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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

(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(2), point (a), thereof,

Whereas:

(1) In accordance with Article 3 of Regulation (EC) No 470/2009, pharmacologically active substances intended for use in the Union in veterinary medicinal products administered to food-producing animals are subject to an opinion of the European Medicines Agency ('the Agency') regarding their maximum residue limits ('MRLs').

(2) Commission Regulation (EU) 2018/782 ([2]) lays down the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009.

(3) Section I.6 of Annex I to Regulation (EU) 2018/782 provides that biological substances, other than those identified in Article 1(2), point (a), of Regulation (EC) No 470/2009, are subject to either an evaluation of all elements set out in Article 6 of Regulation (EC) No 470/2009 ('full MRL evaluation') if chemical-like or a case-by-case evaluation if chemical-unlike.

(4) In accordance with Section I.7 of Annex I to Regulation (EU) 2018/782, the Agency is to assess chemical-unlike biological substances to determine whether there is a need for a full MRL evaluation.

(5) Chemical-unlike biological substances which are not considered to need for a full MRL evaluation are not currently included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([3]), which sets out pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin (allowed substances). Instead, they are included in a list that is published and updated by the Agency ([4]).

(6) The case-by-case evaluation conducted by the Agency ensures that chemical-unlike biological substances falling within the scope of Regulation (EC) No 470/2009 are assessed in line with the objectives of that Regulation. In most cases, residues of those substances fall into groups of substances that are normal constituents of food, such as amino acids, lipids, and carbohydrates, and do not pose risks to public health. Consequently, such chemical-unlike biological substances could be classified as 'no MRL required' in accordance with Article 14(2), point (c), of Regulation (EC) No 470/2009.

([1]) OJ L 152, 16.6.2009, p. 11, ELI: http://data.europa.eu/eli/reg/2009/470/oj.

([2]) 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).

([3]) 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)/oj).

([4]) https://www.ema.europa.eu/en/documents/report/chemical-unlike-biological-substances-considered-not-requiring-mrl-evaluation-regulation-eu-no-2018-782-regard-residues-veterinary-medicinal-products-foodstuffs-animal-origin_en.pdf.

(7) Section I.7 of Annex I to Regulation (EU) 2018/782, should therefore be amended to require the Agency to determine whether, for a given chemical-unlike biological substance, the classification 'no MRL required' is appropriate.

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

HAS ADOPTED THIS REGULATION:

Article 1

In section I.7. of Annex I to Regulation (EU) 2018/782, the second paragraph is replaced by the following:

'The information provided above shall be evaluated in accordance with the guidance published by the European Medicines Agency ("Agency") in order to determine whether a "no MRL required" classification according to the classification provided for under Article 14(2), point (c), of Regulation (EC) No 470/2009 is appropriate.'.

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