COMMISSION IMPLEMENTING REGULATION (EU) No 1235/2013

of 2 December 2013

amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance diclazuril

(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 ('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 are 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) Diclazuril is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for all ruminants and porcine species, for oral use only, and for poultry, applicable to muscle, skin and fat, liver and kidney, excluding animals from which eggs are produced for human consumption.

(4) An application for the extension of the existing entry for diclazuril applicable to rabbits has been submitted to the European Medicines Agency.

(5) The Committee for Medicinal Products for Veterinary Use recommended the establishment of a MRL for diclazuril for rabbits, applicable to muscle, fat, liver and kidney.

(6) Regulation (EU) No 37/2010 should therefore be amended to include the MRL for diclazuril in respect of rabbits.

(7) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take measures that may be required to comply with the newly set MRL.

(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 twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 3 February 2014.

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

Done at Brussels, 2 December 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 152, 16.6.2009, p. 11.
[2] OJ L 15, 20.1.2010, p. 1.

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for diclazuril 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
'Diclazuril	NOT APPLICABLE	All ruminants, porcine	No MRL required	NOT APPLICABLE	For oral use only	NO ENTRY
	Diclazuril	Poultry	500 µg/kg	Muscle	Not for use in animals from which eggs are produced for human consumption	Antiparasitic agents/Agents acting againsts protozoa'
			500 µg/kg	Skin and fat in natural proportions		
			1 500 µg/kg	Liver		
			1 000 µg/kg	Kidney		
		Rabbit	150 µg/kg	Muscle		
			300 µg/kg	Fat		
			2 500 µg/kg	Liver		
			1 000 µg/kg	Kidney		