



2024/2421

16.9.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/2421

of 13 September 2024

postponing the expiry date of the approval of formaldehyde for use in biocidal products of product-types 2 and 3 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) Formaldehyde was approved as an active substance for use in biocidal products of product-types 2 and 3 by Commission Implementing Regulation (EU) 2020/1763 ⁽²⁾ subject to the conditions set out in the Annex to that Regulation ('the approval'). The approval is to expire on 31 January 2025.
- (2) On 7, 11 and 27 July 2023, applications were submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of formaldehyde for use in biocidal products of product-types 2 and 3 ('the applications').
- (3) On 10 November 2023, the evaluating competent authority of Germany 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) Consequently, for reasons beyond the control of the applicants, 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 time-limits for evaluation by the evaluating competent authority, 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 formaldehyde for use in biocidal products of product-types 2 and 3, the expiry date should be postponed to 31 July 2027.
- (7) After the postponement of the expiry date of the approval, formaldehyde remains approved for use in biocidal products of product-types 2 and 3 subject to the conditions set out in Annex to Implementing Regulation (EU) 2020/1763,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

⁽²⁾ Commission Implementing Regulation (EU) 2020/1763 of 25 November 2020 approving formaldehyde as an existing active substance for use in biocidal products of product-types 2 and 3 (OJ L 397, 26.11.2020, p. 17, ELI: http://data.europa.eu/eli/reg_impl/2020/1763/oj).

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of formaldehyde for use in biocidal products of product-types 2 and 3 set out in Implementing Regulation (EU) 2020/1763 is postponed to 31 July 2027.

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, 13 September 2024.

For the Commission
The President
Ursula VON DER LEYEN
