



EUROPEAN
COMMISSION

Brussels, **XXX**
SANCO/12806/2013 ANNEX CIS
(POOL/G1/2013/12806/12806-EN
ANNEX CIS.doc)
[...](2014) **XXX** draft

ANNEX 1

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) No .../..

**concerning the authorisation of preparations of *Enterococcus faecium*
NCIMB 10415, *Enterococcus faecium* DSM 22502, and *Pediococcus acidilactici*
CNCM I-3237 as feed additives for all animal species**

ANNEX

Identifi- cation 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 authori- sation
						CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives.									
1k20601	-	<i>Enterococcus faecium</i> NCIMB 10415	Additive composition: Preparation of <i>Enterococcus faecium</i> NCIMB 10415 containing a minimum of 1x10 ¹⁰ CFU/g additive. ----- Characterisation of the active substance: Viable cells of <i>Enterococcus faecium</i> NCIMB 10415. ----- Analytical method ¹ Enumeration in the feed additive: spread plate method using Bile Esculine Azide agar (EN 15788). Identification: Pulsed Field Gel Electrophoresis (PFGE).	All animal species	-	-	-	1. In the directions for use of the additive and premixture, indicate the storage conditions. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1x10 ⁸ CFU/Kg fresh material. 3. For safety: it is recommended to use breathing protection, eye protection and gloves during handling.	[10 years from the date of entry into force of this Regulation To be completed by the Service responsible for the publication]
1k20602	-	<i>Enterococcus faecium</i> DSM 22502	Additive composition: Preparation of <i>Enterococcus faecium</i> DSM 22502 containing a minimum of 1x10 ¹¹ CFU/g additive. ----- Characterisation of the active substance: Viable cells of <i>Enterococcus faecium</i>	All animal species				1. In the directions for use of the additive and premixture, indicate the storage conditions. 2. Minimum content of the additive when used without	

¹ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

			<p>DSM 22502.</p> <p>-----</p> <p>Analytical method²</p> <p>Enumeration in the feed additive: spread plate method using Bile Esculine Azide agar (EN 15788).</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE).</p>					<p>combination with other micro-organisms as silage additives: 1x10⁸ CFU/Kg fresh material.</p> <p>3. For safety: it is recommended to use breathing protection, eye protection and gloves during handling.</p>	
1k21009	-	<i>Pediococcus acidilactici</i> CNCM I-3237	<p>Additive composition:</p> <p>Preparation of <i>Pediococcus acidilactici</i> CNCM I-3237 containing a minimum of 1x10¹⁰ CFU/g additive.</p> <p>-----</p> <p>Characterisation of the active substance:</p> <p>Viable cells of <i>Pediococcus acidilactici</i> CNCM I-3237.</p> <p>-----</p> <p>Analytical method³</p> <p>Enumeration in the feed additive: spread plate method using MRS agar (EN 15786)</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE).</p>	All animal species	-	-	-	<p>1. In the directions for use of the additive and premixture, indicate the storage conditions.</p> <p>2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 5x10⁷ CFU/Kg fresh material.</p> <p>3. For Safety: it is recommended to use breathing protection, eye protection and gloves during handling.</p>	<p>[10 years from the date of entry into force of this Regulation To be completed by the Service responsible for the publication]</p>

² Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

³ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

1k21010		<i>Pediococcus pentosaceus</i> DSM 23688	<p>Additive composition: Preparation of <i>Pediococcus pentosaceus</i> DSM 23688 containing a minimum of 1×10^{11} CFU/g additive.</p> <p>-----</p> <p>Characterisation of the active substance: Viable cells of <i>Pediococcus pentosaceus</i> DSM 23688.</p> <p>-----</p> <p>Analytical method⁴ Enumeration in the feed additive: spread plate method using MRS agar (EN 15786). Identification: Pulsed Field Gel Electrophoresis (PFGE).</p>	All animal species				<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, indicate the storage conditions. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1×10^8 CFU/Kg fresh material in easy and moderately difficult to ensile material⁵. 3. For safety: it is recommended to use breathing protection, eye protection and gloves during handling. 	
---------	--	--	---	--------------------	--	--	--	---	--

⁴ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

⁵ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forage: 1,5—3,0 % soluble carbohydrates in the fresh material. Regulation (EC) No 429/2008. OJ L 133, 22.5.2008, p. 1.