

**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
						Units of activity/kg of complete feed with a moisture content of 12%			
<b>Category of zootechnical additives. Functional group: digestibility enhancers.</b>									
4a25	Fertinagro Biotech S.L.	3-phytase (EC 3.1.3.8)	<p><b>Additive composition:</b> Preparation of 3-phytase (EC 3.1.3.8) produced by <i>Komagataella phaffii</i> (CECT 13094) having a minimum activity of: Solid form: 10 000 FTU<sup>1</sup>/g Liquid form: 1 000 FTU/ml -----</p> <p><b>Characterisation of the active substance:</b> 3-phytase (EC 3.1.3.8) produced by <i>Komagataella phaffii</i> (CECT 13094) -----</p> <p><b>Analytical method<sup>2</sup></b> For the quantification of 3-phytase activity in the feed additive and premixtures: - colorimetric method based on the enzymatic reaction of phytase on the phytate  For the quantification of 3-phytase activity in feed materials and compound feed:</p>	<ul style="list-style-type: none"> <li>- Turkeys for fattening</li> <li>- Turkeys reared for breeding purposes</li> </ul>	-	500 FTU 1 000 FTU	-	<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 resulting from its 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 skin and breathing protection.</p>	<p>[To be completed by the Service responsible for the publication: insert precise date 10 years from the date of entry into force of this Regulation]</p>

**Formateret:** Listeafsnit, Indrykning: Venstre: -0,1 cm, Hængende: 0,26 cm, Højre: 0,08 cm, Punkttegn + Niveau: 1 + Justeret: 0,63 cm + Indrykning: 1,27 cm

**Formateret:** Fremhævning

**Formateret:** Venstre

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<sup>1</sup> 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from a sodium phytate substrate at pH 5.5 and 37°C.  
<sup>2</sup> 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>.

			<p>- colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024</p>		<p><i>recommended level of 1,000 FTU/kg feed.”</i></p> <p><i>the other relevant EFSA opinion, there is a mention to a recommended dose and not a minimum dose:</i></p> <p><i>“Therefore, the Panel concluded that the additive (3-phytase FLF1000 and FSF10000) is safe for pigs for fattening and minor growing porcine species at the recommended dose of 1,000 FTU/kg feed.</i></p>		
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