Commission Implementing Regulation (EU) No 754/2014 of 11 July 2014 concerning the denial of authorisation of Pediococcus pentosaceus (NCIMB 30068) and Pediococcus pentosaceus (NCIMB 30044) as feed additives (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 754/2014

of 11 July 2014

concerning the denial of authorisation of *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044) as feed additives

(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 in conjunction with Article 10(1) to (4) 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(7) of Regulation (EC) No 1831/2003, *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044), formerly *Lactococcus lactis* (NCIMB 30044), were entered in the Register of Feed Additives as 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 *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044) as feed additives for all animal species, with the request to classify them 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 6 March 2014[(2)] that *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044) are resistant to tetracycline, an antibiotic used in human and veterinary medicine.

(5) The information available does not permit the risk to be excluded that *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044) may

spread to other micro-organisms resistance to that antibiotic. Consequently, it has not been established that *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044) do not have an adverse effect on animal health, human health or the environment, when used as feed additives 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 *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044) as feed additives should be denied.

(7) Since further use of *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044) as feed additives may cause a risk to human and animal health, those feed additives should be withdrawn from the market as soon as possible. Taking into account practical reasons, it is, however, necessary to provide interested parties with a time period during which existing stocks of silage produced with those feed additives may be used up.

(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

Denial of authorisation

Authorisation of *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044) as additives in animal nutrition is denied.

Article 2

Transitional measures

1 Existing stocks of *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044) and premixtures containing them shall be withdrawn from the market as soon as possible and at the latest by 30 September 2014.

2 Silage produced with *Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044) or with premixtures containing them before 1 August 2014 may be used up until 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 is binding in its entirety and directly applicable in all Member States.