COMMISSION IMPLEMENTING REGULATION (EU) 2016/305

of 3 March 2016

amending Regulation (EU) No 37/2010 as regards the substance 'gentamicin'

(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) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit (hereinafter '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 established in a Regulation.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Gentamicin is already included in that table as an allowed substance, for bovine and porcine species, applicable to muscle, fat, liver and kidney, and in bovine milk.

(4) In accordance with Article 27(2) of Regulation (EC) No 470/2009, the Commission submitted to the European Medicines Agency (hereinafter 'EMA') a request for extrapolation of the existing MRLs for gentamicin to other species or tissues.

(5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended the extrapolation of the MRLs for gentamicin to all mammalian food producing species and fin fish.

(6) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(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.

([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).

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*.

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

Done at Brussels, 3 March 2016.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'gentamicin' is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRLs	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Gentamicin	Sum of gentamicin C1, gentamicin C1a, gentamicin C2 and gentamicin C2a	All mammalian food producing species and fin fish	50 µg/kg 50 µg/kg 200 µg/kg 750 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	For fin fish the muscle MRL relates to "muscle and skin in natural proportions" For porcine species the fat relates to "skin and fat in natural proportions"	Anti-infectious agents/ Antibiotics'