

Commission Implementing Regulation (EU) 2017/1559 of 14 September 2017 amending Regulation (EU) No 37/2010 to classify the maximum residue limit of the substance alarelin (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1559

of 14 September 2017

amending Regulation (EU) No 37/2010 to classify  
the maximum residue limit of the substance alarelin

(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 the Council<sup>(1)</sup>, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit ('MRL') 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 is established in a Regulation.
- (2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010<sup>(2)</sup> sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.
- (3) The substance alarelin is not included in that table.
- (4) An application for the establishment of MRLs for alarelin in rabbit has been submitted to the European Medicines Agency ('EMA').
- (5) EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, concluded that the likelihood that a human may be exposed to biologically relevant levels of alarelin after ingesting rabbit tissue is negligible, and has recommended that the establishment of an MRL for alarelin in rabbit is not necessary for the protection of human health.
- (6) According to Article 5 of Regulation (EC) No 470/2009, EMA is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff

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**Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/1559. (See end of Document for details)

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for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.

- (7) EMA has considered that the extrapolation of the ‘no MRL required’ classification for alarelin from rabbit to all food-producing species is appropriate.
- (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, 14 September 2017.

*For the Commission*

*The President*

Jean-Claude JUNCKER

**Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/1559. (See end of Document for details)

## ANNEX

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

<b>Pharmacological active Substance</b>	<b>Milk residue</b>	<b>Animal Species</b>	<b>MRL</b>	<b>Target Tissues</b>	<b>Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)</b>	<b>Therapeutic Classification</b>
'Alarelin	NOT APPLICABLE	All food-producing species	No MRL required	NOT APPLICABLE	NO ENTRY	Agents acting on the reproductive system'

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**Changes to legislation:** There are currently no known outstanding effects for the  
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- (1) [OJ L 152, 16.6.2009, p. 11.](#)
- (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.](#)).

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/1559.