

Brussels, XXX SANTE/5445403/2023 CIS (POOL/G5/2023/5445403/5445403-EN CIS.docx) [...](2024) XXX draft

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

of XXX

concerning the authorisation of a preparation of rosemary extract as a feed additive for cats and dogs

(Text with EEA relevance)

EN EN

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

of XXX

concerning the authorisation of a preparation of rosemary extract as a feed additive for cats and dogs

(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 rosemary extract obtained from dried leaves of *Rosmarinus officinalis* L., by acetone or ethanol extraction. 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 rosemary extract as a feed additive for cats and dogs, requesting that additive to be classified in the category 'technological additives' and in the functional group 'antioxidants'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 November 2021² that, under the proposed conditions of use, the preparation of rosemary extract obtained from dried leaves of *Rosmarinus officinalis* L., by acetone or ethanol extraction, is safe up to the maximum use levels of 300 mg/kg and 50 mg/kg complete feed for dogs and cats, respectively (that corresponds to a concentration of carnosic acid of 34 and 5 mg/kg respectively). It also concluded that the preparation should be considered as irritant to skin and eyes, but it could not conclude on its potential to be skin sensitiser. It considered that exposure through inhalation is unlikely. Since rosemary extract is used as a food additive, and its function in feed would be essentially the same as that in food, the Authority concluded that no further demonstration of efficacy is considered necessary. The Authority also verified the report on the method 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 rosemary extract satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. In addition,

-

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

² EFSA Journal 2022;20(1):6978.

- 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

The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'antioxidants', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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