

## COMMISSION IMPLEMENTING REGULATION (EU) No 357/2013

of 18 April 2013

amending Regulation (EC) No 903/2009 and Implementing Regulation (EU) No 373/2011 as regards the minimum content of a preparation of *Clostridium butyricum* (FERM BP-2789) as a feed additive for chickens for fattening and minor avian species (excluding laying birds) (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.)

(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<sup>(1)</sup>, and in particular Article 13(3) thereof,

Whereas:

- (1) The use of a preparation of *Clostridium butyricum* (FERM BP-2789), belonging to the additive category of 'zoo-technical additives', was authorised for 10 years as a feed additive for use on chickens for fattening by Commission Regulation (EC) No 903/2009<sup>(2)</sup> and for minor avian species (excluding laying birds) and for weaned piglets and minor porcine species (weaned) by Commission Implementing Regulation (EU) No 373/2011<sup>(3)</sup>.
- (2) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of the preparation concerned by reducing its minimum content from  $5 \times 10^8$  CFU/kg to  $2,5 \times 10^8$  CFU/kg complete feedingstuff as regards the use on chickens for fattening and minor avian species (excluding laying birds). The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter 'the Authority').
- (3) The Authority concluded in its opinion of 11 December 2012<sup>(4)</sup> that, under the new proposed conditions of use, the preparation concerned shows some potential to improve performance at the requested minimum dose of  $2,5 \times 10^8$  CFU/kg on chickens for fattening and

minor avian species (excluding laying birds). 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.

- (4) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.
- (5) Regulation (EC) No 903/2009 and Implementing Regulation (EU) No 373/2011 should therefore be amended accordingly.
- (6) 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*

In the Annex to Regulation (EC) No 903/2009, in the column 'Minimum content', the words ' $5 \times 10^8$  CFU' are replaced by the words ' $2,5 \times 10^8$ '.

*Article 2*

In the Annex to Implementing Regulation (EU) No 373/2011, in the column 'Minimum content', for minor avian species (excluding laying birds) the words ' $5 \times 10^8$  CFU' are replaced by the words ' $2,5 \times 10^8$ ' and for piglets (weaned) and minor porcine species (weaned) the words ' $2,5 \times 10^8$  CFU' are replaced by the words ' $2,5 \times 10^8$ '.

*Article 3*

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, 18 April 2013.

For the Commission  
The President

José Manuel BARROSO

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> OJ L 256, 29.9.2009, p. 26.

<sup>(3)</sup> OJ L 102, 16.4.2011, p. 10.

<sup>(4)</sup> EFSA Journal 2013; 11(1):3040.