Commission Implementing Regulation (EU) 2020/146 of 3 February 2020 amending Regulation (EU) No 333/2010, Implementing Regulation (EU) 2017/2312, Implementing Regulation (EU) 2018/1081, Implementing Regulation (EU) 2016/897, Implementing Regulation (EU) 2019/893 and Regulation (EU) No 184/2011 concerning the authorisations of the preparation of Bacillus subtilis C-3102 (DSM 15544) as a feed additive (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/146

of 3 February 2020

amending Regulation (EU) No 333/2010, Implementing Regulation (EU) 2017/2312, Implementing Regulation (EU) 2018/1081, Implementing Regulation (EU) 2016/897, Implementing Regulation (EU) 2019/893 and Regulation (EU) No 184/2011 concerning the authorisations of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive

(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) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) The preparation of *Bacillus subtilis* C-3102 (DSM 15544) was authorised as a feed additive for weaned piglets by Commission Regulation (EU) No 333/2010[(2)], for sows, suckling piglets and dogs by Commission Implementing Regulation (EU) 2017/2312[(3)], for pigs for fattening by Commission Implementing Regulation (EU) 2018/1081[(4)], for laying hens and ornamental fish by Commission Implementing Regulation (EU) 2016/897[(5)], for chickens for fattening by Commission Implementing Regulation (EU) 2019/893[(6)], and for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds by Commission Regulation (EU) No 184/2011[(7)].

(3) On 31 August 2018, Asahi Calpis Wellness Co. Ltd., represented in the Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office, submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003, proposing to modify the minimum content of the additive for use in chickens for fattening from the authorised concentration of 5×10^8 CFU/kg feed to a concentration of 3×10^8 CFU/kg feed. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority ('the Authority').

(4) The Authority concluded in its opinion of 22 January 2019[8] that the reduced minimum content of the additive with a concentration of 3×10^8 CFU/kg feed has the potential to be efficacious in chickens for fattening. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) On 26 March 2019, Asahi Calpis Wellness Co. Ltd., represented in the Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office, submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003, proposing to amend the name of its representative. The applicant claimed that Pen & Tec Consulting S.L.U. is to be considered its representative in the Union for the additive. The application was accompanied by the relevant supporting data.

(6) That proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The Authority was informed of the application.

(7) The assessment of the applications shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.

(8) Regulation (EU) No 333/2010, Implementing Regulation (EU) 2017/2312, Implementing Regulation (EU) 2018/1081, Implementing Regulation (EU) 2016/897, Implementing Regulation (EU) 2019/893 and Regulation (EU) No 184/2011 should therefore be amended accordingly.

(9) Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to provide for a transitional period during which the existing stocks of the preparation of *Bacillus subtilis* C-3102 (DSM 15544), which are in conformity with the provisions applying before the date of entry into force of this Regulation, may continue to be placed on the market and used until they are exhausted.

(10) 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

Amendments to Regulation (EU) No 333/2010

Regulation (EU) No 333/2010 is amended as follows:

(1) in the title, the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’;

(2) in the second column of the Annex, ‘Name of the holder of authorisation’, the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi

Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.'.

Article 2

Amendments to Regulation (EU) No 184/2011

Regulation (EU) No 184/2011 is amended as follows:

(1) in the title, the words 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office' are replaced by the words 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.';

(2) in the second column of the Annex, 'Name of the holder of authorisation', the words 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office' are replaced by the words 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.'.

Article 3

Amendments to Implementing Regulation (EU) 2016/897

Implementing Regulation (EU) 2016/897 is amended as follows:

(1) in the title, the words 'Asahi Calpis Wellness Co. Ltd' are replaced by the words 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.';

(2) in the second column of the Annex, 'Name of the holder of authorisation', the words 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office' are replaced by the words 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.'.

Article 4

Amendments to Implementing Regulation (EU) 2017/2312

Implementing Regulation (EU) 2017/2312 is amended as follows:

(1) in the title, the words 'Asahi Calpis Wellness Co. Ltd, represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office' are replaced by the words 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.';

(2) in the second column of the Annex, 'Name of the holder of authorisation', the words 'Asahi Calpis Wellness Co. Ltd, represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office' are replaced by the words 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.'.