II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 761/2010

of 25 August 2010

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 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 for pharmacologically active substances intended for use in the European 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 maximum residue limits 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) 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 and kidney, excluding animals producing milk for human consumption.

(4) An application for the extension of the existing entry for methylprednisolone applicable to bovine milk has been submitted to the European Medicines Agency.

(5) The Committee for Medicinal Products for Veterinary Use has recommended to establish a provisional maximum residue limit (hereinafter 'MRL') for methylprednisolone for bovine milk and to remove the provision 'not for use in animals from which milk is produced for human consumption'.

(6) The entry for methylprednisolone in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the provisional MRL for bovine milk and to remove the existing provision 'not for use in animals from which milk is produced for human consumption'. The provisional MRL set out in that Table for methylprednisolone should expire on 1 July 2011.

(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,

[1] OJ L 152, 16.6.2009, p. 11.

[2] 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 third day following its publication in the *Official Journal of the European Union*.

It shall apply from 25 October 2010.

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

Done at Brussels, 25 August 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

The entry Methylprednisolone in Table 1 of the Annex to Regulation (EU) No 37/2010 shall be 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
'Methylprednisolone	Methylprednisolone	Bovine	10 µg/kg	Muscle		Corticoides/Glucocorticoides'
			10 µg/kg	Fat		
			10 µg/kg	Liver		
			10 µg/kg	Kidney		
			2 µg/kg	Milk	Provisional MRL shall expire on 1 July 2011.	