# COMMISSION IMPLEMENTING REGULATION (EU) 2018/1080

## of 30 July 2018

## concerning the authorisation of the preparation of *Bacillus subtilis* DSM 29784 as a feed additive for minor poultry species for fattening and reared for laying (holder of authorisation Adisseo France SAS)

**(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* DSM 29784. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of *Bacillus subtilis* DSM 29784 as a feed additive for minor poultry species for fattening and reared for laying, to be classified in the additive category 'zootechnical additives'.

(4) The preparation of *Bacillus subtilis* DSM 29784 belonging to the additive category of 'zootechnical additives', was authorised for 10 years as a feed additive for chickens for fattening and chickens reared for laying by Commission Implementing Regulation (EU) 2018/328 ([2]).

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 21 February 2018 ([3]) that, under the proposed conditions of use, the preparation of *Bacillus subtilis* DSM 29784 does not have an adverse effect on animal health, human health and the environment. The Authority also concluded that it can reasonably be assumed that the mode of action for minor poultry species is the same as for major poultry species (chickens for fattening). Consequently, the conclusion on efficacy for chickens for fattening can be extrapolated to minor poultry species for fattening and reared for laying. The Authority did 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.

(6) The assessment of the preparation of *Bacillus subtilis* DSM 29784 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) 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 'gut flora stabilisers', 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]) Commission Implementing Regulation (EU) 2018/328 of 5 March 2018 concerning the authorisation of the preparation of Bacillus subtilis DSM 29784 as a feed additive for chickens for fattening and chickens reared for laying (holder of authorisation Adisseo France SAS) (OJ L 63, 6.3.2018, p. 10).
([3]) *EFSA Journal* 2018; 16(3):5204.

*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, 30 July 2018.

*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/kg of complete feedingstuff with a moisture content of 12 % | | | |
| **Category of zootechnical additives. Functional group: gut flora stabilisers** | | | | | | | | | |
| 4b1829 | Adisseo France SAS | *Bacillus subtilis* DSM 29784 | *Additive composition*<br>Preparation of *Bacillus subtilis* DSM 29784 containing a minimum of $1 \times 10^{10}$ CFU/g of additive.<br>Solid form<br>*Characterisation of the active substance*<br>Viable spores of *Bacillus subtilis* DSM 29784<br>*Analytical method* (1)<br>For the enumeration of *Bacillus subtilis* DSM 29784 in additive, premixture and feedingstuffs:<br>Spread plate method using tryptone soya agar EN 15784<br>For the identification *Bacillus subtilis* DSM 29784: Identification: Pulsed Field Gel Electrophoresis (PFGE) | Minor poultry species for fattening and reared for laying | — | $1 \times 10^8$ | — | 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.<br>2. The use is permitted in feed containing the following authorised coccidiostats: lasalocid A sodium or diclazuril;<br>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their 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, respiratory and eyes protections. | 20.8.2028 |

(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