COMMISSION IMPLEMENTING REGULATION (EU) No 677/2014

of 19 June 2014

amending Regulation (EU) No 37/2010, as regards the substance 'cabergoline'

(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 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) An application for the establishment of maximum residue limits for cabergoline in bovine species has been submitted to the European Medicines Agency.

(4) The Committee for Medicinal Products for Veterinary Use recommended the establishment of a MRL for cabergoline for bovine species, applicable to fat, liver, kidney, muscle and milk.

(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 concluded that the extrapolation to other food producing species cannot be supported for this substance.

(7) Regulation (EU) No 37/2010 should therefore be amended to include the substance cabergoline for bovine species.

(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.

([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).

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 18 August 2014.

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

Done at Brussels, 19 June 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, an entry for the following substance is inserted in alphabetical order:

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
'Cabergoline	Cabergoline	Bovine	0,10 µg/kg 0,25 µg/kg 0,50 µg/kg 0,15 µg/kg 0,10 µg/kg	Fat Liver Kidney Muscle Milk	NO ENTRY	Prolactin inhibitor'