ANNEX

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	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a63	Genencor International B.V.	Protease (EC 3.4.21.62), *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510	***Additive composition*** Preparation of: — protease (EC 3.4.21.62) produced with *Bacillus subtilis* CBS 148232 with a minimum activity of: 50 000 U ([1])/g, — *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509, and *Bacillus subtilis* NRRL B-50510, containing a minimum total of: *Bacillus* spp. 1.5×10^9 CFU/g (ratio 1:1:1), — Food- grade mineral oil : ≤ 0.4% — Food- grade polyvinyl alcohol : ≤ 1.5% Solid form. ***Characterisation of the active substance*** Protease (EC 3.4.21.62) produced with *Bacillus subtilis* CBS 148232, and viable spores of *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 ***Analytical method*** ([2])	Pigs for fattening of all Suidae species Weaned piglets of minor Suidae species	—	5 000 U Protease $1{,}5 \times 10^8$ CFU *Bacillus* spp.	—	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 the 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 skin and breathing protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*

([1]) 1 unit of protease activity is defined as the amount of enzyme that liberates, under defined assay conditions, 2.3 µg of phenolic compounds (expressed as tyrosine equivalents) from a casein substrate per minute at pH 10.0 and 50 °C.

			For the quantification of protease in the feed additive, premixtures and compound feed: Colorimetric method based on the enzymatic hydrolysis by protease of a dyed cross-linked casein substrate at pH 10.0 and 50 °C. For the identification of *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510: Pulsed Field Gel Electrophoresis (PFGE) - CEN/TS 17697 or DNA sequencing methods. For the enumeration of the overall *Bacillus* spp. (NRRL B-50508, NRRL B-50509 and NRRL B-50510) in the feed additive, premixture and compound feed: Spread plate method on tryptone soya agar (EN 15784).						

(2) 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