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COMMISSION IMPLEMENTING DECISION (EU) 2025/1811

of 11 September 2025

postponing the expiry date of the approval of 4,5-Dichloro-2-octyl-2H-isothiazol-3-one for use in biocidal products of product-types 8 and 21 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) 4,5-Dichloro-2-octyl-2H-isothiazol-3-one ('DCOIT') 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 8. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved until 30 June 2023 under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.

(2) On 23 December 2021, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of DCOIT for use in biocidal products of product-type 8.

(3) On 24 October 2022, the evaluating competent authority of Norway 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 for the renewal of the approval of DCOIT for use in biocidal products of product-type 8 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.

([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).

(6) Commission Implementing Decision (EU) 2023/471 ([3]) postponed the expiry date of the approval of DCOIT for use in biocidal products of product-type 8 to 31 December 2025, in order to allow sufficient time for the examination of the application.

(7) On 26 February 2025, the evaluating competent authority informed the Commission that the evaluation of the application for the renewal of the approval of DCOIT for use in biocidal products of product-type 8 is delayed due to the need for additional time to complete the assessment of endocrine-disrupting properties. The evaluating competent authority expects to submit the renewal assessment report to the Agency in 2027.

(8) DCOIT was also approved as an active substance for use in biocidal products of product-type 21 by Commission Implementing Regulation (EU) No 437/2014 ([4]) subject to the conditions set out in the Annex to that Regulation.

(9) The approval of DCOIT for use in biocidal products of product-type 21 is to expire on 31 December 2025. On 28 June 2024, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of DCOIT for use in biocidal products of product-type 21.

(10) On 26 February 2025, the evaluating competent authority of Norway 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 for the renewal of the approval of DCOIT for use in biocidal products of product-type 21 was necessary.

(11) Consequently, for reasons beyond the control of the applicant, the approval of DCOIT for use in biocidal products of product-types 8 and 21 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 of DCOIT for use in biocidal products of product-types 8 and 21 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 DCOIT, the expiry date for use in biocidal products of product-types 8 and 21 should be postponed to 30 June 2028.

(12) After the postponement of the expiry date of the approval, DCOIT remains approved for use in biocidal products of product-types 8 and 21, subject to the conditions set out in Annex I to Directive 98/8/EC and in the Annex to Implementing Regulation (EU) No 437/2014 respectively,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of 4,5-Dichloro-2-octyl-2H-isothiazol-3-one for use in biocidal products of product-type 8 set out in Annex I to Directive 98/8/EC is postponed to 30 June 2028.

Article 2

The expiry date of the approval of 4,5-Dichloro-2-octyl-2H-isothiazol-3-one for use in biocidal products of product-type 21 set out in the Annex to Implementing Regulation (EU) No 437/2014 is postponed to 30 June 2028.

([3]) Commission Implementing Decision (EU) 2023/471 of 2 March 2023 postponing the expiry date of the approval of 4,5-Dichloro-2-octyl-2H-isothiazol-3-one for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 68, 6.3.2023, p. 179; ELI: http://data.europa.eu/eli/dec_impl/2023/471/oj).

([4]) Commission Implementing Regulation (EU) No 437/2014 of 29 April 2014 approving 4,5-Dichloro-2-octyl-2H-isothiazol-3-one as an existing active substance for use in biocidal products for product-type 21 (OJ L 128, 30.4.2014, p. 64; ELI: http://data.europa.eu/eli/reg_impl/2014/437/oj).

Article 3

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, 11 September 2025.

For the Commission
The President
Ursula VON DER LEYEN