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COMMISSION IMPLEMENTING DECISION (EU) 2025/2282

of 13 November 2025

postponing the expiry date of the approval of cholecalciferol 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) Cholecalciferol was approved as an active substance for use in biocidal products of product-type 14 by Commission Implementing Regulation (EU) 2019/637 ([2]) subject to the conditions set out in the Annex to that Regulation.

(2) The approval of cholecalciferol for use in biocidal products of product-type 14 ('the approval') was to expire on 30 June 2024. On 22 December 2022, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval ('the application').

(3) On 7 August 2023, the evaluating competent authority of Sweden 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 not necessary. Pursuant to Article 14(2), second subparagraph, of that Regulation, the evaluating competent authority is to perform an evaluation of the application within 180 days of the European Chemicals Agency ('the Agency') accepting the application in accordance with Article 13(3) of that Regulation.

(4) On 16 December 2023, the evaluating competent authority submitted a recommendation on the renewal of the approval of cholecalciferol to the Agency.

(5) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for renewal of approval of active substances. The Biocidal Products Committee adopted the opinion of the Agency on 27 February 2024 ([3]), having regard to the conclusions of the evaluating competent authority.

(6) On 1 July 2024, pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([4]) to revise its opinion in order to investigate the use of the substance by the general public (non-professionals) and to conclude with certainty whether there are suitable alternatives to substitute cholecalciferol for indoor treatment of house mice, e.g. by the use of mechanical traps.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Commission Implementing Regulation (EU) 2019/637 of 23 April 2019 approving cholecalciferol as an active substance for use in biocidal products of product-type 14 (OJ L 109, 24.4.2019, p. 13; ELI: http://data.europa.eu/eli/reg_impl/2019/637/oj).
([3]) Biocidal Products Committee (BPC) Opinion on the application for renewal of the approval of the active substance: Cholecalciferol, Product type: 14, ECHA/BPC/412/2024, adopted on 27 February 2024.
([4]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Examination of alternatives to cholecalciferol and its possible use by the general public'; https://www.echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/opinions-on-article-75-1-g.

(7) Commission Implementing Decision (EU) 2024/733 ([5]) postponed the expiry date of the approval of cholecalciferol for use in biocidal products of product-type 14 to 31 December 2025, in order to allow sufficient time to complete the full procedure of the examination of the application.

(8) On 30 April 2025, the Agency informed the Commission that it plans to submit the revised opinion to the Commission in the third quarter of 2025.

(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 complete the examination of the application. Taking into account the time-limits for preparation and submission by the Agency of its revised opinion and the time needed for the Commission to decide whether to renew the approval of cholecalciferol for use in biocidal products of product-type 14, the expiry date should be postponed to 31 December 2026.

(10) After the further postponement of the expiry date of the approval, cholecalciferol remains approved for use in biocidal products of product-type 14 subject to the conditions set out in the Annex to Implementing Regulation (EU) 2019/637,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of cholecalciferol for use in biocidal products of product-type 14 set out in Implementing Regulation (EU) 2019/637 is postponed to 31 December 2026.

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 November 2025.

For the Commission
The President
Ursula VON DER LEYEN

([5]) Commission Implementing Decision (EU) 2024/733 of 28 February 2024 postponing the expiry date of the approval of cholecalciferol 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, 2024/733, 1.3.2024, ELI: http://data.europa.eu/eli/dec_impl/2024/733/oj).