COMMISSION IMPLEMENTING REGULATION (EU) 2020/147

of 3 February 2020

concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for weaned piglets, sows (in order to have a benefit for suckling piglets) and dairy cows and amending Regulations (EC) No 2148/2004, (EC) No 1288/2004 and (EC) No 1811/2005 (holder of authorisation S.I. Lesaffre)

(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) Article 10(2) of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(3) The preparation of *Saccharomyces cerevisiae* CNCM I-4407 (former *Saccharomyces cerevisiae* NCYC Sc 47) was authorised, without a time limit, in accordance with Directive 70/524/EEC as a feed additive for weaned piglets by Commission Regulation (EC) No 2148/2004 ([3]), for sows by Commission Regulation (EC) No 1288/2004 ([4]) and for dairy cows by Commission Regulation (EC) No 1811/2005 ([5]). 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.

(4) In accordance with Article 10(2) of Regulation (EC) No 1831/2003, an application was submitted for the re-evaluation of the preparation of *Saccharomyces cerevisiae* CNCM I-4407 (former *Saccharomyces cerevisiae* NCYC Sc 47) as a feed additive for weaned piglets, sows and dairy cows. 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.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 22 January 2019 ([6]) that, under the proposed conditions of use, the preparation *Saccharomyces cerevisiae* CNCM I-4407 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 parameters in weaned piglets and sows in order to have a benefit in sucking piglets. It also concluded that the additive showed a positive effect on performance in dairy cows in two studies. 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.

(6) Since the additive has already demonstrated the capacity to improve the performance parameters in other dairy ruminants, namely dairy goats, dairy sheep and dairy buffalos, it was considered that the conditions for the demonstration of the efficacy for dairy cows are met by the results of the provided two *in vivo* studies.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (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 Regulation (EC) No 1288/2004 of 14 July 2004 concerning the permanent authorisation of certain additives and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (OJ L 243, 15.7.2004, p. 10).

([5]) Commission Regulation (EC) No 1811/2005 of 4 November 2005 concerning the provisional and permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (OJ L 291, 5.11.2005, p. 12).

([6]) EFSA Journal 2019; 17(3):5600.

(7) The assessment of the preparation of *Saccharomyces cerevisiae* CNCM I-4407 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.

(8) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulations (EC) No 2148/2004, (EC) No 1288/2004 and (EC) No 1811/2005 should be amended accordingly.

(9) 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.

(10) 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.

Article 2

In Annex II to Regulation (EC) No 2148/2004, the entry E 1702 on *Saccharomyces cerevisiae* NCYC Sc 47 is deleted.

Article 3

In Annex I to Regulation (EC) No 1288/2004, the entry E 1702 on *Saccharomyces cerevisiae* NCYC Sc 47 is deleted.

Article 4

In Annex III to Regulation (EC) No 1811/2005, the entry E 1702 on *Saccharomyces cerevisiae* NCYC Sc 47 is deleted.

Article 5

The preparation specified in the Annex and feed containing that preparation which are produced and labelled before 24 August 2020 in accordance with the rules applicable before 24 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 6

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, 3 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

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									
4b1702	S.I. Lesaffre	*Saccharomyces cerevisiae* CNCM I-4407	*Additive composition* Preparation of *Saccharomyces cerevisiae* CNCM I-4407 containing a minimum of 5×10^9 CFU/g of additive Solid form *Characterisation of the active substance* Viable cells of *Saccharomyces cerevisiae* CNCM I-4407 *Analytical method* (1) Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN 15789:2009). Identification: polymerase chain reaction (PCR) method CEN/TS 15790:2008.	Piglets (weaned) Sows Dairy cows	—	5×10^9 4×10^8		1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall be used in feed for sows in order to have a benefit for suckling piglets. 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 breathing protection.	24.2.2030

(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