COMMISSION IMPLEMENTING REGULATION (EU) 2020/180

of 7 February 2020

concerning the authorisation of a preparation of *Bacillus subtilis* KCCM 10673P and *Aspergillus oryzae* KCTC 10258BP as a feed additive for all animal species

(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 subtilis* KCCM 10673P and *Aspergillus oryzae* KCTC 10258BP as a feed additive for all animal species. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns the authorisation of a preparation of *Bacillus subtilis* KCCM 10673P and *Aspergillus oryzae* KCTC 10258BP to be used in soybeans, to be classified in the additive category 'technological additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 8 September 2015 ([2]) and 18 September 2018 ([3]) that, under the proposed conditions of use, the preparation of *Bacillus subtilis* KCCM 10673P and *Aspergillus oryzae* KCTC 10258BP does not have an adverse effect on animal health or the environment. However, it also concluded that the additive is considered as a skin and eye irritant and as a skin and respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the additive has the potential to be efficacious to reduce the concentration of oligosaccharides of the raffinose series and trypsin inhibitor in soybeans. 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 subtilis* KCCM 10673P and *Aspergillus oryzae* KCTC 10258BP 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 'technological additives' and to the functional group 'other technological additives', is authorised as an additive in animal nutrition as set out in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2015;13(9):4230.
([3]) EFSA Journal 2018;16(5):5275.

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, 7 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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 of additive/kg of soybeans			
Category of technological additives. Functional group: other technological additives (reduction of anti-nutritional factors in soybean)								
1o01	*Bacillus subtilis* KCCM 10673P *Aspergillus oryzae* KCTC 10258BP	**Additive composition:** Preparation of *Bacillus subtilis* KCCM 10673P and *Aspergillus oryzae* KCTC 10258BP containing respectively a minimum of $1,2 \times 10^8$ CFU/g additive and $2,0 \times 10^8$ CFU/g additive. **Characterisation of the active substance:** Viable cells of *Bacillus subtilis* KCCM 10673P and *Aspergillus oryzae* KCTC 10258BP. **Analytical method** (1) Enumeration of *Bacillus subtilis* KCCM 10673P in the feed additive, premixtures and feedingstuffs: Spread plate method on tryptone soya agar (EN 15784). Identification of *Bacillus subtilis* KCCM 10673P in the feed additive: Pulsed Field Gel Electrophoresis (PFGE). Identification of *Aspergillus oryzae* KCTC 10258BP in the feed additive: Polymerase Chain Reaction (PCR) typing.	All animal species	—	*Bacillus subtilis* $1,2 \times 10^6$ *Aspergillus oryzae* $2,0 \times 10^6$	—	1. In the directions for use of the additive and premixture, indicate the storage conditions. 2. The additive shall only be used in soybeans. 3. 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, eyes and breathing protection.	1 March 2030

(1) 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