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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* DSM 5749 as a feed additive for suckling piglets (holder of authorisation Chr.Hansen A/S)

(Text with EEA relevance)

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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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[2].

(2) The preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive, for pigs for fattening and piglets by Commission Regulation (EC) No 2148/2004[3]. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003. That preparation was authorised for ten years for weaned piglets, pigs for fattening, sows, calves for rearing and turkeys for fattening by Commission Implementing Regulation (EU) No 2017/447[4].

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) as a feed additive for piglets. The application was also for the assessment of this preparation for a new use in water for drinking. The applicant requested that additive to be classified in the additive category ‘zootechnical additives’. That application was

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1 OJ L 268, 18.10.2003, p. 29.

2 Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

3 Commission Regulation (EC) No 2148/2004 of 16 December 2004 concerning the permanent and provisional authorisations of certain additives and the authorisation of new uses of an additive already authorised in feedingstuffs (OJ L 370, 17.12.2004, p. 24).

4 Commission Implementing Regulation (EU) 2017/447 of 14 March 2017 concerning the authorisation of the preparation of Bacillus subtilis (DSM 5750) and Bacillus licheniformis (DSM 5749) as a feed additive for sows, weaned piglets, pigs for fattening, calves for rearing and turkeys for fattening and amending Regulations (EC) No 1453/2004, (EC) No 2148/2004 and (EC) No 600/2005 (holder of authorisation Chr. Hansen A/S) (OJ L 69, 15.3.2017, p. 19).

accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 July 2016[5] that, under the proposed conditions of use, the preparation of *Bacillus subtilis* **(**DSM 5750) and *Bacillus licheniformis* (DSM 5749) does not have an adverse effect on animal health, human health or the environment. The Authority considered that the additive has the potential to improve weight gain in suckling piglets when used in feed or in water for drinking. 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* **(**DSM 5750) and *Bacillus licheniformis* (DSM 5749) 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) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(7) 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
Authorisation

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

Article 2
Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3
Entry into force

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

[5] EFSA Journal 2016; 14(9):4558.

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER