Commission Implementing Regulation (EU) 2018/721 of 16 May 2018 amending Regulation (EU) No 37/2010 to classify the substance porcine prolactin as regards its maximum residue limit (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/721

of 16 May 2018

amending Regulation (EU) No 37/2010 to classify the substance porcine prolactin 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 opinion of the European Medicines Agency ('EMA') 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 ('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) The substance porcine prolactin is not included in that table.

(4) An application for the establishment of MRLs for porcine prolactin in porcine species has been submitted to EMA.

(5) EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended that the establishment of an MRL for porcine prolactin in porcine species is not necessary for the protection of human health.

(6) According to Article 5 of Regulation (EC) No 470/2009, 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) EMA has considered that the extrapolation of the 'no MRL required' classification for porcine prolactin from porcine species to other species is not appropriate at this time due to insufficient data.

(8) 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*.

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

Done at Brussels, 16 May 2018.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, an entry for 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**
'Porcine prolactin	NOT APPLICABLE	Porcine	No MRL required	NOT APPLICABLE	For oral use in newborn piglets at a dose of up to 0,2 mg/ animal. For use in sows at a total dose of up to 5 mg/animal.	Agents acting on the reproductive system'

(**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) 2018/721.