Commission Implementing Regulation (EU) 2016/1444 of 31 August 2016 amending Regulation (EU) No 37/2010 as regards the substance hydrocortisone aceponate (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1444

of 31 August 2016

amending Regulation (EU) No 37/2010 as regards the substance hydrocortisone aceponate

(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) Article 17 of Regulation (EC) No 470/2009 requires that 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 established in a Regulation.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010[(2)] sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Hydrocortisone aceponate is not yet included in that table.

(4) An application for the establishment of MRLs for hydrocortisone aceponate in bovine species has been submitted to the European Medicines Agency (EMA).

(5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended the establishment of an MRL for hydrocortisone aceponate in bovine tissues and milk and restricted its use to intramammary use only.

(6) According to Article 5 of Regulation (EC) No 470/2009, the EMA 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.

(7) The EMA has considered that the extrapolation of the MRL for hydrocortisone aceponate from bovine milk to the milk of all ruminants and *Equidae* is appropriate, while the establishment of an MRL for hydrocortisone aceponate in all other tissues of all ruminants and *Equidae* is not necessary for the protection of human health.

(8) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(9) It is appropriate to grant the stakeholders concerned a reasonable period of time to take measures that may be required to comply with the new MRL.

(10) 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 31 October 2016.

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

Done at Brussels, 31 August 2016.

For the Commission

The President

Jean-Claude JUNCKER