# Commission Implementing Regulation (EU) 2016/899 of 8 June 2016 concerning the authorisation of a 6-phytase produced by Trichoderma reesei (ATCC SD-6528) as a feed additive for all poultry species and all porcine species (other than suckling piglets) (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) 2016/899

## of 8 June 2016

## concerning the authorisation of a 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528) as a feed additive for all poultry species and all porcine species (other than suckling piglets) (holder of authorisation **[**[F1]Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.**]**)

(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 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528). 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 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528) as a feed additive for poultry and porcine species to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 22 October 2015[(2)] that, under the proposed conditions of use, a 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528) does not have an adverse effect on animal health, human health or the environment, and that it is efficacious in improving the retention of phosphorus in chickens and turkeys for fattening, laying hens, weaned piglets, pigs for fattening and sows, at the recommended dose. The Authority has also concluded that this conclusion can be extrapolated to minor poultry species and minor porcine species. 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 a 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528) 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 Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

**Textual Amendments**

**F1** Substituted by Commission Implementing Regulation (EU) 2019/221 of 6 February 2019 amending Regulations (EC) No 785/2007, (EC) No 379/2009, (EC) No 1087/2009, (EU) No 9/2010, (EU) No 337/2011 and Implementing Regulations (EU) No 389/2011, (EU) No 528/2011, (EU) No 840/2012, (EU) No 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 as regards the name of the holder of the authorisation and the representative of the holder of the authorisation for certain feed additives (Text with EEA relevance).

*Article 1*

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.

*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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/899. (See end of Document for details)*

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 active substance/kg of complete feedingstuff with a moisture content of 12 %** | | | |
| Category: Zootechnical additives. Functional group: digestibility enhancers. | | | | | | | | | |
| 4a24 | [F1Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.] | 6-phytase EC 3.1.3.26 | *Additive composition*<br>Preparation of 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528) having a minimum activity of 15 000 U[a]/g.<br>Liquid form<br>*Characterisation of the active substance*<br>6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (ATCC SD-6528) | All poultry species<br>All porcine species (other than suckling piglets) | — | 250 U | — | 1. In the directions for use of the additive and premixture the storage conditions and stability to pelleting shall be indicated.<br>2. Maximum recommended dose: 2 000 U/kg feed.<br>3. For users of the additive and premixtures in a feed business, operational procedures | 29 June 2026 |

**a** 1 U 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.

**b** Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports