Commission Implementing Regulation (EU) 2017/1126 of 23 June 2017 amending Regulation (EC) No 903/2009 and Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 as regards the name of the EU representative of the holder of the authorisation of a preparation of Clostridium butyricum (FERM-BP 2789) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1126

of 23 June 2017

amending Regulation (EC) No 903/2009 and Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 as regards the name of the EU representative of the holder of the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789)

(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) Miyarisan Pharmaceutical Co. Ltd has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of its EU representative of the holder of the authorisation stated in Commission Regulation (EC) No 903/2009[(2)] and Commission Implementing Regulations (EU) No 373/2011[(3)], (EU) No 374/2013[(4)] and (EU) No 1108/2014[(5)].

(2) The applicant claims that Huvepharma NV Belgium has become the new representative for Miyarisan Pharmaceutical Co. Ltd for the feed additive 4b1830 preparation of *Clostridium butyricum* FERM-BP 2789 with effect from 12 January 2017. The applicant has submitted relevant data supporting its request.

(3) The proposed change of the representative of the holder 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.

(4) In order to allow Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium to exploit its marketing rights, it is necessary to change the conditions of the respective authorisations. Regulation (EC) No 903/2009, Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 should therefore be amended accordingly.

(5) Since safety reasons do not require the immediate application of the amendments provided for by this Regulation to Regulation (EC) No 903/2009, Implementing

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/1126. (See end of Document for details)*

Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014, it is appropriate to provide for a transitional period during which existing stocks may be used up.

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

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 903/2009

Regulation (EC) No 903/2009 is amended as follows:

(1) In the Title, the words ‘holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U’ are replaced by the words ‘holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium’.

(2) In the Annex to Regulation (EC) No 903/2009, in the second column ‘Name of the holder of authorisation’, the words ‘Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.’ are replaced by the words ‘Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium’.

Article 2

Amendment to Implementing Regulation (EU) No 373/2011

Implementing Regulation (EU) No 373/2011 is amended as follows:

(1) In the Title, the words ‘holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U’ are replaced by the words ‘holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium’.

(2) In the Annex to Implementing Regulation (EU) No 373/2011, in the second column, the words ‘Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.’ are replaced by the words ‘Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium’.

Article 3

Amendment to Implementing Regulation (EU) No 374/2013

Implementing Regulation (EU) No 374/2013 is amended as follows:

(1) In the Title, the words ‘holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U’ are replaced by the words ‘holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium’.