COMMISSION IMPLEMENTING REGULATION (EU) No 116/2013

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 eprinomectin

(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 of 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) Eprinomectin is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine species, applicable to muscle, fat, liver kidney and milk.

(4) An application for the extension of the existing entry for eprinomectin applicable to ovine species 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 provisional MRL for eprinomectin for ovine species, applicable to muscle, fat, liver, kidney and milk, and the extrapolation of the MRLs for eprinomectin from ovine and bovine species, applicable to muscle, fat, liver, kidney and milk to caprine species, establishing a provisional MRL, applicable to muscle, fat, liver, kidney and milk.

(6) The CVMP recommended the establishment of a provisional MRL for ovine and caprine species as the scientific data is incomplete for the proposed analytical method for monitoring residues in ovine and caprine species.

(7) The entry for eprinomectin in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the provisional MRLs for ovine and caprine species, applicable to muscle, fat, liver, kidney and milk. The provisional MRLs set out in that Table for ovine and caprine species should expire on 1 July 2014.

(8) 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.

(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.

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 eprinomectin 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
'Eprinomectin	Eprinomectin B1a	Bovine	50 µg/kg 250 µg/kg 1 500 µg/kg 300 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Antiparasitic agents/Agents acting against endo- and ectoparasites'
		Ovine, caprine	50 µg/kg 250 µg/kg 1 500 µg/kg 300 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	The MRLs laid down for these animal species are provisional MRLs. They shall expire on 1 July 2014.	