# COMMISSION IMPLEMENTING REGULATION (EU) No 81/2012

## of 31 January 2012

## concerning the denial of authorisation of *Lactobacillus pentosus* (DSM 14025) as a feed additive

**(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 or denying such authorisation. Article 10(7) of Regulation (EC) No 1831/2003 provides for the evaluation of substances, micro-organisms and preparations used in the Union as silage additives at the date that Regulation became applicable. Silage additives were not subject to evaluation or authorisation under previous Union legislation.

(2) In accordance with Article 10(1)(b) and Article 10(7) of Regulation (EC) No 1831/2003, the preparation *Lactobacillus pentosus* (DSM 14025) was entered in the Register of feed additives as a silage additive for all animal species.

(3) In accordance with Article 10(2) in conjunction with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of *Lactobacillus pentosus* (DSM 14025) as a feed additive for all animal species, with the request to classify it in the category 'technological additives' and in the functional group 'silage 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 16 November 2011 [2] that *Lactobacillus pentosus* (DSM 14025) is resistant to three antibiotics used in human and veterinary medicine.

(5) The information available does not permit the risk to be excluded that *Lactobacillus pentosus* (DSM 14025) may spread resistance to those antibiotics to micro-organisms. Consequently, it has not been established that *Lactobacillus pentosus* (DSM 14025) does not have an adverse effect on animal health, human health and the environment, when used under the proposed conditions.

(6) The conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are therefore not satisfied. Accordingly, the authorisation of *Lactobacillus pentosus* (DSM 14025) as a feed additive should be denied.

(7) Since further use of *Lactobacillus pentosus* (DSM 14025) as a feed additive may cause a risk to human and animal health, respective products should be withdrawn from the market as soon as possible.

(8) 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*

Authorisation of *Lactobacillus pentosus* (DSM 14025) as an additive in animal nutrition is denied.

*Article 2*

Existing stocks of *Lactobacillus pentosus* (DSM 14025) and premixtures containing it shall be withdrawn from the market as soon as possible and at the latest by 22 April 2012. Silage produced with *Lactobacillus pentosus* (DSM 14025) before the date of entry into force of this Regulation may be used up until stocks are exhausted.

*Article 3*

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

[1] OJ L 268, 18.10.2003, p. 29.
[2] *EFSA Journal* 2011; 9(11):2449.

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

Done at Brussels, 31 January 2012.

*For the Commission*
*The President*
José Manuel BARROSO