



2024/2069

1.8.2024

**COMMISSION IMPLEMENTING DECISION (EU) 2024/2069**

**of 31 July 2024**

**refusing the renewal of the authorisation of ProFagus-Smoke R709 (SF-008) as a smoke flavouring primary product**

*(notified under document C(2024) 3707)*

**(Only the German text is authentic)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods <sup>(1)</sup>, and in particular Article 12(3) thereof,

Whereas:

- (1) Regulation (EC) No 2065/2003 provides that only smoke flavourings included in the Union list of authorised smoke flavouring primary products ('the Union list') may be placed on the market within the Union.
- (2) Commission Implementing Regulation (EU) No 1321/2013 <sup>(2)</sup> established the Union list. ProFagus-Smoke R709 (SF-008) was included in that list with expiry date of the authorisation 1 January 2024.
- (3) On 30 June 2022, the company ProFagus GmbH submitted an application for the renewal of the authorisation of ProFagus-Smoke R709 (SF-008) as a smoke flavouring primary product.
- (4) On 28 September 2023, the European Food Safety Authority ('the Authority') adopted its scientific opinion on the safety of ProFagus-Smoke R709 (SF-008) <sup>(3)</sup>.
- (5) In its scientific opinion, the Authority noted that ProFagus-Smoke R709 (SF-008) contains the substance furan-2 (5H)-one and concluded that a concern for genotoxicity for this substance was identified *in vivo* upon oral administration. In line with the Authority's statement on the genotoxicity assessment of chemical mixtures <sup>(4)</sup> and considering that the exposure estimates for this component are above the threshold of toxicological concern (TTC) of 0,0025 µg/kg bw per day for DNA-reactive mutagens and/or carcinogens, the Authority concluded that ProFagus-Smoke R709 (SF-008) raises concern with respect to genotoxicity. Furthermore, the Authority concluded that other three components in ProFagus-Smoke R709 (SF-008) and the unidentified part thereof raise a potential concern for genotoxicity.

<sup>(1)</sup> OJ L 309, 26.11.2003, p. 1, ELI: <http://data.europa.eu/eli/reg/2003/2065/oj>.

<sup>(2)</sup> Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings (OJ L 333, 12.12.2013, p. 54, ELI: [http://data.europa.eu/eli/reg\\_impl/2013/1321/oj](http://data.europa.eu/eli/reg_impl/2013/1321/oj)).

<sup>(3)</sup> EFSA (2023). Scientific opinion on the renewal of the authorisation of proFagus Smoke R709 (SF-008) as a smoke flavouring Primary Product. *EFSA Journal*, 21(11), <https://doi.org/10.2903/j.efsa.2023.8369>.

<sup>(4)</sup> EFSA (2019). EFSA Journal 2019;17(1):5519, 11 pp. <https://doi.org/10.2903/j.efsa.2019.5519>.

- (6) Pursuant to Article 4 of Regulation (EC) No 2065/2003, only smoke flavourings that do not present risks to human health may be authorised and placed on the market. It is therefore appropriate to refuse the renewal of the authorisation of ProFagus-Smoke R709 (SF-008) as a smoke flavouring primary product.
- (7) However, in order to allow food business operators to use ProFagus-Smoke R709 (SF-008) as a smoke flavouring primary product for the production of foods to be placed on the market until 1 July 2029, as provided for in Commission Implementing Regulation (EU) 2024/2067 <sup>(5)</sup>, ProFagus-Smoke R709 (SF-008) should be allowed to be placed on the market until that date.
- (8) The measures provided for in this Decision are in accordance with the opinion of the standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

*Article 1*

The renewal of the authorisation of ProFagus-Smoke R709 (SF-008) as a smoke flavouring primary product is refused.

*Article 2*

ProFagus-Smoke R709 (SF-008) may continue to be placed on the market until 1 July 2029.

*Article 3*

This Decision is addressed to ProFagus GmbH, Strategic Projects, Us larer Straße 30, 37194 Bodenfelde, Germany.

Done at Brussels, 31 July 2024.

*For the Commission*  
Stella KYRIAKIDES  
*Member of the Commission*

---

<sup>(5)</sup> Commission Implementing Regulation (EU) 2024/2067 of 31 July 2024 amending Implementing Regulation (EU) No 1321/2013 as regards the deletion of entries SF-001 to SF-010 from the Union list of authorised smoke flavouring primary products (OJ L, 2024/2067, 1.8.2024, ELI: [http://data.europa.eu/eli/reg\\_impl/2024/2067/oj](http://data.europa.eu/eli/reg_impl/2024/2067/oj)).