CONCLUSION 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)

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:


(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 sows, piglets, pigs for fattening, calves for rearing and turkeys for fattening. The application in accordance with Article 7 of that Regulation 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 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 (6) 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 performance in piglets, pigs for fattening, sows and calves for rearing in feed and in water for drinking. Concerning the use of the additive on turkeys for fattening, it was concluded that in two studies there was some evidence of a positive effect on growth and feed to gain ratio and in a third one a significant greater weight gain was found in females, but no significant difference in weight gain

in males was detected. 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) However these evidences have been judged a substantial indication of the improvement of zootechnical
parameters of weight gain in addition to the long history of use. Therefore it was considered that the provided
data meet the conditions for the demonstration of the efficacy of the additive for turkeys for fattening to be used
in feed and water for drinking.

(6) 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.

(7) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulations (EC)

(8) 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.

(9) 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**

**Amendment to Regulation (EC) No 1453/2004**

Annex I to Regulation (EC) No 1453/2004 is deleted.

**Article 3**

**Amendment to Regulation (EC) No 2148/2004**

In Annex II to Regulation (EC) No 2148/2004 the entry E 1700 on Bacillus *licheniformis* (DSM 5749) and Bacillus *subtilis*
(DSM 5750) is deleted.

**Article 4**

**Amendment to Regulation (EC) No 600/2005**

In Annex III to Regulation (EC) No 600/2005 the entry E 1700 on Bacillus *licheniformis* (DSM 5749) and Bacillus *subtilis*
(DSM 5750) is deleted.
Article 5

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 4 October 2017 in accordance with the rules applicable before 4 April 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 6

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.

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

Done at Brussels, 14 March 2017.

For the Commission

The President

Jean-Claude JUNCKER
### ANNEX

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
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<tbody>
<tr>
<td>4b1700i Chr. Hansen A/S</td>
<td>Bacillus subtilis (DSM 5750) and Bacillus licheniformis (DSM 5749)</td>
<td>Additive composition</td>
<td>Preparation of Bacillus subtilis (DSM 5750) and Bacillus licheniformis (DSM 5749) containing a minimum of $3.2 \times 10^{10}$ CFU/g of additive (1:1 ratio)</td>
<td>Solid form</td>
<td>Viable spores of Bacillus subtilis (DSM 5750) and Bacillus licheniformis (DSM 5749)</td>
<td>Analytical method (¹)</td>
<td>Identification and enumeration of Bacillus subtilis (DSM 5750) and Bacillus licheniformis (DSM 5749) in the feed additive, premixtures, feedingstuffs and water:</td>
<td>Weaned piglets</td>
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<td>2. The additive may be used in water for drinking.</td>
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<td>3. For use of the additive in water for drinking a homogeneous dispersion of the additive shall be ensured.</td>
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<td>4. For use in weaned piglets up to 35 kg of body weight.</td>
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Category of zootechnical additives. Functional group: gut flora stabilisers
<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content CFU/kg of complete feedingstuff with a moisture content of 12 %</th>
<th>Maximum content CFU/kg of complete feedingstuff with a moisture content of 12 %</th>
<th>Minimum content CFU/l of water for drinking</th>
<th>Maximum content CFU/l of water for drinking</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
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<td>5. 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 and skin protection.</td>
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(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