Commission Implementing Regulation (EU) 2020/1712 of 16 November 2020 amending Regulation (EU) No 37/2010 to classify the substance lidocaine as regards its maximum residue limit (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1712

of 16 November 2020

amending Regulation (EU) No 37/2010 to classify the substance lidocaine as regards its maximum residue limit

(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 opinions of the European Medicines Agency formulated on 16 July 2020 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 ('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) Lidocaine is already included in that table as an allowed substance for equidae, for local-regional anaesthetic use only. The existing entry has a 'no MRL required' classification.

(4) An application for the extension of the existing entry for lidocaine to porcine species, for cutaneous and epilesional use only in piglets up to 7 days of age, has been submitted to the European Medicines Agency ('Agency').

(5) An application for the extension of the existing entry for lidocaine to bovine species, applicable to muscle, fat, liver, kidney and milk, has also been submitted to the Agency.

(6) The Agency, based on the opinions of the Committee for Medicinal Products for Veterinary Use, has recommended the establishment of an MRL for lidocaine in bovine species, but has concluded that the establishment of an MRL for lidocaine in porcine

species, of certain age and for certain use, is not necessary for the protection of human health.

(7) According to Article 5 of Regulation (EC) No 470/2009, the 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.

(8) The Agency has considered that the extrapolation of the entry for lidocaine in porcine and bovine to other food-producing species is not appropriate at this time due to insufficient data.

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

(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*.

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

Done at Brussels, 16 November 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance ‘lidocaine’ 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**
‘Lidocaine	NOT APPLICABLE	Equidae	No MRL required	NOT APPLICABLE	For local/ regional anaesthesia only.	Local anaesthetic’
		Porcine			For use in piglets up to 7 days of age only. For cutaneous and epilesional use only.	
	Lidocaine	Bovine	150 µg/kg 200 µg/kg 1 µg/kg 200 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	NOT APPLICABLE	

(**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).

Status:
Point in time view as at 16/11/2020.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1712.