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

**of XXX**

### **authorising the placing on the market of magnesium potassium trichloride hexahydrate as a novel food and amending Implementing Regulation (EU) 2017/2470**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001<sup>1</sup>, and in particular Article 12(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470<sup>2</sup> has established a Union list of novel foods.
- (3) On 21 December 2018, the company BK Guilini GmbH, member of ICL Group, ('the applicant'), submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place magnesium potassium trichloride hexahydrate on the Union market as a novel food. The applicant requested the novel food to be used as a salt substitute in leavened bread or similar, raw cured meat, cooked cured or seasoned meat, preserved or partly preserved sausages, as well as in deep-frozen pizza dishes.
- (4) On 11 September 2019, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of magnesium potassium trichloride hexahydrate as a novel food.

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<sup>1</sup> OJ L 327, 11.12.2015, p. 1.

<sup>2</sup> Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

- (5) During the assessment, on 19 April 2023, the applicant made a request for the protection of proprietary scientific studies and data submitted in support of the application, namely on the compositional data<sup>3</sup>.
- (6) Due to the level of bromide in the novel food and given the ongoing work of the European Food Safety Scientific Committee on the risks to human and animal health from the presence of bromide in food and feed<sup>4</sup>, the Authority requested the applicant to revise the proposed uses and use levels of the novel food on 13 September 2024. On 26 November 2024, the applicant agreed to revise the proposed uses and use levels for magnesium potassium trichloride hexahydrate accordingly. As a result, the novel food is intended to be used in raw cured or seasoned meat, cooked cured or seasoned meat, pastas and rice or other cereal-based dishes and preserved or partly preserved sausages, intended for the adult population.
- (7) On 17 December 2024, the Authority adopted its scientific opinion on the ‘safety of mineral salt containing potassium and magnesium as a novel food pursuant to Article 10 of Regulation (EU) 2015/2283’<sup>5</sup> in accordance with Article 11 of Regulation (EU) 2015/2283.
- (8) In its scientific opinion, the Authority concluded that magnesium potassium trichloride hexahydrate is safe under the proposed conditions of use for the adult population. Therefore, the Authority’s scientific opinion gives sufficient grounds to establish that magnesium potassium trichloride hexahydrate, when used under the proposed conditions of use, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (9) In that opinion, the Authority also noted that the additional intake of potassium and magnesium from the novel food does not represent a safety concern for the general population. Nevertheless, taking into consideration that foods containing the novel food may end up containing an amount of potassium and magnesium that is considered significant under Point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council<sup>6</sup>, the Commission considers that it is appropriate to inform consumers about that fact. In such cases, the nutrition declaration shall contain the amount of potassium and magnesium.
- (10) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on proprietary scientific studies and data submitted in support of the application, namely on the compositional data<sup>7</sup>. without which it could not have assessed the novel food and reached its conclusion.

<sup>3</sup> Certificates of analysis (Annexes C25, C25.1, C25.2 and C28); Full study report LAUS\_Statement Water Solubility\_OECD 105 resp. EU A.6 (Annex S13); Full study report CURRENTA\_X-Ray Diffraction\_Melting Range (Annex S14); Full study report LAUS\_Solubility\_OECD\_105\_b4, b5, b6 (Annexes S4, S5 and S6); Full study report LAUS\_combined water content b4, b5, b6 (Annexes S7, S8 and S9); Full study report LAUS water activity\_b4, b5, b6 (Annexes S10, S11, S12)

<sup>4</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00329>

<sup>5</sup> EFSA Journal. 2025;23:e9205

<sup>6</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18, ELI: <http://data.europa.eu/eli/reg/2011/1169/oj>).

<sup>7</sup> Certificates of analysis (Annexes C25, C25.1, C25.2 and C28); Full study report LAUS\_Statement Water Solubility\_OECD 105 resp. EU A.6 (Annex S13); Full study report CURRENTA\_X-Ray

- (11) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those proprietary scientific studies and data and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.
- (12) The applicant declared that they held proprietary and exclusive rights of reference to those proprietary scientific studies and data at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data and studies.
- (13) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, those proprietary scientific studies and data should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place magnesium potassium trichloride hexahydrate on the market within the Union during a period of five years from the entry into force of this Regulation.
- (14) However, restricting the authorisation of magnesium potassium trichloride hexahydrate and the reference to the scientific studies and data contained in the applicant's file for the sole use by them does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.
- (15) It is appropriate that the inclusion of magnesium potassium trichloride hexahydrate as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (16) Magnesium potassium trichloride hexahydrate should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (17) 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*

1. Magnesium potassium trichloride hexahydrate is authorised to be placed on the market within the Union.  
  
Magnesium potassium trichloride hexahydrate shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.
2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

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Diffraction\_Melting Range (Annex S14); Full study report LAUS\_Solubility\_OECD\_105\_b4, b5, b6 (Annexes S4, S5 and S6); Full study report LAUS\_combined water content b4, b5, b6 (Annexes S7, S8 and S9); Full study report LAUS water activity\_b4, b5, b6 (Annexes S10, S11, S12)

## *Article 2*

Only the company BK Guilini GmbH, member of ICL Group,<sup>8</sup> is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from [the date of entry into force of this Regulation] [OP please insert the date], unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific studies and data protected pursuant to Article 3 or with the agreement of BK Guilini GmbH, member of ICL Group.

## *Article 3*

The scientific studies and data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of BK Guilini GmbH, member of ICL Group.

## *Article 4*

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*

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<sup>8</sup> Address: Am Hafen 2, 68526 Ladenburg, Germany.