

Brussels, **XXX**
SANTE/5408667/2023 CIS
(POOL/G5/2023/5408667/5408667-EN
CIS.docx)
[...](2026) **XXX** draft

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

of **XXX**

**concerning the authorisation of nutmeg essential oil from *Myristica fragrans* Houtt. as a
feed additive for all animal species**

(Text with EEA relevance)

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

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concerning the authorisation of nutmeg essential oil from *Myristica fragrans* Houtt. as a feed additive for all animal species

(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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC².
- (2) The substance nutmeg essential oil from *Myristica fragrans* Houtt. was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. This substance was subsequently entered in the Register of Feed Additives as an existing product, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of nutmeg essential oil from *Myristica fragrans* Houtt. as a feed additive for all animal species, requesting the additive to be classified in the additive category ‘sensory additives’ and in the functional group ‘flavouring compounds’. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The applicant requested the additive to be authorised also for use in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of ‘flavouring compounds’ for use in water for drinking. Therefore, the use of this additive in water for drinking should not be allowed.
- (5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 12 May 2023³ that nutmeg essential oil from *Myristica fragrans* Houtt. is considered to be of no safety concern for target short-living animals and very unlikely to induce adverse effects for long-living and reproductive animals and any other animal species

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

² Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

³ EFSA Journal, 21(6): 8066. <https://doi.org/10.2903/j.efsa.2023.8066>.

at certain maximum concentrations, further specified in that opinion for each animal species. Furthermore, it concluded that no concern for consumer safety was identified from the use of nutmeg essential oil from *Myristica fragrans* Houtt., up to the highest proposed use level in feed. The Authority concluded that the use of nutmeg essential oil from *Myristica fragrans* Houtt. under the proposed conditions is not expected to pose a risk to the environment and that nutmeg essential oil from *Myristica fragrans* Houtt. should be considered as an irritant to skin and eyes, and as a skin and respiratory sensitiser. It also stated that, based on the presence of safrole $\geq 0,1\%$, nutmeg essential oil from *Myristica fragrans* Houtt. is classified as carcinogen (category 1B) and exposure by any route should be minimised. The Authority further concluded that since nutmeg essential oil from *Myristica fragrans* Houtt. is recognised to flavour food and its function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary. It 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.

- (6) In view of the above, the Commission considers that nutmeg essential oil from *Myristica fragrans* Houtt. satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation. The Commission considers that the presence of myristicin, safrole, elemicin and methyleugenol, substances of concern belonging to *p*-allylalkoxybenzenes group, in nutmeg essential oil from *Myristica fragrans* Houtt. requires the setting of a maximum content of this feed additive in complete feed. Furthermore, the Commission considers that nutmeg essential oil from *Myristica fragrans* Houtt. should not be used in combination with other feed additives containing the same substances of concern and that the simultaneous use of nutmeg essential oil from *Myristica fragrans* Houtt. with other feed additives is permitted provided that the combined content of *p*-allylalkoxybenzenes (methyleugenol, estragole, elemicin, safrole, myristicin, dillapiol, and apiole) in feed materials and compound feed remains below the content that would result from using the authorised feed additive with the highest content of those substances at its maximum or recommended maximum content for the relevant species or animal category. 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.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) 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 substance specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘flavouring compounds’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The feed additive nutmeg essential oil from *Myristica fragrans* Houtt., as authorised pursuant to Directive 70/524/EEC and premixtures containing this additive, which are produced and labelled before [6 months from 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 stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before [12 months from 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 stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before [24 months from 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 stocks concerned are exhausted if they are intended for non-food producing animals.

Article 3

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