Commission Regulation (EU) No 362/2011 of 13 April 2011 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 monepantel (Text with EEA relevance)

COMMISSION REGULATION (EU) No 362/2011

of 13 April 2011

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 monepantel

(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 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) Monepantel is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for ovine and caprine species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption. The provisional maximum residue limits (hereinafter ‘MRLs’) for that substance set out for caprine species will expire on 1 January 2011.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 362/2011. (See end of Document for details)*

(4) An application for the extension of the expiry date for provisional MRLs of the existing entry for monepantel applicable to caprine species has been submitted to the European Medicines Agency.

(5) The Committee for Medicinal Products for Veterinary Use has recommended the extension of the time period for which the provisional MRLs for monepantel for caprine species apply.

(6) The entry for monepantel in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to extend the provisional MRLs for caprine species. The provisional MRLs set out in that Table for monepantel for caprine species should expire on 1 January 2012.

(7) 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 third day following its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 13 April 2011.

For the Commission

The President

José Manuel BARROSO