



EUROPEAN
COMMISSION

PAFF 01-02/12/2025

Brussels, **XXX**
SANTE/5901147/2025 CIS
(POOL/G5/2025/5901147/5901147-EN
CIS.docx)
[...](2025) **XXX** draft

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

of **XXX**

concerning the authorisation of a preparation of *Duddingtonia flagrans* NCIMB 30336 as a feed additive for grazing animals of bovine, ovine and caprine species other than for milk production, and for grazing animals of camelids, cervids, equines, porcine species and rabbits (holder of authorisation: International Animal Health Products Pty Ltd, represented by GAB Consulting GmbH)

(Text with EEA relevance)

EN

EN

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

of **XXX**

concerning the authorisation of a preparation of *Duddingtonia flagrans* NCIMB 30336 as a feed additive for grazing animals of bovine, ovine and caprine species other than for milk production, and for grazing animals of camelids, cervids, equines, porcine species and rabbits (holder of authorisation: International Animal Health Products Pty Ltd, represented in the Union by GAB Consulting GmbH)

(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 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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Duddingtonia flagrans* NCIMB 30336. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of *Duddingtonia flagrans* NCIMB 30336 as a feed additive for all grazing animals, requesting that additive to be classified in the category ‘zootechnical additives’, in the functional group ‘other zootechnical additives’.
- (4) Commission Implementing Regulation (EU) 2024/1723² authorised the preparation of *Duddingtonia flagrans* NCIMB 30336 as a feed additive for grazing animals for milk production of bovine species, sheep, and goats since, due to the lack of data, the European Food Safety Authority (‘the Authority’) could not conclude on the safety of the additive for other grazing animal species and categories in its opinions of 2 July 2020³ and 14 November 2023⁴.

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

² Commission Implementing Regulation (EU) 2024/1723 of 20 June 2024 concerning the authorisation of a preparation of *Duddingtonia flagrans* NCIMB 30336 as a feed additive for grazing animals for milk production of bovine species, sheep and goats (holder of authorisation: International Animal Health Products Pty Ltd, represented by GAB Consulting GmbH) (OJ L, 2024/1723, 21.6.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/1723/oj).

³ EFSA Journal. 2020;18(7):6208, <https://doi.org/10.2903/j.efsa.2020.6208>.

⁴ EFSA Journal. 2023;21:e8465, <https://doi.org/10.2903/j.efsa.2023.8465>.

(5) Therefore, only the use of that preparation as a feed additive for all grazing animals other than grazing animals for milk production of bovine species, sheep, and goats remains to be addressed in that application.

(6) The Authority concluded in its opinions of 2 July 2020 and 20 March 2025⁵ that, under the proposed conditions of use, the preparation of *Duddingtonia flagrans* NCIMB 30336 is safe for all grazing bovines, ovines, caprines, rabbits, horses, cervids, camelids and porcine species, as well as for consumers and the environment. The Authority considered that the preparation of *Duddingtonia flagrans* NCIMB 30336 is not irritant to skin and eyes but is irritant to the respiratory tract and is a respiratory sensitiser, while no conclusion could be drawn on its skin sensitisation potential. The Authority further concluded that the preparation of *Duddingtonia flagrans* NCIMB 30336 can reduce the number of parasitic nematodes on pasture to the benefit of grazing animals, when used at the recommended application rate of 3×10^4 chlamydospores/kg body weight and per day. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) On 18 June 2025, the applicant withdrew the application for the authorisation of the preparation for all grazing animals other than bovines, ovines, caprines, camelids, cervids, equines, porcine species and rabbits.

(8) In view of the above, the Commission considers that the preparation of *Duddingtonia flagrans* NCIMB 30336 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for grazing animals of bovine, ovine and caprine species other than for milk production, and for grazing animals of camelid species, cervid species, horses, porcine species and rabbits. Considering the conclusion of the Authority on the safety of the preparation of *Duddingtonia flagrans* NCIMB 30336 for grazing horses and taking into account that interspecies extrapolation of data can be applied between physiologically similar species⁶, the Commission considers that the authorisation of that preparation should be extended to grazing equines. In addition, it is appropriate, for practical and control reasons, to express the dosage of the preparation per kilogram of complete feedingstuff and to provide for the additive to be used only in feed for grazing animals. Finally, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

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

⁵ EFSA Journal. 2025;23:e9366, <https://doi.org/10.2903/j.efsa.2025.9366>.

⁶ As set out in the Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021, <https://doi.org/10.2903/j.efsa.2017.5021>.

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 ‘other zootechnical additives’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
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