Commission Regulation (EC) No 478/2009 of 8 June 2009 amending Annexes I and III to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as regards monepantel (Text with EEA relevance)

COMMISSION REGULATION (EC) No 478/2009

of 8 June 2009

amending Annexes I and III to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as regards monepantel

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin[(1)], and in particular Article 2 and the third paragraph of Article 4 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) All pharmacologically active substances used in the Community in veterinary medicinal products intended for food-producing animals should be evaluated in accordance with Regulation (EEC) No 2377/90.

(2) An application for establishing maximum residue limits for monepantel, an agent acting against endoparasites, has been submitted to the European Medicines Agency. On the basis of the recommendation of the Committee for Medicinal Products for Veterinary Use, this substance should be added to Annex I to Regulation (EEC) No 2377/90 for ovine species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption.

(3) The same substance should be added in Annex III to Regulation (EEC) No 2377/90 for caprine species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption. The provisional maximum residue limits set out in this Annex for this substance should expire on 1 January 2011.

(4) For reasons of clarity, it is appropriate to add a new subdivision entitled ‘Others’ to Annexes I and III, as monepantel is a new class of compound which does not fit into the existing subdivisions. Within the subcategory of ‘Agents acting against endoparasites’ the existing subdivisions are based on the chemistry of the compounds and a number of these chemical subdivisions include only single substances. It is preferable to create

an 'Others' subdivision rather than to go on creating new chemical subdivisions for each new substance class as that would lead to an expanding number of subdivisions containing single substances. For monepantel it is not clear which part of the molecule is key for the pharmacological effect and consequently it is not clear what the appropriate name for a new chemical subdivision for monepantel would be.

(5) Regulation (EEC) No 2377/90 should therefore be amended accordingly.

(6) An adequate period should be allowed before the amendments contained in this Regulation become applicable, in order to enable Member States to make any adjustment which may be necessary in the light of this Regulation with respect to the authorisations to place the veterinary medicinal products concerned on the market which have been granted in accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products[(2)] to take account of the provisions of this Regulation.

(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

Annexes I and III to Regulation (EEC) No 2377/90 are 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 8 August 2009.

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

Done at Brussels, 8 June 2009.

For the Commission

Günter VERHEUGEN

Vice-President of the Commission