PAFF 09/10/2024

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/4832787/2024 CIS
(POOL/G5/2024/4832787/4832787-EN CIS.docx)
[…](2024) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of *Enterococcus lactis* NCIMB 11181 as a feed additive for calves for rearing and for fattening and weaned piglets (holder of authorisation: Chr. Hansen A/S) and repealing Implementing Regulation (EU) No 797/2013

(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[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 and renewing such an authorisation.

(2) A preparation of *Enterococcus faecium* NCIMB 11181 was authorised for 10 years as a feed additive for calves for rearing and for fattening and weaned piglets by Commission Implementing Regulation (EU) No 797/2013[2].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Enterococcus lactis* NCIMB 11181 as a feed additive, for calves for rearing and for fattening and weaned piglets, requesting the additive to be classified in the category of zootechnical additives and in the functional group of gut flora stabilisers. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 14 November 2023[3] that the preparation of *Enterococcus lactis* NCIMB 11181 (strain originally taxonomically identified as *Enterococcus faecium* and reclassified as *Enterococcus lactis*) remains safe for calves for rearing and for fattening (up to 6 months) and weaned piglets (up to 35 kg), the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of *Enterococcus lactis* NCIMB 11181 in the solid water-soluble formulation 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) No 797/2013 of 21 August 2013 concerning the authorisation of a preparation of Enterococcus faecium NCIMB 11181 as a feed additive for calves for rearing and for fattening and weaned piglets (holder of authorisation Chr. Hansen A/S) and repealing Regulation (EC) No 1333/2004. OJ L 224, 22.8.2013, p. 6. ELI: http://data.europa.eu/eli/reg_impl/2013/797/oj.

[3] *EFSA Journal.* 2023;21:e8466.

additive is considered not irritant to skin or eyes. Due to the proteinaceous nature of the active agent, both solid and solid water-soluble formulations of the additive are considered respiratory sensitisers. The Authority could not conclude on the potential of the solid formulation of the additive to be irritant for skin and eyes or on the potential of both formulations of the additive to cause skin sensitisation. The opinion also indicated that it is not necessary to assess the efficacy of the preparation of *Enterococcus lactis* NCIMB 11181 in the context of the renewal of the authorisation as the application for renewal of the authorisation does not include a proposal to amend or supplement the conditions of the original authorisation that would have an impact on the efficacy of the additive. According to the conclusions of the Authority in its opinion of 1 February 2012[4], the preparation of *Enterococcus lactis* NCIMB 11181 is efficacious in improving zootechnical performance of piglets and calves, with the minimum effective dose for piglets being in the order of 1×10^{10} CFU/kg feed and for calves in the region of 2×10^{9} CFU/kg milk replacer, independently of route of delivery provided that the same dose is given. The Authority did not consider that there is the need for specific requirements of post-market monitoring.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of the preparation of *Enterococcus lactis* NCIMB 11181 as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005[5], an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers that the preparation of *Enterococcus lactis* NCIMB 11181 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that the minimum contents specified in the Annex need to be adjusted to the effective dose of the additive, and that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive. Those protective measures should be without prejudice to other workers' safety requirements under Union law.

(7) As a consequence of the renewal of the authorisation of the preparation of *Enterococcus lactis* NCIMB 11181 as a feed additive, Implementing Regulation (EU) No 797/2013 should be repealed.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Enterococcus lactis* NCIMB 11181, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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4 *EFSA Journal* 2012;10(2):2574.

5 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).

HAS ADOPTED THIS REGULATION:

Article 1
Renewal of authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is renewed subject to the conditions laid down in that Annex.

Article 2
Repeal

Implementing Regulation (EU) No 797/2013 is repealed.

Article 3
Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, 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 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