Commission Implementing Regulation (EU) No 1390/2014 of 19 December 2014 amending the Annex to Regulation (EU) No 37/2010, as regards the substance ‘eprinomectin’ (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1390/2014

of 19 December 2014

amending the Annex to Regulation (EU) No 37/2010, 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 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 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) Eprinomectin is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine, ovine and caprine species, applicable to muscle, fat, liver, kidney and milk. The provisional maximum residue limits for that substance set out for ovine and caprine species, applicable to muscle, fat, liver, kidney and milk expired on 1 July 2014.

(4) The Committee for Medicinal Products for Veterinary Use (CVMP) recommended an extension of the provisional MRL as the analytical method for monitoring residues in ovine and caprine species is not sufficiently validated. The incomplete scientific data on the validation of the analytical method is not considered to constitute a hazard to human health.

(5) In accordance with 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 CVMP concluded that the extrapolation to other food producing species cannot be supported for this substance.

(6) The entry for eprinomectin in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to extend the provisional MRL to 30 June 2016.

(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 22 February 2015.

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

Done at Brussels, 19 December 2014.

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 ‘eprinomectin’ 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	Provisional maximum residue limits expire on 30 June 2016	

(**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).

Status:
Point in time view as at 19/12/2014.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1390/2014.