

COMMISSION IMPLEMENTING REGULATION (EU) No 292/2014

of 21 March 2014

concerning the authorisation of a preparation of 6-phytase produced by *Trichoderma reesei* (CBS 126897) as a feed additive for poultry, weaned piglets, pigs for fattening and sows (holder of the authorisation ROAL Oy)

(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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of 6-phytase produced by *Trichoderma reesei* (CBS 126897). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of 6-phytase produced by *Trichoderma reesei* (CBS 126897) as a feed additive for poultry and pigs to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 11 September⁽²⁾ and 9 October 2013⁽³⁾ that, under the proposed conditions of use, the preparation of 6-phytase produced by *Trichoderma reesei* (CBS 126897) does not have an adverse effect on animal health, human health or the

environment, and that it has a potential to improve the phosphorus utilisation, digestibility and bone mineralisation or the performance in chickens and turkeys for fattening. These conclusions can be extended to chickens reared for laying and turkeys reared for breeding. Since the mode of action of the additive can be considered similar in all poultry species, this conclusion can be extrapolated to minor poultry species for fattening or reared for laying or breeding. Furthermore, the Authority concluded that the additive has a potential to increase bone mineralisation, ileal digestibility, phosphorus utilisation and performance of the laying hens. These conclusions can be extrapolated to minor laying poultry species. The Authority also concluded that the additive has the potential to improve the phosphorus digestibility, phosphorus retention or the performance parameters in piglets, pigs for fattening and sows. 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 6-phytase produced by *Trichoderma reesei* (CBS 126897) 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) 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 preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2013; 11(10):3364.

⁽³⁾ EFSA Journal 2013; 11(10):3433.

Article 2

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, 21 March 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX

| Identification number of the additive | Name of the holder of authorisation | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|--|-------------------------------------|--------------------------|---|---------------------------------|-------------|---|-----------------|---|--------------------------------|
| | | | | | | Units of activity/kg of complete feedingstuff with a moisture content of 12 % | | | |
| Category of zootechnical additives. Functional group: digestibility enhancers | | | | | | | | | |
| 4a19 | ROAL Oy | 6-phytase EC 3.1.3.26 | <p><i>Additive composition</i></p> <p>Preparation of 6-phytase produced by <i>Trichoderma reesei</i> (CBS 126897)</p> <p>having a minimum activity of:</p> <p>Liquid and solid form: 5 000 FTU ⁽¹⁾/g</p> <p><i>Characterisation of the active substance</i></p> <p>6-phytase (EC 3.1.3.26)</p> <p>produced by <i>Trichoderma reesei</i> (CBS 126897)</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>Determination of 6-phytase:</p> <p>colorimetric method based on the enzymatic reaction of 6-phytase on phytate: EN ISO 30024.</p> | Poultry other than laying birds | — | 250 FTU | | <p>1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to heating treatment.</p> <p>2. For use in compound feed containing more than 0,23 % phytin-bound phosphorus.</p> <p>3. Recommended Maximum dose:</p> <p>— 2 500 FTU/kg of complete feedingstuff for poultry,</p> <p>— 1 750 FTU/kg of complete feedingstuff for weaned piglets, pigs for fattening and sows.</p> <p>4. For safety: breathing protection, glasses and gloves shall be used during handling.</p> | 11 April 2024 |
| | | | | Laying birds | | 150 FTU | | | |
| | | | | Weaned piglets | | 500 FTU | | | |
| | | | | Pigs for fattening and sows | | 250 FTU | | | |

⁽¹⁾ 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from a sodium phytate substrate at pH 5,5 and 37 °C.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx