Commission Implementing Regulation (EU) No 1109/2014 of 20 October 2014 concerning the authorisation of the preparation of Saccharomyces cerevisiae CBS 493.94 as a feed additive for cattle for fattening, minor ruminant species for fattening, dairy cows and minor dairy ruminant species and amending Regulations (EC) No 1288/2004 and (EC) No 1811/2005 (holder of authorisation Alltech France) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1109/2014

of 20 October 2014

concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CBS 493.94 as a feed additive for cattle for fattening, minor ruminant species for fattening, dairy cows and minor dairy ruminant species and amending Regulations (EC) No 1288/2004 and (EC) No 1811/2005 (holder of authorisation Alltech France)

(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) The preparation of *Saccharomyces cerevisiae* CBS 493.94 was authorised in accordance with Directive 70/524/EEC without a time limit as a feed additive for calves and cattle for fattening by Commission Regulation (EC) No 1288/2004[(3)] and for dairy cows by Commission Regulation (EC) No 1811/2005[(4)]. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003. That preparation was authorised for a period of 10 years for horses by Commission Regulation (EC) No 886/2009[(5)].

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 and in conjunction with Article 7 of the same Regulation, an application was submitted for the re-evaluation of the preparation of *Saccharomyces cerevisiae* CBS 493.94 as a feed additive for cattle for fattening, minor ruminant species for fattening, dairy cows and minor dairy ruminant species, requesting 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1109/2014. (See end of Document for details)*

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 8 April 2014[6] that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* CBS 493.94 does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the use of the preparation has the potential to increase milk yield of dairy cows and that its efficacy can be extrapolated to minor dairy ruminant species. The Authority further concluded that the use of the preparation has the potential to improve the production of cattle raised for fattening and that this efficacy can be extrapolated to minor ruminant species raised for fattening. 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 the preparation of *Saccharomyces cerevisiae* CBS 493.94 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.

(6) Regulations (EC) No 1288/2004 and (EC) No 1811/2005 should therefore be amended accordingly.

(7) 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.

(8) 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

Authorisation

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

Amendment to Regulation (EC) No 1288/2004

In Annex I to Regulation (EC) No 1288/2004 the entry on E 1704, *Saccharomyces cerevisiae* CBS 493.94 referring to cattle for fattening, is deleted.

Article 3

Amendment to Regulation (EC) No 1811/2005

In Annex III to Regulation (EC) No 1811/2005 the entry on E 1704, *Saccharomyces cerevisiae* CBS 493.94, is deleted.

Article 4

Transitional measures

The preparation specified in the Annex, and feed containing that preparation, which are produced and labelled before 10 May 2015 in accordance with the rules applicable before 10 November 2014 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

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, 20 October 2014.

For the Commission

The President

José Manuel BARROSO