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COMMISSION IMPLEMENTING REGULATION (EU) 2025/1103

of 3 June 2025

amending Implementing Regulation (EU) 2017/12 as regards the requirements for applications and requests for the establishment of a 'no MRL required' classification for chemical-unlike biological substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]), and in particular Article 13(1) thereof,

Whereas:

(1) Pharmacologically active substances are classified on the basis of opinions on maximum residue limits (MRLs) issued by the European Medicines Agency (EMA).

(2) Commission Implementing Regulation (EU) 2017/12 ([2]) sets out the form and content of the applications and requests submitted to EMA requesting the opinion to establish MRLs.

(3) Commission Regulation (EU) 2018/782 ([3]) establishes the methodological principles for the risk assessment and risk management recommendations to be applied by EMA when preparing opinions on the MRLs. Section I.7 of Annex I to Regulation (EU) 2018/782 was amended by Commission Regulation (EU) 2025/1101 ([4]) to introduce a requirement for EMA to determine whether for a given chemical-unlike biological substance a classification 'no MRL required' is appropriate.

(4) The content of particulars and documents accompanying an application or a request for a 'no MRL required' classification for chemical-unlike biological substances should thus be clearly specified.

(5) Implementing Regulation (EU) 2017/12 should therefore be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

([1]) OJ L 152, 16.6.2009, p. 11, ELI: http://data.europa.eu/eli/reg/2009/470/oj.
([2]) Commission Implementing Regulation (EU) 2017/12 of 6 January 2017 regarding the form and content of the applications and requests for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 4, 7.1.2017, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2017/12/oj).
([3]) Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 (OJ L 132, 30.5.2018, p. 5, ELI: http://data.europa.eu/eli/reg/2018/782/oj).
([4]) Commission Regulation (EU) 2025/1101 of 3 June 2025 amending Regulation (EU) 2018/782 concerning the assessment by the European Medicines Agency of maximum residue limits for chemical-unlike biological substances (OJ L 2025/1101, 4.6.2025, ELI: http://data.europa.eu/eli/reg/2025/1101/oj).

HAS ADOPTED THIS REGULATION:

Article 1

In Article 1(2) of Implementing Regulation (EU) 2017/12, the following subparagraph is added:

'However, with regard to requests for a "no MRL required" classification for chemical-unlike biological substances, the particulars and documents shall be those specified in section I.7, first paragraph, points (a) to (e), of Annex I to Commission Regulation (EU) 2018/782 (*).

(*) Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 (OJ L 132, 30.5.2018, p. 5, ELI: https://data.europa.eu/eli/reg/2018/782/oj)'.

Article 2

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

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

Done at Brussels, 3 June 2025.

For the Commission
The President
Ursula VON DER LEYEN