Commission Implementing Regulation (EU) No 221/2012 of 14 March 2012 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 closantel (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 221/2012

of 14 March 2012

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 closantel

(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 should 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 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin[(2)].

(3) Closantel is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine and ovine species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption.

(4) Ireland has submitted to the European Medicines Agency a request for an opinion for the extrapolation of the existing entry for closantel applicable to bovine and ovine milk.

(5) The Committee for Medicinal Products for Veterinary Use has recommended the establishment of provisional MRL for closantel for bovine and ovine milk and the

removal of the provision 'Not for use in animals from which milk is produced for human consumption'.

(6) The entry for closantel in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the recommended provisional MRL for bovine and ovine 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 closantel should expire on 1 January 2014. The CVMP recommended a two-year period to allow for the completion of scientific studies required to respond to the list of questions addressed by the CVMP to Ireland.

(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,

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 14 May 2012.

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

Done at Brussels, 14 March 2012.

For the Commission

The President

José Manuel BARROSO