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Delegations will find attached document COM(2023) 78 final.

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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the power to adopt delegated acts conferred on the Commission pursuant 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. INTRODUCTION AND LEGAL BASIS

The Regulation on medicated feed (MF)[1] lays down a robust legal framework for the safe manufacture, storage, transport, placing on the market, including import from third countries, use and export to third countries of medicated feed and intermediate products. The MF is essential to protect animal health by providing instruments to safely use veterinary medicinal products in medicated feed and intermediate products, while at the same time taking into account the serious animal and public health risk posed by antimicrobial resistance.

The MF empowers the Commission to adopt delegated acts as referred to in Article 20(1), with a view to:

- supplement the MF by establishing specific maximum levels of cross-contamination for active substances in non-target feed, unless such levels are already established in accordance with Directive 2002/32/EC[2], as provided for in Article 7(2); those delegated acts may also set out methods of analysis for active substances in feed;
- supplement the MF by establishing, as regards the antimicrobial active substances in Annex II of the MF, specific maximum levels of cross-contamination for active substances in non-target feed and methods of analysis for such active substances, as provided for in Article 7(3); and,
- amend Annexes I to V of the MF, in order to take into account technical progress and scientific developments, as provided for in Article 19.

The present report is required under Article 20(2) of the MF. Under Article 20(2) the Commission has the power to adopt delegated acts referred to in Articles 7 and 19 for a period of five years from 27 January 2019. The Commission is required to prepare a report in respect to this delegation of power not later than nine months before the end of the five-year period.

2. Exercise of the delegation

2.1 Supplementing the MF to establish specific maximum levels of cross-contamination for active substances in non-target feed unless such levels are already established in accordance with Directive 2002/32/EC, and methods of analysis for active substances (Article 7, paragraph 2)

The empowerment under this Article 7(2) has not been used during the reporting period because priority was given to establishing specific maximum levels of cross-contamination for active antimicrobial substances in non-target feed and methods of analysis for these active substances (Article 7(3)). The adoption of delegated acts under both empowerments needs to be based on a scientific risk assessment carried out by the

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

European Food Safety Authority (EFSA). Such assessment in view of a delegated Regulation in accordance with Article 7(3) was very time and resource consuming for EFSA (see 2.2).

2.2 Supplementing the MF to establish specific maximum levels of cross-contamination for active antimicrobial substances, listed in Annex II of the MF in non-target feed and methods of analysis for these active substances (Article 7, paragraph 3)

At the request of the Commission, EFSA delivered its opinion needed for establishing specific maximum levels of cross-contamination for active antimicrobial substances in non-target feed, in 13[3] different parts: one regarding "methodology, general data and uncertainties" and another twelve for the 24 antimicrobials of Annex II of the MF to be assessed.

The assessment for each of the 24 antimicrobials was composed of two parts, considered essential to establish the specific maximum level of cross-contamination, in particular related to antimicrobial resistance and to growth promotion/increase. Based on the scientific data available,

- EFSA was able to determine the "feed antimicrobial resistance selection concentration" for six of the 24 antimicrobials; this is the concentration of the antimicrobial in the non-target feed that would no longer select for resistant bacteria;
- EFSA was also able to identify the levels below which 14 of the 24 antimicrobials would no longer cause an effect on growth promotion/increased yield.

In addition, the European Reference Laboratory for Feed Additives was mandated and provided recommended methods of analysis in feed for all 24 antimicrobials. Each method has a minimum limit of quantification, being the lowest concentration that can be detected.

All this information only became available mid-2022 and, unfortunately, does not provide a straight way forward to address the empowerment delegated to the Commission under Article 7(3) since data were missing to assess several antimicrobials and since the lowest concentrations that can be detected were significantly higher than the feed antimicrobial resistance selection concentrations of the same antimicrobial.

Based on additional consultations of all relevant stakeholders, the Commission is currently preparing a Delegated Regulation establishing specific maximum levels of cross-contamination for active antimicrobial substances in non-target feed and methods of analysis for these active substances, being as strict as possible. However, requirements should still be feasible and practical, including in case of small feed business operators. A balance needs to be sought between the possible development of some antimicrobial resistance and the availability of appropriate treatments for animals which depends on the availability of medicated feed. Future revisions might be needed when currently missing scientific information becomes available. In addition, technical

[3] https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/(ISSN)1831-4732.cross-contamination

progress in the coming years may allow to detect lower concentrations of antimicrobials, providing input to reconsider specific maximum levels of cross-contamination.

2.3 Amendments to Annexes I to V (Article 19)

The empowerment under this Article 19 has not been used during the reporting period because the period between the date of application (27 January 2022) and the deadline for the reporting period (27 April 2023) is very short. Experiences in the practical implementation, technical progress and scientific developments are therefore still limited.

3. Conclusion

The Commission sees the need for the tacit extension of the delegation of power as provided for in Article 20(2) of the MF for a period of five years, in accordance with that Article. This is due to the fact that the need to develop rules based on the empowerments referred to by Article 20(2) of the MF will continue to exist in the future. The extension of the delegation of powers will be particularly important to provide the necessary flexibility in the new legal framework, to complement and adjust it regularly, taking into account technical progress and the latest scientific developments, and to allow the Commission to act in the areas where it did not act to this moment, but may need to do so in the future.

With this report, the Commission complies with the reporting requirement under Article 20(2) of Regulation (EU) 2019/4 and invites the European Parliament and the Council to take note of this report.