COMMISSION IMPLEMENTING REGULATION (EU) No 115/2013

of 8 February 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 (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 should 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 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin [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.

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

(5) According to Article 5 of Regulation (EC) No 470/2009 the European Medicines Agency 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. The Committee for Medicinal Products for Veterinary Use recommended the establishment of a MRL for diclazuril for chicken and pheasant, applicable to muscle, skin and fat, liver and kidney, excluding animals from which eggs are produced for human consumption, and the extrapolation of MRLs for diclazuril from chicken and pheasant to poultry, applicable to muscle, skin and fat, liver and kidney, excluding animals from which eggs are produced for human consumption.

(6) The entry for diclazuril in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the MRL for poultry.

(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 10 April 2013.

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

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

Done at Brussels, 8 February 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

The entry corresponding to diclazuril in Table 1 of the Annex to Regulation (EU) No 37/2010 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
		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		