



2024/2077

1.8.2024

**COMMISSION IMPLEMENTING DECISION (EU) 2024/2077**

**of 31 July 2024**

**refusing the renewal of the authorisation of Fumokomp (SF-009) as a smoke flavouring primary product**

*(notified under document C(2024) 3708)*

**(Only the Hungarian 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. Fumokomp (SF-009) was included in that list with expiry date of the authorisation 1 January 2024.
- (3) On 27 June 2022, the company Kompozíció Kft submitted an application for the renewal of the authorisation of Fumokomp (SF-009) 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 Fumokomp (SF-009) <sup>(3)</sup>.
- (5) In its scientific opinion, the Authority noted that the absence of the genotoxic substance furan-2(5H)-one from Fumokomp (SF-009) was not convincingly demonstrated and that the whole mixture testing in an *in vitro* mouse lymphoma assay gave positive results which would require an adequate *in vivo* follow-up study. In addition, the Authority considered that the potential for aneugenicity of Fumokomp (SF-009) had not been adequately investigated. Accordingly, the Authority concluded that the potential safety concern for genotoxicity of Fumokomp (SF-009) cannot be ruled out.
- (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 Fumokomp (SF-009) as a smoke flavouring primary product.

<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 Fumokomp (SF-009) as a smoke flavouring Primary Product. EFSA Journal, 21(11), <https://doi.org/10.2903/j.efsa.2023.8370>.

- (7) However, in order to allow food business operators to use Fumokomp (SF-009) 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>(4)</sup>, Fumokomp (SF-009) 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 Fumokomp (SF-009) as a smoke flavouring primary product is refused.

*Article 2*

Fumokomp (SF-009) may continue to be placed on the market until 1 July 2029.

*Article 3*

This Decision is addressed to Kompozíció Kft, 2053 Herceghalom, Hungary.

Done at Brussels, 31 July 2024.

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

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<sup>(4)</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))