



EUROPEAN
COMMISSION

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

of **XXX**

**concerning the denial of the renewal of the authorisation of a preparation containing a
smoke flavouring extract-2b0001 as a feed additive for dogs and cats and repealing
Implementing Regulation (EU) No 1076/2014.**

(Text with EEA relevance)

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

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concerning the denial of the renewal of the authorisation of a preparation containing a smoke flavouring extract-2b0001 as a feed additive for dogs and cats and repealing Implementing Regulation (EU) No 1076/2014

(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 or denying such an authorisation.
- (2) A preparation containing a smoke flavouring extract-2b0001 was authorised for 10 years as a feed additive for dogs and cats by Commission Implementing Regulation (EU) No 1076/2014².
- (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 containing a smoke flavouring extract-2b0001 as a feed additive for dogs and cats, requesting that additive to be classified in the additive category 'sensory additives' and the functional group 'flavouring compounds'. That application included a proposal for amending the conditions of the original authorisation, by changing the specifications. The change consists of a reduction of the level of carbonyl compounds and a reduction of the minimum level of phenols. According to the applicant, the difference in the concentration range of carbonyl compounds is not due to changes in the manufacturing process of the additive but is related to differences in the performance of the analyses that are based on the reaction of carbonyls with hydroxylamine. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) As provided for by Article 5(1) of Regulation (EC) No 1831/2003, it is for the applicant of an authorisation of a feed additive to adequately and sufficiently demonstrate, in accordance with the implementing rules referred to in Article 7 of that Regulation, that the conditions for authorisation set out in Article 5(2) and (3) of that

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 1076/2014 of 13 October 2014 concerning the authorisation of a preparation containing a smoke flavouring extract-2b0001 as feed additive for dogs and cats (OJ L 296, 14.10.2014, p. 19), ELI: http://data.europa.eu/eli/reg_impl/2014/1076/oj.

Regulation are satisfied. As regards applications for the renewal of an authorisation, Regulation (EC) No 429/2008³ requires, in particular, that the applicant presents evidence that, in the light of the current scientific knowledge, the additive remains safe under the approved conditions for target species, consumers, workers and the environment.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 September 2024⁴ that the applicant has provided data which showed that the additive currently on the market does not fully comply with the specifications of the current authorisation. The Authority noted that there are discrepancies between the analytical data on the volatile components submitted for the renewal of the additive and the data provided by the applicant at the time of the previous assessment. In addition, the Authority was not in the position to conclusively comment on the new proposed specifications and the composition of the additive because no new analytical data were submitted and evaluated. The Authority was not in the position to conclude on the safety of the additive for cats and dogs considering that it contains benzofuran and styrene, which are substances of potential concern for genotoxicity, and that the whole mixture raises a potential concern for genotoxicity. In this regard, the Authority stated in its opinion that it agrees with a similar outcome of the genotoxicity assessment made by the Authority's Panel on Food Additives and Flavourings⁵ concerning the use in food of the same smoke flavouring extract - and based on the same genotoxicity dataset - as the one contained in the preparation being the subject of the opinion of 18 September 2024, which was based notably on an updated approach followed by the Authority concerning the evaluation of the genotoxicity of chemical mixtures. The Authority also concluded that the additive should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser. It further concluded that uncertainty remains on the genotoxic potential of benzofuran and styrene and of individual substances present in the unidentified volatile and non-volatile fractions of the mixture and that therefore, when handling the additive, exposure of unprotected users to potential genotoxic substances may occur, which requires that to reduce the risk the exposure of the users should be minimised.

(6) It derives from the Authority's opinion of 18 September 2024 that the applicant has not adequately and sufficiently demonstrated that smoke flavouring extract-2b0001 remains safe for cats and dogs.

(7) In view of the above, the preparation containing a smoke flavouring extract-2b0001 does not satisfy the conditions for the renewal of the authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. As regards the use in food of the same smoke flavouring extract, the renewal of the authorisation of this product has been refused by Commission Implementing Decision (EU) 2024/2072⁶, taking account of

³ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives.(OJ L 133, 22.5.2008, p. 1), ELI: <http://data.europa.eu/eli/reg/2008/429/oj>.

⁴ EFSA Journal, 22(10), e9030. <https://doi.org/10.2903/j.efsa.2024.9030>

⁵ Scientific opinion adopted on 28 September 2023 on the renewal of the authorisation of Scansmoke SEF7525 (SF-004) as a smoke flavouring Primary Product. EFSA Journal, 21(11), 1-50. <https://doi.org/10.2903/j.efsa.2023.8366>.

⁶ Commission Implementing Decision (EU) 2024/2072 of 31 July 2024 refusing the renewal of the authorisation of Scansmoke SEF 7525 (SF-004) as a smoke flavouring primary product (*notified under*

the Authority's opinion of 28 September 2023. As regards the use of the preparation containing a smoke flavouring extract-2b0001 as a feed additive, it is intended for long-living animals and therefore the potential concern for genotoxicity identified by the Authority in its opinion of 18 September 2024 is even more relevant. First, long living animals are more exposed to the mutagenic substances that may produce genetic alterations with serious health effects even at low exposure levels. Second, the exposure of the target long-living animals to the additive is expected to be higher than the exposure of consumers thereto in food products, due to a generally less varied diet of cats and dogs over their whole life or longer periods of life, while consumers of various food products would be exposed to this additive only occasionally. Accordingly, the renewal of the authorisation of the preparation containing a smoke flavouring extract-2b0001 belonging to the category 'sensory additives' and the functional group 'flavouring compounds' for use for dogs and cats should be denied.

- (8) Therefore, the preparation containing a smoke flavouring extract-2b0001 as a feed additive and feed containing it should be withdrawn from the market as soon as possible as far as the use for dogs and cats is concerned. However, a limited period should be allowed for the withdrawal from the market of the existing stocks of those products, in order to enable operators to comply properly with the withdrawal obligation.
- (9) As a consequence of the denial of the renewal of the authorisation of the preparation containing a smoke flavouring extract-2b0001 as a feed additive for dogs and cats, Implementing Regulation (EU) No 1076/2014 should be repealed.
- (10) 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

Denial of renewal of the authorisation

The renewal of the authorisation of the preparation containing a smoke flavouring extract-2b0001 as an additive in animal nutrition, belonging to the category 'sensory additives' and the functional group 'flavouring compounds', for use for dogs and cats, is denied.

Article 2

Repeal of Implementing Regulation (EU) No 1076/2014

Implementing Regulation (EU) No 1076/2014 is repealed.

Article 3

Withdrawal from the market

document C(2024) 3704). (OJ L, 2024/2072, 1.8.2024,
ELI:http://data.europa.eu/eli/dec_impl/2024/2072/obj).

1. Existing stocks of the additive referred to in Article 1, which are intended for dogs and cats, and of premixtures containing it, shall be withdrawn from the market by *[3 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*
2. Feed materials and compound feed which have been produced with the additive or the premixtures referred to in paragraph 1 before *[3 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*, and which are intended for dogs and cats, shall be withdrawn from the market by *[6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.

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*