

Official Journal of the European Union

L 15



English edition

Legislation

Volume 63

20 January 2020

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⁽¹⁾ Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/41

of 13 January 2020

entering a name in the register of protected designations of origin and protected geographical indications ('Αρσενικό Νάξου' (Arseniko Naxou) (PDO))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Greece's application to register the name 'Αρσενικό Νάξου' (Arseniko Naxou) was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Αρσενικό Νάξου' (Arseniko Naxou) should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Αρσενικό Νάξου' (Arseniko Naxou) (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.3. — Cheeses, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.*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, 13 January 2020.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 271, 13.8.2019, p. 68.

⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

COMMISSION IMPLEMENTING REGULATION (EU) 2020/42**of 17 January 2020****amending Regulation (EU) No 37/2010 to classify the substance bambermycin as regards its maximum residue limit****(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 ⁽¹⁾, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated on 16 April 2019 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 ⁽²⁾ sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.
- (3) The substance bambermycin is not included in that table.
- (4) An application for the establishment of MRLs for bambermycin in rabbit tissue has been submitted to the European Medicines Agency ('EMA').
- (5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended that the establishment of an MRL for bambermycin in rabbits is not necessary for the protection of human health.
- (6) According to Article 5 of Regulation (EC) No 470/2009, the EMA is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff 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) The EMA has considered that the extrapolation of the 'no MRL required' classification for bambermycin from rabbit tissue to the tissue of other food-producing species is not appropriate at this time due to insufficient data.
- (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.

⁽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).

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, 17 January 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

Pharmacologically active Substance	Marker residue	Animal Species	MRLs	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
Bambermycin	NOT APPLICABLE	Rabbit	No MRL required	NOT APPLICABLE	For oral use only	Anti-infectious agent/Antibiotics'

COMMISSION IMPLEMENTING REGULATION (EU) 2020/43**of 17 January 2020****amending Regulation (EU) No 37/2010 to classify the substance ciclesonide as regards its maximum residue limit****(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 ⁽¹⁾, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated on 21 February 2019 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 ⁽²⁾ sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.
- (3) The substance ciclesonide is not included in that table.
- (4) An application for the establishment of MRLs for ciclesonide in equidae has been submitted to the European Medicines Agency (EMA).
- (5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended the establishment of an MRL for ciclesonide in equidae tissues, excluding animals producing milk for human consumption.
- (6) According to Article 5 of Regulation (EC) No 470/2009, the EMA is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff 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) The EMA has considered that the extrapolation of the MRL for ciclesonide from equidae to other food-producing species is not appropriate at this time due to insufficient data.
- (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

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Pharmacologically active Substance	Marker residue	Animal Species	MRLs	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
Ciclesonide	The sum of ciclesonide and desisobutyryl-ciclesonide, measured as desisobutyryl-ciclesonide after hydrolysis of ciclesonide to desisobutyryl-ciclesonide	<i>Equidae</i>	0,6 µg/kg 4 µg/kg 0,6 µg/kg 0,6 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	Corticoides/Glucocorticoides'

ISSN 1977-0936 (electronic edition)
ISSN 1725-2431 (paper edition)



Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

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