Official Journal
of the European Union

EN
L series

2026/578

18.3.2026

COMMISSION IMPLEMENTING DECISION (EU) 2026/578

of 17 March 2026

postponing the expiry date of the approval of alphachloralose for use in biocidal products of product-type 14 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) Alphachloralose was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) as an active substance for use in biocidal products of product-type 14. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved until 30 June 2021 under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.

(2) On 24 December 2019, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of alphachloralose for use in biocidal products of product-type 14 ('the application').

(3) On 15 October 2020, the evaluating competent authority of Poland informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application 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) Commission Implementing Decision (EU) 2021/333 ([3]) postponed the expiry date of the approval of alphachloralose for use in biocidal products of product-type 14 to 31 December 2023, in order to allow sufficient time for the examination of the application.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1, ELI: http://data.europa.eu/eli/dir/1998/8/oj).
([3]) Commission Implementing Decision (EU) 2021/333 of 24 February 2021 postponing the expiry date of approval of alphachloralose for use in biocidal products of product-type 14 (OJ L 65, 25.2.2021, p. 58, ELI: http://data.europa.eu/eli/dec_impl/2021/333/oj).

(7) Commission Implementing Decision (EU) 2023/2378 ([4]) postponed again the expiry date of the approval to 30 June 2026 due to the need of the evaluating competent authority to assess additional data on the reference specification, and potential carcinogenicity, reproductive toxicity, endocrine disruptor and persistent-bioaccumulation-toxic properties of the active substance.

(8) On 2 October 2025, the evaluating competent authority informed the Commission that the evaluation is delayed due to additional studies needed by the authority to complete the evaluation with respect to the determination of endocrine-disrupting properties of the substance. The evaluating competent authority expects to submit the renewal assessment report to the Agency in the second quarter of 2026.

(9) 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 further postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the Agency of its opinion and the time needed for the Commission to decide whether to renew the approval of alphachloralose for use in biocidal products of product-type 14, the expiry date should be postponed to 31 December 2027.

(10) After the further postponement of the expiry date of the approval, alphachloralose remains approved for use in biocidal products of product-type 14 subject to the conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of alphachloralose for use in biocidal products of product-type 14 set out in Implementing Decision (EU) 2023/2378 is postponed to 31 December 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, 17 March 2026.

For the Commission
The President
Ursula VON DER LEYEN

([4]) Commission Implementing Decision (EU) 2023/2378 of 28 September 2023 postponing the expiry date of the approval of alphachloralose for use in biocidal products of product-type 14 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2023/2378, 3.10.2023, ELI: http://data.europa.eu/eli/dec_impl/2023/2378/oj).