

**EN**  
**ANNEX**

PAFF 12-13/05/2025

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	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						PFU/l of water for drinking			
Category: zootechnical additives. Functional group: other zootechnical additives (reduction of the environmental contamination by poultry with <i>Salmonella</i> Enteritidis)									
4d29	Proteon Pharmaceuticals S.A.	Bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097	<b>Additive composition</b> Preparation of the bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097 containing a minimum of $5 \times 10^7$ PFU <sup>(1)</sup> /ml additive (1:1:1:1 ratio). Liquid form.  <b>Characterisation of the active substance</b> Lytic bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097 infecting <i>Salmonella</i> <i>enterica</i> ser. Gallinarum B/00111.  <b>Analytical method <sup>(2)</sup></b> Identification: phage- specific PCR method. Enumeration in the feed additive and water for drinking: double agar overlay plaque assay.	Poultry	-	$6 \times 10^6$	-	1. In the directions for use of the additive, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated.  2. The additive shall only be used in water for drinking.  3. The additive shall be used ensuring a minimum dose of: $2 \times 10^6$ PFU/bird/day.  4. On the label of the additive the following shall be indicated: ‘The additive 4d29 cannot be considered as a replacement for the standard hygiene farming conditions.’  5. A post-market monitoring programme addressing the potential selection and spread of resistant variants of <i>Salmonella</i> to the bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097 shall be planned and executed by the holder of authorisation, in accordance with Commission Regulation (EC) No 429/2008 <sup>(3)</sup> .  6. For users of the additive, 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	[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publica- tion]

								such procedures and measures, the additive shall be used with personal breathing and skin protective equipment.	
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- (1) PFU: plaque forming unit.
- (2) Details of the analytical methods are available at the following address of the Reference Laboratory: [https://joint-research-centre.ec.europa.eu/eur-l-fa-eur-l-feed-additives/eur-l-fa-authorisation/eur-l-fa-evaluation-reports\\_en](https://joint-research-centre.ec.europa.eu/eur-l-fa-eur-l-feed-additives/eur-l-fa-authorisation/eur-l-fa-evaluation-reports_en).
- (3) Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/429/oj>).