Commission Implementing Regulation (EU) 2016/897 of 8 June 2016 concerning the authorisation of a preparation of Bacillus subtilis (C-3102) (DSM 15544) as a feed additive for laying hens and ornamental fish (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.) and amending Regulations (EC) No 1444/2006, (EU) No 333/2010 and (EU) No 184/2011 as regards the holder of the authorisation (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/897

of 8 June 2016

concerning the authorisation of a preparation of *Bacillus subtilis* (C-3102) (DSM 15544) as a feed additive for laying hens and ornamental fish (holder of authorisation **[**F1Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.**]**) and amending Regulations (EC) No 1444/2006, (EU) No 333/2010 and (EU) No 184/2011 as regards the holder of the authorisation

(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 9(2) and 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) In accordance with Article 7 of Regulation (EC) No 1831/2003 applications were submitted for the authorisation of a preparation of *Bacillus subtilis* (C-3102). Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) Those applications concern the authorisation of a preparation of *Bacillus subtilis* (C-3102) as a feed additive for all laying birds and ornamental fish to be classified in the additive category ‘zootechnical additives’.

(4) That preparation was already authorised as a feed additive for use in chickens for fattening by Commission Regulation (EC) No 1444/2006[(2)] in piglets by Commission Regulation (EU) No 333/2010[(3)], and in chickens reared for laying and turkeys, minor avian species and other ornamental and game birds by Commission Regulation (EU) No 184/2011[(4)].

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 28 September 2015[(5)] and of 11 November 2015[(6)] that, under the proposed conditions of use, the preparation of *Bacillus subtilis* (C-3102) is presumed not to have an adverse

effect on animal health, human health or the environment. It concluded that, under the proposed condition of use, the additive has the potential to be efficacious in reducing the amount of feed per unit of mass egg production over the entire laying period. The Authority also concluded that the additive has the potential to improve the grow and feed utilisation in ornamental fish. It 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.

(6) The assessment of the preparation of *Bacillus subtilis* (C-3102) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(7) The applicant has also 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 and the name of its representative in the EU in Regulations (EC) No 1444/2006, (EU) No 333/2010 and (EU) No 184/2011. The applicant claims that, with effect from 1 January 2016, it has changed its name from ‘Calpis Co. Ltd’ to ‘Asahi Calpis Wellness Co. Ltd’. The name of its representative in the EU has changed from ‘Calpis Co. Ltd Europe Representative Office’ to ‘Asahi Calpis Wellness Co. Ltd Europe Representative Office’. The applicant has submitted relevant data supporting its request.

(8) In order to enable Asahi Calpis Wellness Co. Ltd to exploit its marketing rights it is necessary to change the terms of the authorisations.

(9) Regulations (EC) No 1444/2006, (EU) No 333/2010 and (EU) No 184/2011 should therefore be amended accordingly.

(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:

Textual Amendments

F1 Substituted by 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).

Article 1

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

In the Annex to Regulation (EC) No 1444/2006, in the second column, name of the holder of authorisation, the term 'Calpis Co., Ltd represented in the Community by Orffa International Holding BV' is replaced by the term 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office'.

Article 3

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

(a) in the title, the term 'holder of authorisation Calpis Co. Ltd Japan, represented in the European Union by Calpis Co. Ltd Europe Representative Office' is replaced by the term 'holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office';

(b) in the Annex, in the second column, name of the holder of authorisation, the term 'Calpis Co. Ltd Japan, represented in the European Union by Calpis Co. Ltd Europe Representative Office, France' is replaced by the term 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office'.

Article 4

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

(a) in the title, the term 'holder of authorisation Calpis Co. Ltd Japan, represented by Calpis Co. Ltd Europe Representative Office' is replaced by the term 'holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office';

(b) in the Annex, in the second column, name of the holder of authorisation, the term 'Calpis Co. Ltd Japan, represented by Calpis Co. Ltd Europe Representative Office, France' is replaced by the term 'Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office'.

Article 5

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.