

EUROPEAN COMMISSION

> Brussels, XXX SANCO/12806/2013 CIS (POOL/G1/2013/12806/12806-EN CIS.doc) [...](2014) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) No .../..

of XXX

concerning the authorisation of preparations of *Enterococcus faecium* NCIMB 10415, *Enterococcus faecium* DSM 22502, and *Pediococcus acidilactici* CNCM I-3237 as feed additives for all animal species

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No .../..

of XXX

concerning the authorisation of preparations of *Enterococcus faecium* NCIMB 10415, *Enterococcus faecium* DSM 22502, and *Pediococcus acidilactici* CNCM I-3237 as feed additives for all animal species

(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 nutrition¹, 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(7) of Regulation (EC) No 1831/2003 thereof sets out specific provisions for the evaluation of products used in the Union as silage additives at the date that Regulation became applicable.
- (2) In accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003, the preparations of *Enterococcus faecium* NCIMB 10415, *Enterococcus faecium* DSM 22502, and *Pediococcus acidilactici* CNCM I-3237 were entered in the Register of Feed Additives as existing products belonging to the functional group of silage additives, for all animal species.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the authorisation of those preparations as feed additives for all animal species, requesting those additives to be classified in the category 'technological additives' and in the functional group 'silage additives'. Those applications were 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 10 September 2013² and 10 October 2013³ that, under the proposed conditions of use, the use of these microorganisms in the production of silage is presumed safe for livestock species, consumers of products from animals fed the treated silage and for

¹ OJ L 268, 18.10.2003, p. 29.

² *EFSA Journal 2013*; 11(10):3363.

³ *EFSA Journal 2013*; 11(10):3436.

the environment. The Authority also concluded that the preparations of *Enterococcus faecium* NCIMB 10415 and *Enterococcus faecium* DSM 22502 have the potential to improve the production of silage. It was also concluded that *Pediococcus acidilactici* CNCM I-3237 has the potential to improve the production of silage by reducing the pH and increasing preservation of dry matter. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of the preparations concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations should be authorised as specified in the Annex to this Regulation.
- (6) 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.
- (7) 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

The preparations specified in the Annex belonging to the additive category 'technological additives' and to the functional group 'silage additives', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

The preparations specified in the Annex and feed containing them, which are produced and labelled before [6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation - Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3 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,

For the Commission The President José Manuel BARROSO