

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									
4b1825	Lactosan GmbH & Co. KG	Bacillus subtilis DSM 28343	Additive composition Preparation of <i>Bacillus subtilis</i> DSM 28343 containing a minimum of 1x10 ¹⁰ CFU /g of additive	Calves for rearing	-	1x10 ⁹	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks 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.	[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]
			Solid form ----- Characterisation of the active substance: Viable spores of <i>Bacillus subtilis</i> DSM 28343 ----- Analytical method¹ For identification enumeration of <i>Bacillus subtilis</i> DSM 28343 in the feed additive, premixtures and feedingstuffs: - Identification: Pulsed Field Gel Electrophoresis (PFGE) For enumeration of <i>Bacillus subtilis</i> DSM 28343 in the feed additive, premixtures and feedingstuffs: - Enumeration: Spread plate method using tryptone soya agar - EN 15784	Pigs for fattening	-	2x10 ⁸			

¹ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>