

COMMISSION IMPLEMENTING REGULATION (EU) No 1334/2013

of 13 December 2013

amending Regulation (EC) No 1290/2008 as regards the name of the holder of the authorisation and as regards the recommended dose of a preparation of *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699)

(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 13(3) thereof,

Whereas:

- (1) Danisco France SAS has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation as regards Commission Regulation (EC) No 1290/2008⁽²⁾.
- (2) The applicant claims that it has transferred the marketing authorisation for the preparation *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699) to Danisco (UK) Ltd and that the latter now owns the marketing rights for this additive.
- (3) The aim of the application is also to enable the marketing of the feed additive with a concentration five times higher than the minimum concentration. In order to ensure that the minimum and maximum contents set out in the Annex to Regulation (EC) No 1290/2008 are respected, the recommended dose per kilogram of complete feedingstuff has to be modified.
- (4) The proposed change of the authorisation holder is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The latter has been authorised on the basis of a European Food

Safety Authority Opinion⁽³⁾. The subsequent request to change the recommended dose is in accordance with this same Opinion and does not entail a new assessment. The European Food Safety Authority was informed of the application.

- (5) In order to adapt to current practice the trade name should be deleted from Regulation (EC) No 1290/2008.
- (6) To allow Danisco (UK) Ltd to exploit its marketing rights it is necessary to change the terms of the respective authorisation.
- (7) Regulation (EC) No 1290/2008 should therefore be amended accordingly.
- (8) Since safety reasons do not require the immediate application of the amendments made by this Regulation to Regulation (EC) No 1290/2008, it is appropriate to provide for a transitional period during which existing stocks may be used up.
- (9) 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

Amendment to Regulation (EC) No 1290/2008

Regulation (EC) No 1290/2008 is amended as follows:

- (1) in the title, the word '(Sorbiflore)' is deleted;

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 1290/2008 of 18 December 2008 concerning the authorisation of a preparation of *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699) (Sorbiflore) as a feed additive (OJ L 340, 19.12.2008, p. 20).

⁽³⁾ Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on a request from the European Commission on the safety and efficacy of the product Sorbiflore, a preparation of *Lactobacillus rhamnosus* and *Lactobacillus farciminis*, as feed additive for piglets. *The EFSA Journal* (2008) 771, 1-13.

(2) the Annex is amended as follows:

- (a) in the second column, the words 'Danisco France SAS' are replaced by 'Danisco (UK) Ltd';
- (b) in the third column, the word '(Sorbiflore)' is deleted;
- (c) in the ninth column, point 2 is replaced as follows:

'2. Recommended dose per kilogram of complete feedingstuff: 5×10^8 FU'.

Article 2

Transitional measures

Existing stocks which have been produced and labelled before 3 January 2014 in accordance with the rules applicable before 3 January 2014 may continue to be placed on the market and used until 3 July 2014.

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.

Done at Brussels, 13 December 2013.

For the Commission
The President
José Manuel BARROSO
