II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2016/576

of 14 April 2016

amending Regulation (EU) No 37/2010 as regards the substance 'rafoxanide'

(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 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 (hereinafter '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) Rafoxanide is currently included in that table as an allowed substance, for bovine and ovine species, applicable to muscle, fat, liver, kidney and milk. The provisional maximum residue limits for that substance set out for bovine and ovine milk expired on 31 December 2015.

(4) An application for the extension of the time period applying to the provisional MRL for rafoxanide in bovine and ovine milk has been submitted to the European Medicines Agency (hereinafter 'EMA').

(5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use has considered that an extension of the existing provisional MRL for rafoxanide in bovine and ovine milk would allow completion of scientific studies in progress and has therefore recommended the extension of the provisional MRL until 31 December 2017.

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

([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).

(7) Since the provisional MRL for rafoxanide in bovine and ovine milk expired on 31 December 2015 and in order to protect the legitimate expectations of market operators regarding the use of that substance, the extension of the provisional MRL should enter into force as a matter of urgency and should apply with effect from 1 January 2016.

(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

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 day of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2016.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 April 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'rafoxanide' is replaced by the following:

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
'Rafoxanide	Rafoxanide	Bovine	30 µg/kg 30 µg/kg 10 µg/kg 40 µg/kg	Muscle Fat Liver Kidney	NO ENTRY	Antiparasitic agents/Agents against endoparasites'
		Ovine	100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney		
		Bovine, ovine	10 µg/kg	Milk	Provisional MRL shall expire on 31 December 2017	