



EUROPEAN
COMMISSION

Brussels, **XXX**
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[...] (2023) **XXX** draft

COMMISSION IMPLEMENTING DECISION

of **XXX**

**refusing the authorisation for the inclusion of Prosmoke BW 01 in the Union list of
authorised smoke flavouring primary products**

(Only the Hungarian text is authentic)

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refusing the authorisation for the inclusion of Prosmoke BW 01 in the Union list of authorised smoke flavouring primary products

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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 to be used in or on foods¹, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 2065/2003 provides that only smoke flavourings authorised and included in the Union list of authorised smoke flavouring primary products ('the Union list') may be placed on the market within the Union.
- (2) Pursuant to Article 6 of Regulation (EC) No 2065/2003, Commission Implementing Regulation (EU) No 1321/2013² has established the Union list.
- (3) On 20 June 2019, the company 'M Profood Zrt.' ('the applicant') submitted an application to the Hungarian competent Authority (Ministry of Agriculture/Department of Food Economy and Origin Protection) in accordance with Article 7 of Regulation (EC) No 2065/2003 to place 'Prosmoke BW 01' on the Union market as a smoke flavouring primary product.
- (4) On 2 July 2019, the Hungarian Ministry of Agriculture requested the European Food Safety Authority ('the Authority') to carry out an assessment of Prosmoke BW 01 as a smoke flavouring primary product.
- (5) On 31 March 2022, the Authority adopted its scientific opinion on the safety of Prosmoke BW 01³ in accordance with Article 8 of Regulation (EC) No 2065/2003.
- (6) In its scientific opinion, the Authority noted that furan-2(5H)-one was present in all batches of the primary product. That substance was evaluated by the Authority as genotoxic in vivo after oral exposure. The Authority considered that the genotoxicity studies available on the whole mixture were not adequate to support the safety assessment of Prosmoke BW 01, due to limitations in those studies and because they were performed with a batch which may not be representative for the material of commerce. Moreover, considering that the exposure estimates for furan-2(5H)-one are

¹ OJ L309, 26.11.2003, p. 1.

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).

³ EFSA Journal 2022;20(5):7299.

above the 'Threshold of Toxicological Concern' (TTC) value of 0.0025 µg/kg bw per day for DNA-reactive mutagens and/or carcinogens, the Authority concluded that Prosmoke BW 01 raises a concern with respect to genotoxicity.

- (7) It is therefore appropriate to refuse the authorisation for the inclusion of Prosmoke BW 01 in the Union list.
- (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 authorisation for the placing on the market within the Union of Prosmoke BW 01 as a smoke flavouring is refused.

Article 2

This Decision is addressed to 'M Profood Zrt.', Laskó u. 1., H-7622 Pécs, Hungary.

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission