Commission Implementing Regulation (EU) No 19/2014 of 10 January 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 chloroform (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 19/2014

of 10 January 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 chloroform

(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) Chloroform is currently included in Table 2 of the Annex to Regulation (EU) No 37/2010 as a prohibited substance.

(4) An application for the establishment of maximum residue limits for chloroform in all ruminants and porcine species has been submitted to the European Medicines Agency.

(5) The Committee for Medicinal Products for Veterinary Use ('CVMP') recommended that there is no need to establish an MRL for chloroform for all ruminants and porcine species.

(6) For the protection of human health it has to be ensured that consumer exposure to residues will remain below the acceptable daily intake, as specified in Article 6 of Regulation (EC) No 470/2009. Therefore, it is necessary to restrict the use of chloroform to excipients in vaccines and to limit the amount of the substance that can be administered.

(7) 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 another species. The CVMP recommended the extrapolation of the absence of the need to establish a MRL for chloroform from all ruminants and porcine species to all mammalian food producing species.

(8) Table 1 of the Annex to Regulation (EU) No 37/2010 should be amended to include the substance chloroform for all mammalian food producing species, while establishing the absence of the need to establish a MRL, and the entry for chloroform in Table 2 of that Annex should be deleted.

(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*.

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

Done at Brussels, 10 January 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

The Annex to Regulation (EU) No 37/2010 is amended as follows:

(1) in Table 1 the substance chloroform is inserted as follows:

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**
‘Chloroform	NOT APPLICABLE	All mammalian food producing species	No MRL required	NOT APPLICABLE	Only to be used as an excipient in vaccines and only at concentrations not exceeding 1 % w/v and total doses not exceeding 20 mg per animal.	NO ENTRY’

(2) in Table 2 the substance chloroform is deleted.

(**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 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 19/2014.