



2025/1102

4.6.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1102
of 3 June 2025
amending Regulation (EU) No 37/2010 as regards 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 14 thereof,

Whereas:

- (1) Commission Regulation (EU) No 37/2010 ⁽²⁾ sets out the pharmacologically active substances and their classification regarding maximum residue limits ('MRLs') in foodstuffs of animal origin.
- (2) Commission Regulation (EU) 2018/782 ⁽³⁾ provides that chemical-unlike biological substances for which it is concluded that a standard MRL evaluation is not required are to be published by the European Medicines Agency ('Agency') in a list of such substances.
- (3) The following five chemical-unlike biological substances were included in the list published by the Agency ⁽⁴⁾: (i) bovine casein hydrolysate (bCNH), produced from sodium caseinate hydrolysed with trypsin, heat treated, for intramammary use in cows, (ii) probiotic components including bacteria and yeasts, (iii) recombinant bovine IL-8 (His-tag) for intrauterine use in cattle at a dose of up to 1 000 µg per animal, (iv) stem cells and (v) varroa destructor calmodulin gene-specific double-stranded interfering RNA EP15 (naked unmodified dsRNA).
- (4) Regulation (EU) 2018/782 was amended by Commission Regulation (EU) 2025/1101 ⁽⁵⁾ providing that chemical-unlike biological substances are to be evaluated by the Agency in order to determine whether a 'no MRL required' classification is appropriate.
- (5) On 13 September 2024, the Commission requested the Agency to provide scientific advice on whether, a classification as 'no MRL required' is appropriate for the five chemical-unlike biological substances included by the Agency in the list of chemical-unlike biological substances considered as not requiring an MRL evaluation.

⁽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](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⁾ Chemical-unlike biological substances considered as not requiring an MRL evaluation as per Regulation (EU) 2018/782, with regard to residues of veterinary medicinal products in foodstuffs of animal origin of 20 November 2023, EMA/CVMP/572629/2019–Rev.2, Committee for Veterinary Medicinal Products of European Medicines Agency.

⁽⁵⁾ 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>).

- (6) On 15 January 2025, the Agency ⁽⁶⁾, based on the opinion of the Committee for Veterinary Medicinal Products, concluded that the five chemical-unlike biological substances do not pose a risk to public health and that the classification thereof as 'no MRL required' is appropriate.
- (7) Those substances should therefore be included in table 1 of the Annex to Regulation (EU) No 37/2010.
- (8) Regulation (EU) No 37/2010 should therefore be amended accordingly.
- (9) 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, 3 June 2025.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁶⁾ Scientific advice on MRL classification of chemical-unlike biological substances considered as not requiring an MRL evaluation according to Regulation (EU) 2018/782. EMA/CVMP/375793/2024.

ANNEX

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

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Bovine casein hydrolysate (bCNH), produced from sodium caseinate hydrolysed with trypsin, heat treated – chemical-unlike biological substance	NOT APPLICABLE	Bovine	No MRL required	NOT APPLICABLE	For intramammary use only	NO ENTRY
Probiotic components including bacteria and yeasts – chemical-unlike biological substance	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY
Recombinant bovine IL-8 (His-tag) – chemical-unlike biological substance	NOT APPLICABLE	Bovine	No MRL required	NOT APPLICABLE	For intrauterine use only at a dose of up to 1 000 µg per animal	NO ENTRY
Stem cells – chemical-unlike biological substance	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY
Varroa destructor calmodulin gene-specific double-stranded interfering RNA EP15 (naked unmodified dsRNA) – chemical-unlike biological substance	NOT APPLICABLE	Bees	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY