Commission Implementing Regulation (EU) 2018/347 of 5 March 2018 concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for piglets and sows and amending Regulations (EC) No 1847/2003 and (EC) No 2036/2005 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/347

of 5 March 2018

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(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. 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 *Saccharomyces cerevisiae* CNCM I-1079 was authorised without a time limit as feed additive for piglets by Commission Regulation (EC) No 1847/2003[(3)] and for sows by Commission Regulation (EC) No 2036/2005[(4)]. That additive 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.

(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 *Saccharomyces cerevisiae* CNCM I-1079 as feed additive for sows and piglets. 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 opinions of 20 April 2016 and 4 July 2017[(5)] that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* CNCM I-1079 does not have an adverse effect on animal health, human health or the environment. It also concluded that the additive is efficacious in sows in order to have a benefit in suckling piglets and in weaned piglets

in order to have a significant improvement of feed to gain ratio. 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 *Saccharomyces cerevisiae* CNCM I-1079 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) Regulations (EC) No 1847/2003 and (EC) No 2036/2005 should be amended accordingly.

(7) 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.

(8) 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 1847/2003

Regulation (EC) No 1847/2003 is amended as follows:

(1) Article 2 is deleted;

(2) Annex II is deleted.

Article 3

Amendment to Regulation (EC) No 2036/2005

In Annex I to Regulation (EC) No 2036/2005, entry E1703 is deleted.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/347. (See end of Document for details)*

Article 4

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 29 September 2018 in accordance with the rules applicable before 29 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

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, 5 March 2018.

For the Commission

The President

Jean-Claude JUNCKER