Commission Implementing Regulation (EU) 2015/1078 of 3 July 2015 amending Regulation (EU) No 37/2010 as regards the substance 'clodronic acid (in the form of disodium salt)' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1078

of 3 July 2015

amending Regulation (EU) No 37/2010 as regards the substance 'clodronic acid (in the form of disodium salt)'

(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) 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 to be 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) Clodronic acid (in the form of disodium salt) is not yet included in this table.

(4) An application for the establishment of MRLs for clodronic acid (in the form of disodium salt) in equidae has been submitted to the European Medicines Agency (hereinafter 'EMA').

(5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended that the establishment of maximum residue limits for clodronate disodium in equine species is not necessary for the protection of human health, provided that the substance is not used for animals producing milk for human consumption.

(6) According to Article 5 of Regulation (EC) No 470/2009, the EMA 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 EMA has considered that the extrapolation of the MRL for clodronic acid (in the form of disodium salt) for equidae to other food producing species is not appropriate, because based on the proposed indication and mode of action, it is not likely that this active substance would be used in any food species other than horses.

(8) Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.

(9) 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 2 September 2015.

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

Done at Brussels, 3 July 2015.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the following substance is inserted in alphabetical order:

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**
‘Clodronic acid (in the form of disodium salt)	NOT APPLICABLE	Equidae	No MRL required	NOT APPLICABLE	Not for use in animals from which milk is produced for human consumption	Musculoskeletal system/ drugs for treatment of bone diseases’

(**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).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1078.