COMMISSION IMPLEMENTING REGULATION (EU) 2016/898

of 8 June 2016

concerning the authorisation of a preparation of *Bacillus licheniformis* (ATCC 53757) and its protease (EC 3.4.21.19) as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying and ornamental birds (holder of authorisation Novus Europe SA/NV)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of *Bacillus licheniformis* (ATCC 53757) and its protease (EC 3.4.21.19). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of *Bacillus licheniformis* (ATCC 53757) and its protease (EC 3.4.21.19) as a feed additive for chickens for fattening, chickens reared for laying and minor avian species for fattening and to point of lay and ornamental birds, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 March 2015 ([2]) that, under the proposed conditions of use, the preparation of *Bacillus licheniformis* (ATCC 53757) and its protease (EC 3.4.21.19) does not have an adverse effect on animal health, human health or the environment, and that it has a potential to be efficacious in feed to gain ratio in chickens for fattening at the recommended dose but only when a reduced-protein diet was provided. It is also considered that this conclusion can be extended to chickens reared for laying, to minor avian species for fattening and those reared for laying and ornamental birds The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of *Bacillus licheniformis* (ATCC 53757) and its protease (EC 3.4.21.19) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2015;13(3):4055.

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 June 2016.

For the Commission
The President
Jean-Claude JUNCKER

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
						CFU/Units of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of zootechnical performance)									
4d12	Novus Europe SA/NV	*Bacillus licheniformis* ATCC 53757 and its protease EC 3.4.21.19	*Additive composition* Preparation of *Bacillus licheniformis* (ATCC 53757) and its protease EC 3.4.21.19 and containing a minimum of: — *Bacillus licheniformis* (ATCC 53757): 1×10^9 CFU/g of additive — protease 6×10^5 U/g of additive (1) Solid form *Characterisation of the active substance* Viable spores of *Bacillus licheniformis* (ATCC 53757) and its protease EC 3.4.21.19 *Analytical method* (2) Identification and enumeration of *Bacillus licheniformis* ATCC 53757 in the feed additive, premixtures and feedingstuffs: — Identification: Pulsed field gel electrophoresis (PFGE)	Chickens for fattening and reared for laying Minor poultry species for fattening and reared for laying Ornamental birds	—	5×10^8 CFU *Bacillus licheniformis* 3×10^5 U protease	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended minimum dose 500 mg of additive/kg of complete feed. 3. For users of the additive and premixtures in a feed business, operational procedures and appropriate organisational measures shall be established to address hazards by inhalation, dermal contact or eye contact. Where the dermal, inhalator or eye exposure cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	29 June 2026

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
						CFU/Units of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			— Enumeration: Spread plate method using tryptone soya agar — EN 15784 Quantification of protease in the feed additive, premixtures and feedingstuffs: — Colorimetric method measuring para-nitroaniline (pNA) released by the enzymatic reactionof protease on Suc-Ala-Ala-Pro-Phe-pNA substrate at 37 °C					4. The use is permitted in feed containing the following authorised coccidiostats: diclazuril, nicarbazin, decoquinate, semduramycin sodium, lasalocid sodium, monensin sodium robenidine hydrochloride, maduramicin ammonium, narasin or salinomycin sodium 5. Recommended use in protein-reduced rations.	

(1) 1 U is the amount of protease that liberates 1 micromole of para-nitroaniline (pNA) from the Succinyl-Ala-Ala-Pro-Phe-pNA ($C_{30}H_{36}N_6O_9$) substrate per minute at pH 8,0 and 37 °C.
(2) 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