EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2023/1707
(POOL/G5/2023/1707/1707-EN.docx)
[…](2023) XXX draft

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2019/4 of the European Parliament and of the Council[1] lays down specific provisions regarding medicated feed and intermediate products. The purpose of this Delegated Regulation is to supplement Regulation (EU) 2019/4 by establishing, as regards the 24 antimicrobial active substances listed in Annex II to that Regulation, specific maximum levels of cross-contamination for antimicrobial active substances in non-target feed and methods of analysis for these antimicrobial active substances in feed.

The maximum levels of cross-contamination are based on scientific risk assessments carried out by the European Food Safety Authority ('EFSA'). The European Union Reference Laboratory for feed additives recommended methods of analysis for those 24 antimicrobial active substances in feed.

A cross-contamination level in non-target feed of 1% of the antimicrobial active substance in the medicated feed or the intermediate product (to be contained in the medicated feed derived from that intermediate product) is laid down in this Delegated Regulation, based on the experience gained in the Member States and representing a good balance between:

– the control of antimicrobial resistance and the levels causing effects on growth promotion or increased yield, based on the scientific opinions of the EFSA;

– feasibility for the feed industry;

– enforceability by the competent authorities of the Member States.

Stricter limits are needed, for example, after the production of medicated feed or intermediate products intended for fish and to avoid residues in certain food.

Reference methods of analysis for the antimicrobial active substances in feed are also laid down in this Delegated Regulation. This Delegated Regulation should apply twelve months from the date of its entry into force in order to give the official laboratories in the Member States sufficient time to adapt to these methods.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The draft Delegated Regulation has been discussed during meetings of the relevant expert group, representing the competent authorities of all Member States and private stakeholders, the last one on 7 December 2023, and is largely supported by those experts.

Before adopting this Delegated Regulation, the Commission conducted public consultations in an open and transparent way in accordance with the procedures laid down in the Interinstitutional Agreement of 13 April 2016 between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making[2].

[1] 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 (OJ L 4, 7.1.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/4/oj).

[2] OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The Commission is obliged to adopt this Delegated Regulation pursuant to Article 7(3) of Regulation (EU) 2019/4.

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)

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 the antimicrobial active substances in non-target feed and methods of analysis for the 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 ('EFSA').

(3) At the Commission's request, EFSA 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) EFSA 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 as feed additives, other than coccidiostats or histomonostats, has been phased out since 1 January 2006 in accordance with Article 11(2) of Regulation (EC) No 1831/2003 of the European

[1] OJ L 4, 7.1.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/4/oj.

Parliament and of the Council[2]. The specific maximum level of each antimicrobial 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'), EFSA 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, EFSA only identified levels causing effects on growth promotion or increased yield for 14 of the 24 antimicrobial active substances and not for all relevant animal species, again 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 EFSA 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 EFSA could indicate in its Opinions of 15 September 2021 as causing a growth promotion or increased yield effect, are significantly higher than the LOQ for 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 promotion 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 logistical 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, the 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

---

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, ELI: http://data.europa.eu/eli/reg/2003/1831/2021-03-27).

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, ELI: http://data.europa.eu/eli/reg/2002/178/oj).

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 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 the 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. Intermediate products contain higher concentrations of active substances than medicated feed. Therefore, where non-target feed is manufactured, processed, stored or transported after the manufacturing, processing storage or transport of intermediate products, a cross-contamination level of 1% of the substance to be contained in the derived medicated feed, should apply.

(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 which are achievable by applying good practices to minimise cross-contamination.

(12) Medicated feed or intermediate products intended for fish often contains substantially higher doses of antimicrobial active substances than medicated feed or intermediate products 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 or intermediate products 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

[6] EMA/CVMP/508559/2019.

[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, ELI: http://data.europa.eu/eli/reg/2010/37(1)/2023-06-11).

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) 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 in feed. Alternative methods of analysis should only be allowed when validated and considered as equivalent by the competent authorities of the Member States.

(15) It is appropriate to provide official laboratories carrying out the methods of analysis for antimicrobial active substances in feed with sufficient time to adapt to the LOQs and prove their competence for carrying out such methods of analysis by generally accepted means, such as by accreditation, sound in-house validation or proficiency test data targeting a timely accreditation. Therefore, this Regulation should apply 12 months after the date of its entry into force,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

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

Article 2

Specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed

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:

   (a) where the last batch manufactured, processed, stored or transported before the manufacturing, processing, storage or transport of the non-target feed is medicated feed, at 1% of the antimicrobial active substance contained in that last batch of medicated feed, relative to a moisture content of 12 % in the non-target feed;

   (b) where the last batch manufactured, processed, stored or transported before the manufacturing, processing, storage or transport of the non-target feed is an intermediate product, at 1% of the antimicrobial active substance to be contained in the medicated feed derived from that last batch of intermediate product, relative to a moisture content of 12 % in 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 listed in Annex II to Regulation (EU) 2019/4 shall be set at the limit of quantification ('LOQ') laid down in the Annex to this Regulation, where the non-target feed is intended 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 or intermediate products 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 the target animal species.

Article 3

Methods of analysis for antimicrobial active substances in feed

The reference methods of analysis for the quantification of the level of cross-contamination in non-target feed for each antimicrobial active substance listed in Annex II to Regulation (EU) 2019/4, as referred to in Article 2(1) and (2) of this Regulation, 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, are suitable to detect the same or a lower LOQ as the LOQ for the same antimicrobial active substance laid down in the Annex to this Regulation and are considered as equivalent by the competent authorities of the Member States.

Article 4

Entry into force and application

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 [*12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*].

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN