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COMMISSION IMPLEMENTING DECISION (EU) 2025/953

of 23 May 2025

postponing the expiry date of the approval of medetomidine for use in biocidal products of product-type 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) Medetomidine was approved as an active substance for use in biocidal products of product-type 21 by Commission Implementing Regulation (EU) 2015/1731 ([2]) until 31 December 2022 subject to the conditions set out in the Annex to that Regulation.

(2) On 27 June 2021, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of medetomidine for use in biocidal products of product-type 21 ('the application').

(3) On 10 December 2021, 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 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) 2022/1495 ([3]) postponed the expiry date of the approval of medetomidine for use in biocidal products of product-type 21 to 30 June 2025, in order to allow sufficient time for the examination of the application.

(7) On 18 August 2023, the evaluating competent authority submitted the renewal assessment report and the conclusions of its evaluation to the Agency.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([2]) Commission Implementing Regulation (EU) 2015/1731 of 28 September 2015 approving medetomidine as an active substance for use in biocidal products for product-type 21 (OJ L 252, 29.9.2015, p. 33, ELI: http://data.europa.eu/eli/reg_impl/2015/1731/oj).

([3]) Commission Implementing Decision (EU) 2022/1495 of 8 September 2022 postponing the expiry date of the approval of medetomidine for use in biocidal products of product-type 21 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 234, 09/09/2022, p. 26, ELI: http://data.europa.eu/eli/dec_impl/2022/1495/oj).

(8) On 28 May 2024, the Agency adopted its opinion ([4]) on renewal of the approval of medetomidine in accordance with Article 14(3) of Regulation (EU) No 528/2012 and submitted it to the Commission.

(9) Medetomidine is considered as having endocrine disrupting properties that may cause adverse effects in humans, and therefore meets the exclusion criterion set out in Article 5(1), point (d), of Regulation (EU) No 528/2012. While the examination by the Commission whether at least one of the conditions of Article 5(2), first subparagraph, of that Regulation is fulfilled, and whether the approval of medetomidine may therefore be renewed, is ongoing, it will not be possible to complete this examination before the current expiry of approval.

(10) 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 needed for the Commission to decide whether to renew the approval of medetomidine for use in biocidal products of product-type 21, the expiry date should be postponed to 30 June 2026.

(11) After the further postponement of the expiry date of the approval, medetomidine remains approved for use in biocidal products of product-type 21 subject to the conditions set out in the Annex to Implementing Regulation (EU) 2015/1731,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of medetomidine for use in biocidal products of product-type 21 set out in Implementing Decision (EU) 2022/1495 is postponed to 30 June 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, 23 May 2025.

For the Commission
The President
Ursula VON DER LEYEN

([4]) Biocidal Products Committee (BPC) opinion on the application for renewal of the approval of the active substance: medetomidine, Product type: 21, ECHA/BPC/422/2024, adopted on 28 May 2024.