ANNEX

Part I

number h	ame of the holder of thorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	com feedingst	content of	Mini- mum content CFU/I of drin	Maxi- mum content water for king	Other provisions	End of period of authorisa tion
Category: zoote	technical add	itives. Functiona	l group: gut flora stal	bilisers							
Proc repr DSM Nutr	tritional ducts Ltd, resented by M tritional ducts Sp. z	Enterococcus lactis NCIMB 10415	Additive composition Preparation of Enterococcus lactis NCIMB 10415 containing a minimum of: — encapsulated form: 1 × 10 ¹⁰ CFU/g additive, or — granulated non- coated form: 3.5 × 10 ¹⁰ CFU/g additive. Solid form Characterisation of the active substance Viable cells of Enterococcus lactis NCIMB 10415 Analytical method (¹) Identification: DNA	All poultry species for fattening All poultry species reared for laying All poultry species reared for breeding Ornamental birds Sows of all Suidae species Suckling piglets of all Suidae species	-	3 x 10 ⁸ 7 x 10 ⁸ 1 x 10 ⁹		1.5 x 10 ⁸ 3.5 x 10 ⁸ 0.5 x 10 ⁹	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used via water for drinking. 3. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: decoquinate, monensin sodium, robenidine hydrochloride, diclazuril, semduramicin, lasalocid A sodium, maduramicin ammonium, narasin, a combination of narasin with nicarbazin, salinomycin	[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) - CEN/TS 17697. Enumeration in the feed additive, premixtures, compound feed and water: spread plate method using bile esculin azide agar (EN 15788)	Calves, kids, lambs and minor ruminant species for rearing Calves, kids, lambs and minor ruminant species for fattening Weaned piglets of all Suidae species Pigs for	3.5 x 10 ⁸	2 x 10 ⁸	sodium. 4. 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment, and also eye protective equipment for the granulated non-coated form.
	species Pigs for fattening of all <i>Suidae</i> species			granulated non-coated form.

Part II

Identi- fication number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	feedingst	Maximum content f complete uff with a ntent of 12%	Other provisions	End of period of authorisa tion		
Category: zootechnical additives. Functional group: gut flora stabilisers											
4b1705i	DSM	Enterococcus	Additive composition	All poultry	-	3 x 10 ⁸	-	1. In the directions for use	[10 years		
	Nutritional	lactis NCIMB	Preparation of	species for				of the additive and	from the		
	Products Ltd,	10415	Enterococcus lactis	fattening				premixture, the storage	date of		
	represented by		NCIMB 10415					conditions and stability to	entry into		
	DSM		containing a	All poultry				heat treatment shall be	force of this		

l l	Nutritional	minimum of:	species			indicated.	Regulation.
F	Products Sp. z	 encapsulated and 	reared for laying				To be
C	0.0.	coated form with				2. The additive may be	completed
		shellac: 2×10^{10}	All poultry			used simultaneously with	by the
		CFU/g additive	species			the following	Service
		Solid form	reared for			coccidiostats, in	responsible
			breeding			accordance with their	for the
		Characterisation of				respective conditions of	publica-
		the active substance	Ornamental birds			authorisation as feed	tion]
		Viable cells of	Sows of all Suidae	7	x 10 ⁸	additives: decoquinate,	
		Enterococcus lactis	species			monensin sodium,	
		NCIMB 10415	Suckling piglets	1	x 10 ⁹	robenidine hydrochloride,	
			of all <i>Suidae</i>			diclazuril, semduramicin,	
		Analytical method (2)	species			lasalocid A sodium,	
			•			maduramicin ammonium,	
		Identification: DNA	Calves, kids,			narasin, a combination of	
		sequencing methods or Pulsed Field Gel	lambs and minor			narasin with nicarbazin,	
		Electrophoresis	ruminant species			salinomycin sodium.	
		(PFGE) - CEN/TS	for rearing				
		17697.				3. For users of the additive	
			Calves, kids,			and premixtures, feed	
		Enumeration in the	lambs and minor			business operators shall	
		feed additive,	ruminant species			establish operational	
		premixtures,	for fattening			procedures and	
		compound feed and	Weaned piglets of	3.5	5 x 10 ⁸	organisational measures to	
		water: spread plate	all Suidae species			address potential risks	
		method using bile	1			resulting from their use.	
		esculin azide agar	Pigs for fattening			Where those risks cannot	
		(EN 15788)	of all <i>Suidae</i>			be eliminated by such	
			species			procedures and measures,	
			•			the additive and	
						premixtures shall be used	
						with personal breathing	
						and skin protective	
						equipment.	

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <a href="https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en_additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en_additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en_additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en_additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en_additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en_additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en_additives/eurl-fa-evaluation-reports