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## COMMISSION IMPLEMENTING DECISION (EU) 2022/1488

## of 7 September 2022

postponing the expiry date of the approval of K-HDO 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

(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) K-HDO was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council (<sup>2</sup>) 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 2020 under that Regulation subject to the requirements set out in Annex I to Directive 98/8/EC.
- (2) On 14 December 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of K-HDO for use in biocidal products of product-type 8 ('the application').
- (3) On 6 May 2019, the evaluating competent authority of Austria 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) 2019/1950 (<sup>3</sup>) postponed the expiry date of the approval of K-HDO for use in biocidal products of product-type 8 to 31 December 2022 in order to allow sufficient time for the examination of the application.

<sup>&</sup>lt;sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(&</sup>lt;sup>2</sup>) 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).

<sup>&</sup>lt;sup>(3)</sup> Commission Implementing Decision (EU) 2019/1950 of 25 November 2019 postponing the expiry date of approval of K-HDO for use in biocidal products of product-type 8 (OJ L 304, 26.11.2019, p. 19).

- (7) On 11 April 2022, the evaluating competent authority informed the Commission that the evaluation is delayed because studies are needed to assess the criteria for the determination of endocrine-disrupting properties of K-HDO. The evaluating competent authority expects to submit the renewal assessment report to the Agency in the first quarter of 2025.
- (8) 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 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 evaluations by the evaluating competent authority, for preparation and submission by the Agency of its opinion and for the Commission to decide whether to renew the approval of K-HDO for use in biocidal products for product-type 8, the expiry date should be postponed to 31 December 2026.
- (9) After the postponement of the expiry date of the approval, K-HDO remains approved for use in biocidal products of product-type 8 subject to the requirements set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

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## Article 1

The expiry date of the approval of K-HDO for use in biocidal products of product-type 8 set out in Implementing Decision (EU) 2019/1950 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, 7 September 2022.

For the Commission The President Ursula VON DER LEYEN