II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 418/2014

of 24 April 2014

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 ivermectin

(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 ('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) Ivermectin is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for all mammalian food producing species, applicable to fat, liver and kidney, excluding animals producing milk for human consumption.

(4) On 15 December 2010 the Commission requested that the European Medicines Agency issue a new opinion on the substance ivermectin to include the possibility of establishing a MRL for tissue muscle.

(5) On 9 June 2011 the Committee for Medicinal Products for Veterinary Use ('CVMP') adopted an opinion recommending the establishment of MRLs for ivermectin in tissues, including muscle, for all mammalian food producing species.

(6) On 25 October 2011 the Commission requested that the CVMP reconsider its opinion of 9 June 2011 and amend the part referring to residue levels at the injection site in the 'Other provisions' of Table 1 of the Annex to Regulation (EU) No 37/2010.

([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).

(7) On 12 September 2013, the CVMP adopted a revised opinion recommending the establishment of a MRL for ivermectin for all mammalian food producing species, applicable to muscle, fat, liver and kidney, excluding animals from which milk is produced for human consumption. The CVMP recommended in its revised opinion that, for the purpose of monitoring the residues of ivermectin that, where the entire carcass is available, fat, liver or kidney should be sampled in preference to muscle as residues in these tissues deplete more slowly than residues in muscle.

(8) The entry for ivermectin in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include MRLs for the pharmaceutical substance for all mammalian food producing species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption.

(9) 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.

(10) 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 twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 24 June 2014.

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

Done at Brussels, 24 April 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance ivermectin is 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
'Ivermectin	22, 23-Dihydroavermectin B 1a	All mammalian food producing species	30 µg/kg 100 µg/kg 100 µg/kg 30 µg/kg	Muscle Fat Liver Kidney	For porcine species the fat MRL relates to "skin and fat in natural proportions" Not for use in animals from which milk is produced for human consumption	Antiparasitic agents/Agents acting against endo and ectoparasites'