

▼B**COMMISSION IMPLEMENTING REGULATION (EU) 2018/1081****of 30 July 2018**

concerning the authorisation of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for pigs for fattening (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 | ►M1 Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U. ◀ | <i>Bacillus subtilis</i> C-3102 (DSM 15544) | <p><i>Additive composition</i></p> <p><i>Bacillus subtilis</i> C-3102 (DSM 15544) with minimum of $1,0 \times 10^{10}$ CFU/g</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Viable spores (CFU) of <i>Bacillus subtilis</i> C-3102 (DSM 15544)</p> <p><i>Analytical method</i> ⁽¹⁾</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> | Pigs for fattening | — | $1,5 \times 10^8$ | — | <p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks of 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.</p> | 20.8.2028 |

⁽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