# Commission Implementing Regulation (EU) No 1138/2014 of 27 October 2014 concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by Talaromyces versatilis sp. nov. IMI CC 378536 as a feed additive for sows (holder of the authorisation Adisseo France S.A.S.) (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) No 1138/2014

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(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) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(2) That application concerns the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 as a feed additive for sows to be classified in the additive category ‘zootechnical additives’.

(3) A preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 was authorised for 10 years for poultry, weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) No 290/2014[(2)].

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 20 May 2014[(3)] that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase EC 3.2.1.8 and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 does not have an adverse effect on animal health, human health or the environment. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the

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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 Authority also determined that the results of the meta-analysis showed that supplementing sows' diets with the additive at the recommended dose resulted in a statistically significant lower body weight loss of the sows during lactation, without affecting the other parameters evaluated. Since the low level of weight reduction, questioned by the Authority because of lack of biological/physiological relevance, was judged a significant zootechnical parameter, it was considered that the provided *in vivo* studies meet the conditions for the demonstration of the efficacy in lactating sows.

(6) The assessment of the preparation of endo-1,4-beta-xylanase EC 3.2.1.8 and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 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.

(7) 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 ‘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.

Done at Brussels, 27 October 2014.

*For the Commission*

*The President*

José Manuel BARROSO

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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** | | | | | | | | | |
| 4a1604i | Adisseo France S.A.S. | Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 | *Additive composition* Preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 having a minimum activity of: — solid form: endo-1,3(4)-beta-glucanase 30 000 VU/g[a] and endo-1,4-beta- | Sows | — | endo-1,3(4)-beta-glucanase 1 500 VU endo-1,4-beta-xylanase 1 100 VU | | 1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.<br>2. For use in sows from one week before farrowing to whole lactation period.<br>3. For safety: breathing protection, | 17 November 2024 |

**a** 1 VU (viscosimetry unit) is the amount of enzyme which hydrolyzes the substrate (barley betaglucan and wheat arabinoxylan, respectively), reducing the viscosity of the solution, to give a change in relative fluidity of 1 (dimensionless unit)/min at 30 °C and pH 5,5.

**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

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| | | | — | xylanase 22 000 VU/g; liquid form: endo-1,3(4)-beta-glucanase activity of 7 500 VU/ml and endo-1,4-beta-xylanase activity of 5 500 VU/ml. *Characterisation of the active substance* endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536. *Analytical method*[b] For the quantification | | | glasses and gloves shall be used during handling. |

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