, due to a lack of data. In addition, the Authority identified levels causing effects on growth promotion or increased yield for only 14 of the 24 antimicrobial active substances and not for all relevant animal species, due to an absence of relevant data.

(7) In April 2022 and February 2023, the Reference Laboratory issued two reports on the methods of analysis and minimum achievable levels of quantification ('LOQ') in feed for the 24 antimicrobial active substances[4] ('Reports of April 2022 and February 2023').

(8) The specific concentrations concerning AMR established by the Authority for six antimicrobial active substances, in the Opinions of 15 September 2021, are significantly lower than the minimum LOQs established by the Reference Laboratory in the Reports of April 2022 and February 2023. This means, in practice, that the specific concentrations are not measurable and would therefore not be enforceable by the Member States in accordance with Article 17(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[5].

(9) The lowest levels of the 14 antimicrobial active substances, for which the Authority could indicate in its Opinions of 15 September 2021 as causing a growth promotion or increased yield effect, are significantly higher than the LOQ of the same substance and are therefore measurable and enforceable by the Member States in accordance with Article 17(2) of Regulation (EC) No 178/2002. To avoid a growth promoting or increased yield effect, the maximum levels of cross-contamination for the antimicrobial active substances in non-target feed should be below the lowest levels causing a growth promotion or increased yield effect.

(10) High economic investment and increased logistic costs to comply with the maximum levels of cross-contamination in non-target feed if such levels are very low is likely to result in a reduction of the production of medicated feed. In addition, EMA Advice of 28 August 2020 on implementing measures under Article 106(6) of Regulation (EU) 2019/6 on veterinary medicinal products – scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via routes other than medicated feed[6], concludes that it may also result in an increased recourse to methods of oral administration of antimicrobial

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3 EFSA Journal 2021;19(10):6852 to 6865.

4 [*a reference will be added when published*] *[DG: This must, of course, be done before adoption of the draft delegated regulation.]*

5 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).

6 EMA/CVMP/508559/2019

active substances other than medicated feed, such as the administration on the surface of solid feed, that may increase the risk of AMR and the inability to treat certain bacterial infections in certain species due to the absence of other appropriate routes of administration, for example, in aquaculture. The maximum levels of cross-contamination should, therefore, not be detrimental to the production of medicated feed, in particular, by small and medium size feed manufacturing plants, excluding them in practice from the production of medicated feed, which would result in possible issues for public health, and animal health and welfare. It is therefore appropriate to establish a maximum level of cross-contamination that is strict but also feasible to achieve by applying good practices to minimise cross-contamination. In addition to the Opinions of 15 September 2021, the experience gained in Member States in applying national law indicates that a cross-contamination level in the non-target feed of 1% of the active substance in the medicated feed, represents a good balance between feasibility and AMR control.

(11) The maximum levels of cross-contamination for some antimicrobial active substances in non-target feed should be reviewed if new scientific evidence becomes available, allowing to further control antimicrobial resistance in the non-target feed with enforceable maximum levels and which are achievable by applying good practices to minimise cross-contamination.

(12) Medicated feed intended for fish often contains substantially higher doses of antimicrobial active substances than medicated feed intended for food-producing animals other than fish. In addition, no levels of antimicrobial active substances creating a growth promotion or increased yield effect in fish, have been identified in the Opinions of 15 September 2021. Stricter specific maximum levels of cross-contamination in non-target feed intended for food-producing animals other than fish therefore are needed where the cross-contamination originates from medicated feed intended for fish, in order to avoid a growth promotion or increased yield effect in food-producing animals other than fish. Since these stricter specific maximum levels of cross-contamination in non-target feed intended for food-producing animals other than fish, should be measurable and enforceable by the Member States, they should be set at the LOQ.

(13) It should be ensured that food derived from animals fed with the non-target feed complies with the maximum residue levels in food laid down in Table 1 set out in the Annex to Commission Regulation (EU) 37/2010[7]. Stricter specific maximum levels of cross-contamination for antimicrobial active substances in non-target feed should therefore be laid down in this Regulation, in particular for milk- or egg-producing animals and for animals close to the date of slaughter. Since these stricter specific maximum levels of cross-contamination in non-target feed should be measurable and enforceable by the Member States, they should be set at the LOQ.

(14) Manufacturing, processing, storage or transport facilities might be flushed with feed materials to remove left-overs from the medicated feed in these facilities. To avoid disposal, namely feed waste, it should be allowed to use these feed materials from flushing in non-target feed provided that such non-target feed complies with the maximum levels of cross-contamination for active substances laid down in this Regulation.

[7] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

(15) The methods of analysis recommended by the Reference Laboratory in the Reports of April 2022 and February 2023 should be used as reference methods for the analysis of the 24 antimicrobial active substances. Alternative methods of analysis should only be allowed when validated and considered as equivalent by the competent authorities of the Member States.

(16) It is appropriate to provide official laboratories carrying out the methods of analysis with sufficient time to adapt to the set LOQs and prove their competence for their analysis by generally accepted means e.g., by accreditation, sound in-house validation or proficiency test data targeting a timely accreditation. Therefore, this Regulation should apply 6 months from the date of entry into force of this Regulation.

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation establishes, for the antimicrobial active substances listed in Annex II to Regulation (EU) 2019/4, specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed and methods of analysis for active substances in feed, as provided for in Article 7(3) of that Regulation.

Article 2

1. The specific maximum levels of cross-contamination in non-target feed for the antimicrobial active substances listed in Annex II to Regulation (EU) 2019/4 shall be set at 1% of the active substance in the last batch of medicated feed or the intermediate product manufactured, processed, stored or transported before the manufacturing, processing, storage or transport of the non-target feed.

2. By way of derogation from paragraph 1, the specific maximum levels of cross-contamination in non-target feed for the antimicrobial active substances shall be set at the limit of quantification ('LOQ'), laid down in the Annex to this Regulation for the following animals:

   (a) food-producing animals other than fish where the non-target feed is manufactured, processed, stored or transported after the manufacturing, processing, storage or transport of medicated feed intended for aquaculture;

   (b) animals during the production of eggs or milk intended for human consumption;

   (c) food-producing animals intended for slaughter in the period for slaughter corresponding to the longest withdrawal period for target animal species.

3. By way of derogation from paragraph 1, feed materials, used in the flushing of the manufacturing, processing, storage or transport facilities after the manufacturing, processing, storage or transport of medicated feed, even if not complying with the specific maximum levels of cross-contamination laid down in paragraphs 1 or 2, may be used for the production of non-target feed, but only if such non-target feed complies with the specific maximum levels of cross-contamination laid down in paragraphs 1 or 2.

Article 3

The reference methods of analysis for the quantification of the level of cross-contamination of each antimicrobial active substance listed in Annex II to Regulation (EU) 2019/4, in the non-target feed referred to in Article 2(1) and (2), are laid down in the Annex to this Regulation.

However, alternative methods of analysis may be used provided they are validated in accordance with internationally accepted scientific protocols and have the same or a lower LOQ as the LOQ of the same antimicrobial active substance laid down in the Annex to this Regulation.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from … [*6 months from the date of entry into force of this Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN