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► **B** COMMISSION IMPLEMENTING REGULATION (EU) 2017/2312
of 13 December 2017

concerning the authorisation of a new use of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for sows, suckling piglets and dogs (holder of the authorisation ► **M1** Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U. ◀)

(Text with EEA relevance)

(OJ L 331, 14.12.2017, p. 41)

Amended by:

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

▼B**COMMISSION IMPLEMENTING REGULATION (EU) 2017/2312****of 13 December 2017****concerning the authorisation of a new use of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for sows, suckling piglets and dogs (holder of the authorisation ►M1 Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U. ◀)****(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

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.

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	►MI Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U. ◀	<i>Bacillus subtilis</i> DSM 15544	<p><i>Additive composition</i></p> <p>Preparation of <i>Bacillus subtilis</i> C-3102</p> <p>DSM 15544 containing a minimum of 1×10^{10} CFU/g additive in solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Bacillus subtilis</i> DSM 15544</p> <p><i>Analytical method</i></p> <p>Enumeration: spread plate method using tryptone soya agar in all target matrices (EN 15784:2009)</p> <p>Identification: pulsed-field gel electrophoresis (PFGE).</p>	Sows Suckling piglets Dogs	—	3×10^8	—	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. Indicate in the instruction for the use: 'The additive shall be fed to lactating sows and suckling piglets simultaneously' For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 	3 January 2028