COMMISSION IMPLEMENTING REGULATION (EU) 2015/149

of 30 January 2015

amending the Annex to Regulation (EU) No 37/2010 as regards the substance 'methylprednisolone'

(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 (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) Methylprednisolone 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 methylprednisolone to equidae has been submitted to the European Medicines Agency.

(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.

(6) The Committee for Medicinal Products for Veterinary Use recommended the establishment of a MRL for methylprednisolone for equidae, and the extrapolation of the MRL for methylprednisolone from bovine milk to horse milk.

(7) The entry for methylprednisolone in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the MRL for equidae, applicable to muscle, fat, liver, kidney and milk.

(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,

([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).

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 1 April 2015.

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

Done at Brussels, 30 January 2015.

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 'methylprednisolone' is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRLs	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Methylprednisolone	Methylprednisolone	Equidae	10 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg 2 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Corticoides/Glucocorti-coides'
		Bovine	10 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg 2 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	