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**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of XXX**

**amending Implementing Regulations (EU) 2020/1755 and (EU) 2024/1054 as regards the terms of the authorisation of a preparation of *Weizmannia faecalis* DSM 32016 as a feed additive for all poultry species for fattening, reared for breeding and laying and ornamental birds (holder of authorisation: Biochem Zusatzstoffe Handels- und Produktionsges. mbH)**

(Text with EEA relevance)

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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<sup>1</sup>, and in particular Article 13(3) 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 and modifying such authorisation.
- (2) A preparation of *Weizmannia faecalis* DSM 32016 was authorised for a period of 10 years as a feed additive for use in feed for suckling and weaned Suidae piglets, poultry for fattening and ornamental birds by Commission Implementing Regulation (EU) 2020/1755<sup>2</sup> and as a feed additive for use in feed and in water for drinking for all poultry species reared for laying or breeding and for use in water for drinking for all poultry species for fattening, ornamental birds, suckling and weaned Suidae piglets by Commission Implementing Regulation (EU) 2024/1054<sup>3</sup>.
- (3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted on 08 August 2024 for the modification of the terms of the authorisation of the preparation of *Weizmannia faecalis* DSM 32016 as a feed additive for use in feed and in water for drinking for all poultry species for fattening, reared for

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

<sup>2</sup> Commission Implementing Regulation (EU) 2020/1755 of 24 November 2020 concerning the authorisation of a preparation of *Weizmannia faecalis* DSM 32016 as a feed additive for suckling and weaned Suidae piglets, poultry species for fattening and ornamental birds (holder of authorisation Biochem Zusatzstoffe Handels- und Produktionsges. mbH) (OJ L 395, 25.11.2020, pp. 5; ELI: [http://data.europa.eu/eli/reg\\_impl/2020/1755/2024-05-01](http://data.europa.eu/eli/reg_impl/2020/1755/2024-05-01)).

<sup>3</sup> Commission Implementing Regulation (EU) 2024/1054 of 10 April 2024 concerning the authorisation of a preparation of *Weizmannia faecalis* DSM 32016 as a feed additive for use in feed and in water for drinking for all poultry species reared for laying or breeding and for use in water for drinking for all poultry species for fattening, ornamental birds, suckling and weaned Suidae piglets (holder of the authorisation: Biochem Zusatzstoffe Handels- und Produktionsges. mbH), and amending Implementing Regulation (EU) 2020/1755 as regards the terms of the authorisation of that preparation (OJ L, 2024/1054, 11.4.2024, ELI: [http://data.europa.eu/eli/reg\\_impl/2024/1054/oj](http://data.europa.eu/eli/reg_impl/2024/1054/oj)).

breeding and laying and ornamental birds, requesting to allow the simultaneous use of that preparation with the coccidiostat amprolium and a combination of coccidiostats narasin and nicarbazin, which are authorised as feed additives. The request was accompanied by the relevant supporting data.

- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 25 June 2025<sup>4</sup> that the proposed modification in the terms of the authorisation of the preparation of *Weizmannia faecalis* DSM 32016 would not change the conclusions previously drawn regarding the safety of that additive for the target species, consumers and the environment. The Authority also concluded that the preparation of *Weizmannia faecalis* DSM 32016 is not a skin or eye irritant but should be considered a skin and respiratory sensitiser, and inhalation and dermal exposure are considered a risk. It also concluded that the use of that preparation is compatible with the coccidiostat amprolium and the combination of coccidiostats narasin and nicarbazin under the currently authorised conditions of use. The Authority did not consider that there is a need for specific requirements for a post-market monitoring.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinion of 25 May 2020<sup>5</sup> are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005<sup>6</sup>, an evaluation report of the Reference Laboratory was therefore not required.
- (6) In view of the above, the Commission considers that the preparation of *Weizmannia faecalis* DSM 32016 still satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 when modifying the terms of the authorisation laid down in Implementing Regulations (EU) 2020/1755 and (EU) 2024/1054, by specifying the compatibility of the use of that preparation with the coccidiostat amprolium and a combination of coccidiostats narasin and nicarbazin. In addition, considering that those coccidiostats may not be authorised as feed additives for each of the species or categories listed in Annexes I and II, their simultaneous use with the preparation of *Weizmannia faecalis* DSM 32016 should only be possible in accordance with their respective conditions of authorisation as feed additives.
- (7) Implementing Regulations (EU) 2020/1755 and (EU) 2024/1054 should therefore be amended accordingly.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Weizmannia faecalis* DSM 32016 for all poultry species for fattening, reared for breeding and laying and ornamental birds, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the modification of the authorisation concerned.

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<sup>4</sup> EFSA Journal. 2025;23:e9548. <https://doi.org/10.2903/j.efsa.2025.9548>

<sup>5</sup> EFSA Journal 2020;18(6):6158. <https://doi.org/10.2903/j.efsa.2020.6158>

<sup>6</sup> Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

- (9) 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*

#### **Amendment to Implementing Regulation (EU) 2020/1755**

The Annex to Implementing Regulation (EU) 2020/1755 is replaced by Annex I to this Regulation.

#### *Article 2*

#### **Amendment to Implementing Regulation (EU) 2024/1054**

The Annex to Implementing Regulation (EU) 2024/1054 is replaced by Annex II to this Regulation.

#### *Article 3*

#### **Transitional measures**

1. The feed additive *Weizmannia faecalis* DSM 32016, as authorised by Implementing Regulations (EU) 2020/1755 and (EU) 2024/1054 and premixtures containing that additive, which are intended for all poultry species for fattening, reared for breeding and laying and ornamental birds, and which are produced and labelled before [6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for all poultry species for fattening, reared for breeding and laying and ornamental birds, and which are produced and labelled before [12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the stocks concerned are exhausted.

#### *Article 4*

#### **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 shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
Ursula VON DER LEYEN