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

of XXX

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

(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 nutrition¹, and in particular Articles 9(2) and 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 (previously taxonomically identified as *Bacillus coagulans* 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 species for fattening and ornamental birds by Commission Implementing Regulation (EU) 2020/1755².
- (3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, a first application was submitted 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 for suckling and weaned Suidae piglets, poultry species for fattening and ornamental birds, requesting to update the taxonomic identification of the strain and to allow the simultaneous use of that preparation with some other coccidiostats, in addition to halofuginone and diclazuril. A second application was submitted, in accordance with Article 7 of Regulation (EC) No 1831/2003, for the authorisation of new uses of that same preparation as a feed additive for use in feed and in water for drinking for all poultry species reared for laying and reared for breeding, and the recognition of the

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² Commission Implementing Regulation (EU) 2020/1755 of 24 November 2020 concerning the authorisation of a preparation of *Bacillus coagulans* DSM 32016 as a feed additive for suckling and weaned Suidae piglets, poultry for fattening and ornamental birds (holder of authorisation Biochem Zusatzstoffe Handels- und Produktionsges. mbH) (OJ L 395, 25.11.2020, p. 5, ELI: http://data.europa.eu/eli/reg_impl/2020/1755/oj).

compatibility of the use of that preparation with a number of coccidiostats, for use in water for drinking for suckling and weaned Suidae piglets and for all poultry species for fattening and ornamental birds. Both applications requested that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘gut flora stabilisers’. The second application for the authorisation of new uses was accompanied by the relevant supporting data and the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 26 September 2023³ that, under the proposed conditions of use, the preparation of *Weizmannia faecalis* DSM 32016 is safe for the target species, the consumers and the environment. It also concluded that the preparation of *Weizmannia faecalis* DSM 32016 is not a skin/eye irritant but is a respiratory sensitiser. The Authority could not conclude on the skin sensitisation potential of that preparation. The Authority concluded that the preparation is considered to be efficacious in feed for poultry reared for laying or breeding and in water for drinking for poultry species reared for fattening, poultry reared for laying/breeding, ornamental birds and suckling and weaned Suidae piglets. In addition, it indicated that the preparation of *Weizmannia faecalis* DSM 32016 is compatible with the coccidiostats halofuginone, diclazuril, monensin sodium, robenidine hydrochloride, salinomycin sodium a combination of monensin sodium with nicarbazin, but not with narasin or a combination of narasin with nicarbazin, while no conclusions could be drawn on its compatibility with decoquinate, lasalocid A sodium, semduramicin sodium, nicarbazin or amprolium hydrochloride. The Authority did not consider that there is a need for specific requirements of post-market monitoring.
- (5) In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁴, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same additive regarding the methods of analysis are valid and applicable for the current applications.
- (6) On 23 January 2024, the applicant withdrew the application as regards the recognition of the compatibility of use of the preparation of *Weizmannia faecalis* DSM 32016 with the following coccidiostats: narasin, a combination of narasin with nicarbazin, decoquinate, lasalocid A sodium, semduramicin sodium, nicarbazin, amprolium hydrochloride.
- (7) In view of the above, the Commission considers that the preparation of *Weizmannia faecalis* DSM 32016 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for use in feed and in water for drinking for all poultry species reared for laying or breeding, as well as in water for drinking for all poultry species for fattening, ornamental birds and suckling and weaned Suidae piglets. It is appropriate to indicate the compatibility of the use of that preparation with the coccidiostats halofuginone, diclazuril, monensin sodium, robenidine hydrochloride, salinomycin sodium, a combination of monensin sodium with nicarbazin. In addition, the Commission

³ EFSA Journal 2023;21(11):8355.

⁴ 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>).

considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

- (8) The Commission also 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 Regulation (EU) 2020/1755, by specifying the compatibility of use of that preparation with the coccidiostats monensin sodium, robenidine hydrochloride, salinomycin sodium and a combination of monensin sodium with nicarbazin, in addition to halofuginone and diclazuril. In addition, considering that those coccidiostats may not be authorised as feed additives for each of the species or categories listed in Implementing Regulation (EU) 2020/1755, 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. Furthermore, the Commission considers that the taxonomic identification of the strain contained in the preparation authorised by Implementing Regulation (EU) 2020/1755 should be updated, as well as the provision on appropriate protective measures to prevent adverse effects on the health of the users of the additive.
- (9) Implementing Regulation (EU) 2020/1755 should therefore be amended accordingly.
- (10) 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 by Implementing Regulation (EU) 2020/1755, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the modified terms of that authorisation.
- (11) 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 ‘gut flora stabilisers’, is authorised for use in feed and in water for drinking for all poultry species reared for laying or breeding, as well as in water for drinking for all poultry species for fattening, ornamental birds and suckling and weaned Suidae piglets, subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) 2020/1755

Implementing Regulation (EU) 2020/1755 is amended as follows:

- (1) the title is replaced by the following:

‘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)’;

- (2) the Annex is amended as follows:

- (a) in the column ‘Additive’, the expression ‘*Bacillus coagulans* DSM 32016’ is replaced by ‘*Weizmannia faecalis* DSM 32016’.
- (b) in the column ‘Composition, chemical formula, description, analytical method’, and in the sections ‘Additive composition’ and ‘Characterisation of the active substance’ thereof, the expression ‘*Bacillus coagulans* DSM 32016’ is replaced by ‘*Weizmannia faecalis* DSM 32016’;
- (c) in the column ‘other provisions’, points 2 and 3 are replaced by the following:
 - ‘2. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: halofuginone, diclazuril, monensin sodium, robenidine hydrochloride, salinomycin sodium, a combination of monensin sodium with nicarbazin.’
 - 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.’

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are intended for use in feed for suckling and weaned Suidae piglets, poultry species for fattening and ornamental birds, and which are produced and labelled before [6 months after 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 existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are intended for suckling and weaned Suidae piglets, poultry species for fattening and ornamental birds, and which are produced and labelled before [12 months after 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 existing stocks 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