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COMMISSION IMPLEMENTING REGULATION (EU) 2026/1806

of 24 July 2026

amending Regulation (EU) No 37/2010 as regards the classification of the substance recombinant equine chorionic gonadotropin with respect to its maximum residue limit in foodstuffs of animal origin

(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 14, in conjunction with Article 17, thereof,

Whereas:

(1) In accordance with Regulation (EC) No 470/2009, the Commission is to establish, by way of a Regulation, maximum residue limits ('MRLs') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry.

(2) Commission Regulation (EU) No 37/2010 ([2]) sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Commission Regulation (EU) 2018/782 ([3]) lays down the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009.

(4) 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.

(5) Section I.7 of Annex I to Regulation (EU) 2018/782 further provides that the European Medicines Agency ('the Agency') is to assess chemical-unlike biological substances in order to determine whether a full MRL evaluation is required and whether a 'no MRL required' classification according to Article 14(2), point (c), of Regulation (EC) No 470/2009 is appropriate.

(6) On 19 December 2025, Syn Vet-Pharma Ireland Limited submitted an application to the Agency for the evaluation of the chemical-unlike biological substance recombinant equine chorionic gonadotropin (reCG).

(7) On 16 April 2026, the Committee for Veterinary Medicinal Products ('CVMP') concluded that no further MRL assessment is necessary and that the substance can be included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 with a 'No MRL required' classification ([4]).

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

([2]) 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).

([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]) Recombinant equine Chorionic Gonadotropin (reCG): Summary of assessment. (EMA/CVMP/5612/2026-16 April 2026): https://www.ema.europa.eu/en/documents/mrl-summary/recombinant-equine-chorionic-gonadotropin-recg-summary-assessment_en.pdf.

(8) On the basis of the assessment of the CVMP, the Commission considers it appropriate that the chemical-unlike biological substance recombinant equine chorionic gonadotropin (reCG) is included in Table 1 of the Annex to Regulation (EU) No 37/2010.

(9) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(10) 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

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

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, 24 July 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the following entry is inserted in alphabetical order:

Pharmaco-logically active substance	Marker residue	Animal species	MRL	Target Tissues	Other provisions *(according to Article 14(7) of Regulation (EC) No 470/2009)*	Therapeutic classification
'Recombinant equine chorionic gonadotropin (reCG, recombinant analogues of pregnant mare serum gonadotrophin) – chemical-unlike biological substance	NOT APPLICABLE	All food-producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY'