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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 ►M1 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)

(OJ L 152, 9.6.2016, p. 7)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Implementing Regulation (EU) 2020/146 of 3 February 2020	L 31	3	4.2.2020

▼B

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(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’;

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(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.

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ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1820	►**M1** Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U. ◄	*Bacillus subtilis* C-3102 (DSM 15544)	*Additive composition* *Bacillus subtilis* C-3102 (DSM 15544) with minimum of 1,0 × 10^{10} CFU/g *Characterisation of the active substance* Viable spores (CFU) of *Bacillus subtilis* C-3102 (DSM 15544) *Analytical method* (1) Enumeration: spread plate method using tryptone soya agar in all target matrices (EN 15784:2009) Identification: pulsed-field gel electrophoresis (PFGE).	Laying hens Ornamental fish	—	3 × 10^{8} 1 × 10^{10}	—	1. In the directions for use of the additive, premixture and compound feedingstuff indicate the storage temperature, storage life and stability to pelleting shall be indicated. 2. For users of the additive and premixtures in a feed business, operational procedures and appropriate organisational measures shall be established to address hazards by inhalation, dermal contact or eyes contact. Where the dermal, inhalator or eyes exposure cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	29 June 2026

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: www.irmm.jrc.ec.europa.eu/crl-feed-additives