



2024/2078

1.8.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/2078

of 31 July 2024

refusing the renewal of the authorisation of SmokEz Enviro-23 (SF-006) as a smoke flavouring primary product

(notified under document C(2024) 3706)

(Only the English 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 ⁽¹⁾, 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 ⁽²⁾ established the Union list. SmokEz Enviro-23 (SF-006) was included in that list with expiry date of the authorisation 1 January 2024.
- (3) By letter dated 27 June 2022, Kerry Inc. informed the Commission that it had acquired the assets of Red Arrow Products Company LLC and that it now owns the rights for SmokEz Enviro-23 (SF-006).
- (4) On 30 June 2022, the company Kerry Inc submitted an application for the renewal of the authorisation of SmokEz Enviro-23 (SF-006) as a smoke flavouring primary product.
- (5) On 28 September 2023, the European Food Safety Authority ('the Authority') adopted its scientific opinion on the safety of SmokEz Enviro-23 (SF-006) ⁽³⁾.
- (6) In its scientific opinion, the Authority noted that SmokEz Enviro-23 (SF-006) contains the substances furan-2(5H)-one and benzene-1,2-diol and concluded that a concern for genotoxicity for those substances was identified *in vivo* upon oral administration. In line with the Authority's statement on the genotoxicity assessment of chemical mixtures ⁽⁴⁾ and considering that the exposure estimates for those two components 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 SmokEz Enviro-23 (SF-006) raises concern with respect to genotoxicity. Furthermore, the Authority concluded that other four components in SmokEz Enviro-23 (SF-006) and the unidentified part thereof raise a potential concern for genotoxicity.

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

⁽²⁾ 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).

⁽³⁾ EFSA (2023). Scientific opinion on the renewal of the authorisation of SmokEz Enviro-23 (SF-006) as a smoke flavouring Primary Product. EFSA Journal, 21(11), <https://doi.org/10.2903/j.efsa.2023.8368>

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

- (7) 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 SmokEz Enviro-23 (SF-006) as a smoke flavouring primary product.
- (8) However, in order to allow food business operators to use SmokEz Enviro-23 (SF-006) 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 ⁽³⁾, SmokEz Enviro-23 (SF-006) should be allowed to be placed on the market until that date.
- (9) 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 SmokEz Enviro-23 (SF-006) as a smoke flavouring primary product is refused.

Article 2

SmokEz Enviro-23 (SF-006) may continue to be placed on the market until 1 July 2029.

Article 3

This Decision is addressed to Kerry Inc, Global Technology and Innovation Centre, 3400 Milington Road, Beloit, WI 53511, United States.

Done at Brussels, 31 July 2024.

For the Commission
Stella KYRIAKIDES
Member of the Commission

⁽³⁾ 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).