COMMISSION IMPLEMENTING REGULATION (EU) No 1074/2011

of 24 October 2011

concerning the authorisation of *Saccharomyces cerevisiae* NCYC R-625 as a feed additive for weaned piglets (holder of the authorisation Integro Gida SAN. ve TIC. A.S. represented by RM Associates Ltd)

(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 *Saccharomyces cerevisiae* NCYC R-625. 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 the preparation set out in the Annex as a feed additive for weaned piglets, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 May 2011 ([2]) that *Saccharomyces cerevisiae* NCYC R-625, under the proposed conditions of use, does not have an adverse effect on animal health, human health or the environment, and that this additive has the potential to improve the growth performance in weaned piglets. 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 *Saccharomyces cerevisiae* NCYC R-625 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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

This Regulation shall enter into force on the 20th day following 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, 24 October 2011.

For the Commission
The President
José Manuel BARROSO

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2011; 9 (5):2173.

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									
4b1872	Integro Gida SAN. ve TIC. A.S. represented by RM Associates Ltd	*Saccharomyces cerevisiae* NCYC R-625	*Additive composition* Preparation of *Saccharomyces cerevisiae* NCYC R-625 containing a minimum of 1 x 10^{10} CFU/g additive *Characterisation of the active substance* *Saccharomyces cerevisiae* NCYC R-625 *Method of analysis* (1) Enumeration: pour plate method using yeast extract dextrose chloramphenicol (CGYE) agar (EN 15789) Identification: polymerase chain reaction (PCR)	Piglets (weaned)	—	4 x 10^{10}	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For use in weaned piglets up to approximately 35 kg. 3. For safety: breathing protection shall be used during handling.	14.11.2021

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.asp