Commission Implementing Regulation (EU) 2019/138 of 29 January 2019 amending Regulations (EC) No 1356/2004, (EC) No 1464/2004, (EC) No 786/2007, (EC) No 971/2008, (EU) No 1118/2010, (EU) No 169/2011 and Implementing Regulations (EU) No 888/2011 and (EU) No 667/2013 as regards the name of the holder of the authorisation for feed additives (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/138

of 29 January 2019

amending Regulations (EC) No 1356/2004, (EC) No 1464/2004, (EC) No 786/2007, (EC) No 971/2008, (EU) No 1118/2010, (EU) No 169/2011 and Implementing Regulations (EU) No 888/2011 and (EU) No 667/2013 as regards the name of the holder of the authorisation for feed additives

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)] and in particular Article 13(3) thereof,

Whereas:

(1) In accordance with Council Directive 70/524/EEC[(2)] monensin sodium and narasin, were authorised as feed additives by, respectively, Commission Regulations (EC) No 1356/2004[(3)] and (EC) No 1464/2004[(4)].

(2) In accordance with Regulation (EC) No 1831/2003, endo-1,4-beta-mannanase and diclazuril were authorised as feed additives by, respectively, Commission Regulations (EC) No 786/2007[(5)], (EC) No 971/2008[(6)], (EU) No 1118/2010[(7)], (EU) No 169/2011[(8)] and Commission Implementing Regulations (EU) No 888/2011[(9)] and (EU) No 667/2013[(10)].

(3) The holder of authorisation, Eli Lilly and Company Ltd, has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation for the feed additives concerned.

(4) The holder of authorisation claims that, with effect from 30 March 2018, Elanco GmbH, a division of Eli Lilly and Company Ltd owns the marketing rights for the additives concerned. The holder of authorisation has submitted relevant data supporting its request.

(5) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additives concerned. The European Food Safety Authority was informed of the application.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/138. (See end of Document for details)*

(6) To allow Elanco GmbH to exploit its marketing rights it is necessary to change the terms of the authorisations concerned.

(7) Regulations (EC) No 1356/2004, (EC) No 1464/2004, (EC) No 786/2007, (EC) No 971/2008, (EU) No 1118/2010, (EU) No 169/2011 and Implementing Regulations (EU) No 888/2011 and (EU) No 667/2013, should, therefore, be amended accordingly.

(8) Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to allow a transitional period during which existing stocks may be used up.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 1356/2004

In the second column of the Annex to Regulation (EC) No 1356/2004, the words ‘Eli Lilly and Company Limited’ are replaced by the words ‘Elanco GmbH’.

Article 2

Amendment to Regulation (EC) No 1464/2004

In the second column of the Annex to Regulation (EC) No 1464/2004, the words ‘Eli Lilly and Company Limited’ are replaced by the words ‘Elanco GmbH’.

Article 3

Amendment to Regulation (EC) No 786/2007

In the second column of the Annex to Regulation (EC) No 786/2007, the words ‘Eli Lilly and Company Ltd’ are replaced by the words ‘Elanco GmbH’.

Article 4

Amendment to Regulation (EC) No 971/2008

In the second column of the Annex to Regulation (EC) No 971/2008, the words ‘Eli Lilly and Company Ltd’ are replaced by the words ‘Elanco GmbH’.

Article 5

Amendment to Regulation (EU) No 1118/2010

In the second column of the Annex to Regulation (EU) No 1118/2010, the words ‘Eli Lilly and Company Ltd’ are replaced by the words ‘Elanco GmbH’.

Article 6

Amendment to Regulation (EU) No 169/2011

In the second column of the Annex to Regulation (EU) No 169/2011, the words ‘Eli Lilly and Company Ltd’ are replaced by the words ‘Elanco GmbH’.

Article 7

Amendment to Regulation (EU) No 888/2011

In the second column of the Annex to Regulation (EU) No 888/2011 the words ‘Eli Lilly and Company Ltd’ are replaced by the words ‘Elanco GmbH’.

Article 8

Amendment to Regulation (EU) No 667/2013

Regulation (EU) No 667/2013 is amended as follows:

(1) In the title, the words ‘Eli Lilly and Company Ltd’ are replaced by the words ‘Elanco GmbH’;

(2) In the second column of the Annex, the words ‘Eli Lilly and Company Ltd’ are replaced by the words ‘Elanco GmbH’.

Article 9

Transitional measure

Monensin sodium, narasin, endo-1,4-beta-mannanase, and diclazuril produced and labelled before the date of entry into force of this Regulation in accordance with the rules applicable before that date may continue to be placed on the market and used until stocks are exhausted.

Article 10

Entry into force

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.