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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

(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) In accordance with Article 9(1)(a) of Regulation (EU) No 528/2012, cholecalciferol has been approved as an active substance for use in biocidal products of product-type 14 subject to the conditions set out in Annex to Commission Implementing Regulation (EU) 2019/637 ([2]).

(2) The approval of cholecalciferol for use in biocidal products of product-type 14 ('the approval') is 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.

(4) Within 90 days of receipt of a recommendation from the evaluating competent authority, 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.

(5) On 3 November 2023, the Agency informed the Commission that the evaluating competent authority intends to submit its evaluation report to the Agency in December 2023, since the evaluating competent authority needed to take into account also the information coming from a public consultation (8 September – 7 November 2023 ([3])) on potential candidates for substitution organized by the Agency in accordance with Article 10(3) of Regulation (EU) No 528/2012. The Agency intends to submit its opinion on the renewal of the approval of cholecalciferol to the Commission in March 2024.

(6) Cholecalciferol is considered as having endocrine-disrupting properties that may cause adverse effects in humans in accordance with Commission Implementing Regulation (EU) No 2019/637, and therefore meets the exclusion criterion set out in point (d) of Article 5(1) of Regulation (EU) No 528/2012. Since the examination to decide whether at least one of the conditions of the first subparagraph of Article 5(2) of that Regulation is fulfilled, and whether the approval of cholecalciferol may therefore be renewed, will be performed once the Agency submits its opinion to the Commission, it will not be possible to complete this examination before the current expiry of approval.

([1]) OJ L 167, 27.6.2012, p. 1.
([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).
([3]) Consultation on potential candidates for substitution - ECHA (europa.eu)

(7) Consequently, for reasons beyond the control of the applicant, the approval of cholecalciferol for use in biocidal products of product-type 14 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 complete the full procedure of the examination of the application. Taking into account 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 2025.

(8) After the 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 Annex to Commission 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 Annex to Commission Implementing Regulation (EU) 2019/637 is postponed to 31 December 2025.

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, 28 February 2024.

For the Commission
The President
Ursula VON DER LEYEN