Commission Implementing Regulation (EU) No 1056/2013 of 29 October 2013 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 neomycin (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1056/2013

of 29 October 2013

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 neomycin

(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 are 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) Neomycin is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for all food-producing species, applicable to muscle, fat, liver, kidney, milk and eggs.

(4) An application for the modification of the existing entry for neomycin has been submitted to the European Medicines Agency.

(5) Additional data on neomycin was provided and assessed by the Committee for Medicinal Products for Veterinary Use. As a result that Committee recommends the modification of the current MRLs for neomycin.

(6) According to Article 5 of Regulation (EC) No 470/2009 the European Medicines Agency is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.

(7) The Committee for Medicinal Products for Veterinary Use recommended the establishment of a revised MRL for neomycin for bovine species, applicable to kidney and liver, and the extrapolation of the revised MRLs for neomycin from cattle to all food-producing species.

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

(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 30 December 2013.

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

Done at Brussels, 29 October 2013.

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 neomycin 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**
'Neomycin (including framycetin)	Neomycin B	All food producing species	500 µg/kg	Muscle	For fin fish the muscle MRL relates to "muscle and skin in natural proportions". MRLs for fat, liver and kidney do not apply to fin fish. For porcine and poultry species the fat MRL relates to "skin and fat in natural proportions"	Anti-infectious agents/ Antibiotics'
			500 µg/kg	Fat		
			5 500 µg/kg	Liver		
			9 000 µg/kg	Kidney		
			1 500 µg/kg	Milk		
			500 µg/kg	Eggs		

(**1**) OJ L 152, 16.6.2009, p. 11.

(**2**) OJ L 15, 20.1.2010, p. 1.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1056/2013.