COMMISSION IMPLEMENTING REGULATION (EU) No 682/2014

of 20 June 2014

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

(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) 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 to be established in accordance with Regulation (EC) No 470/2009.

(2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 ([2]).

(3) Closantel is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 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 1 January 2014.

(4) Additional data were provided and assessed by the Committee for Medicinal Products for Veterinary Use who recommended that the provisional MRLs for closantel for bovine and ovine milk should be set as definitive.

(5) The entry for closantel in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.

(6) 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, 20 June 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'closantel' 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
'Closantel	Closantel	Bovine	1 000 µg/kg 3 000 µg/kg 1 000 µg/kg 3 000 µg/kg 45 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Antiparasitic agents/ Agents against endo-parasites'
		Ovine	1 500 µg/kg 2 000 µg/kg 1 500 µg/kg 5 000 µg/kg 45 µg/kg	Muscle Fat Liver Kidney Milk		