EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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)

(Text with EEA relevance)

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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 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 as a feed additive. 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) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 2 July 2020[2] and 14 November 2023[3] that, the preparation of *Duddingtonia flagrans* NCIMB 30336 is safe for all dairy bovines, ovines and caprines, consumers and the environment under the proposed conditions of use with a margin of safety of 10. Due to the lack of data, it could not conclude on the safety of the additive for other grazing species/categories. 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 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 x 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

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/.
[2] EFSA Journal. 2020;18(7):6208.
[3] EFSA Journal. 2023;21:e8466.

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.

(5) 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 dairy cows, dairy cows of minor bovine species, dairy sheep and dairy goats, while the assessment process continues for grazing animals other than dairy cows, dairy cows of minor bovine species, dairy sheep and dairy goats. 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 dairy cows, dairy cows of minor bovine species, dairy sheep and dairy goats. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(6) 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 ‘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