COMMISSION IMPLEMENTING REGULATION (EU) 2016/1833

of 17 October 2016

concerning the authorisation of a preparation of kidney bean lectins (*Phaseolus vulgaris* lectins) as a feed additive for suckling piglets (holder of authorisation Biolek Sp. z o.o.)

(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 kidney bean lectins (*Phaseolus vulgaris* lectins). 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 kidney bean lectins (*Phaseolus vulgaris* lectins) as a feed additive for suckling piglets to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 29 October 2014 ([2]) and 22 October 2015 ([3]) that, under the proposed conditions of use, the preparation of kidney bean lectins (*Phaseolus vulgaris* lectins) does not have an adverse effect on animal health, human health or the environment. It further concluded that the additive should be considered as a respiratory sensitizer and there is a potential hazard by inhalation exposure. The Authority has also concluded that it can have some potential to improve the performance of the piglets during the post-weaning period. 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 kidney bean lectins (*Phaseolus vulgaris* lectins) 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,

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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2015;13(1):3903.
([3]) EFSA Journal 2015;13(11):4276.

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, 17 October 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
						Units of activity animal/day			
Category of zootechnical additives. Functional group: other zootechnical additives (performance enhancer in weaned piglets)									
4d13	Biolek Sp. z o.o.	Kidney bean lectins	*Additive composition* Preparation of kidney bean lectins (*Phaseolus vulgaris* lectins), having a minimum of activity: 1 280 HAU/g (1) *Characterisation of the active substance* Mixture of phytohaemagglutinin (PHA) isoforms: PHA-E_4, PHA-E_3L, PHA-E_2L_2, PHA-EL_3, PHA-L_4 CAS (PHA-L) 9008-97-3 *Analytical methods* (2) For the quantification of the kidney bean lectin in the additive: Haemagglutination assay	Suckling piglets	14 days	220 HAU	660 HAU	1. In the directions for use of the additive and premixture, indicate the storage temperature and storage life. 2. The additive shall be fed only via a complementary feed to suckling piglets from 10th to 14th day of age with the maximum dose of: — 220 HAU/suckling piglet/day for 3 days or — 660 HAU/suckling piglet (in one day). 3. On the label of the additive, the instructions for use via complementary feed shall be indicated. 4. 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 breathing protection.	7 November 2026

(1) 1 HAU (Haemagglutination Activity Units) is the amount of material (1 mg/ml) in the last dilution giving 50 % agglutination (clumping) of the red blood cells.
(2) Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports