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COMMISSION IMPLEMENTING DECISION (EU) 2026/1103

of 22 May 2026

postponing the expiry date of the approval of PHMB (1415; 4.7) for use in biocidal products of product-types 2 and 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) PHMB (1415; 4.7) was approved as an active substance for use in biocidal products of product-types 2 and 4 by Commission Implementing Regulation (EU) 2018/613 ([2]) subject to the conditions set out in the Annex to that Regulation.

(2) The approval of PHMB (1415; 4.7) for use in biocidal products of product-types 2 and 4 ('the approval') is to expire on 31 October 2026. On 25 April 2025, applications were submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of PHMB (1415; 4.7) for use in biocidal products of product-types 2 and 4 ('the applications').

(3) On 10 July 2025, the evaluating competent authority of France informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the applications was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(6) On 23 February 2026, the evaluating competent authority informed the Commission that the evaluation is delayed. That delay is linked to the assessment of data related with 5-batch analysis, developmental neurotoxicity and the endocrine-disrupting properties of PHMB (1415; 4.7). The evaluating competent authority expects to submit the renewal assessment report to the Agency in the third quarter of 2028.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Commission Implementing Regulation (EU) 2018/613 of 20 April 2018 approving PHMB (1415; 4.7) as an existing active substance for use in biocidal products of product-types 2 and 4 (OJ L 102, 23.4.2018, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2018/613/oj).

(7) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the applications. Taking into account the expected finalisation of the evaluation by the evaluating competent authority, the time-limit for preparation and submission by the Agency of its opinions and the time needed for the Commission to decide whether to renew the approval of PHMB (1415; 4.7) for use in biocidal products of product-types 2 and 4, the expiry date should be postponed to 30 April 2029.

(8) After the postponement of the expiry date of the approval, PHMB (1415; 4.7) remains approved for use in biocidal products of product-types 2 and 4 subject to the conditions set out in the Annex to Implementing Regulation (EU) 2018/613,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of PHMB (1415; 4.7) for use in biocidal products of product-types 2 and 4 set out in the Annex to Implementing Regulation (EU) 2018/613 is postponed to 30 April 2029.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 22 May 2026.

For the Commission
The President
Ursula VON DER LEYEN