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COMMISSION IMPLEMENTING DECISION (EU) 2026/2567

of 19 November 2026

not renewing the approval of medetomidine as an active substance 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(4), first subparagraph, point (b), thereof,

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'). The application was evaluated by the competent authority of Norway ('the evaluating competent authority').

(3) On 10 December 2021, the evaluating competent authority 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.

(4) Pursuant to Commission Implementing Decision (EU) 2022/1495 ([3]), the expiry date of approval of medetomidine for use in biocidal products of product-type 21 was postponed to 30 June 2025, in order to allow sufficient time for the examination of the application. Commission Implementing Decision (EU) 2025/953 ([4]) further postponed the expiry date of that approval to 30 June 2026, and Commission Implementing Decision (EU) 2026/1089 ([5]) postponed again the expiry date to 31 December 2026.

(5) On 18 August 2023, the evaluating competent authority submitted the renewal assessment report and the conclusions of its evaluation to the European Chemicals Agency ('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, 9.9.2022, p. 26, ELI: http://data.europa.eu/eli/dec_impl/2022/1495/oj).

([4]) 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 (OJ L, 2025/953, 23.5.2025, ELI: http://data.europa.eu/eli/dec_impl/2025/953/oj).

([5]) Commission Implementing Decision (EU) 2026/1089 of 20 May 2026 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, 2026/1089, 22.5.2026, ELI: http://data.europa.eu/eli/dec_impl/2026/1089/oj).

(6) In accordance with Article 14(3) of Regulation (EU) No 528/2012, on 28 May 2024 the Agency adopted its opinion ([6]), formulated by its Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(7) According to the opinion of the Agency, medetomidine has endocrine-disrupting properties that may cause adverse effects in humans according to Section A of the Annex of Commission Delegated Regulation (EU) 2017/2100 ([7]), therefore it meets the exclusion criterion set out in Article 5(1), point (d), of Regulation (EU) No 528/2012. The opinion also concludes that medetomidine has endocrine-disrupting properties that may cause adverse effects in non-target organisms according to Section B of the Annex of Delegated Regulation (EU) 2017/2100, that it is very persistent (vP) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([8]), and that it contains a significant proportion of non-active isomers or impurities. Therefore, medetomidine meets also the conditions set out in Article 10(1), points (d), (e) and (f), of Regulation (EU) No 528/2012 and should thus be considered a candidate for substitution.

(8) Pursuant to Regulation (EU) No 528/2012, active substances meeting an exclusion criterion may only be approved if they meet the conditions laid down in Article 4(1), and at least one of the conditions set out in Article 5(2), first subparagraph, of that Regulation.

(9) In its opinion, the Agency could not conclude whether the risks for human health and the environment of using the representative biocidal product containing medetomidine are acceptable or not considering its endocrine-disrupting properties because it was not possible to derive a safe threshold with respect to the endocrine-disrupting properties of medetomidine, in particular due to the limitation of data in regard to vulnerable groups of the human population and due to a variety of uncertainties in regard to the environment. Therefore, the Commission considers that it has ultimately not been demonstrated based on the data contained in the application that the representative biocidal product containing medetomidine for use in biocidal products of product-type 21 may be expected not to have unacceptable effects itself, or as a result of its residues, on human health and on the environment, and that it may be expected to satisfy the criteria set out in Article 19(1), point (b)(iii) and (iv), of Regulation (EU) No 528/2012. Thus, it is not possible to determine whether medetomidine still meets the conditions of approval laid down in Article 4(1) of Regulation (EU) No 528/2012.

(10) According to the opinion of the Agency, several suitable and sufficient alternative substances or technologies exist for medetomidine for the use supported in the application dossier. Based on that opinion, there are 8 suitable alternative active substances to medetomidine for both commercial and pleasure craft: 4,5-Dichloro-2-octyl-2H-isothiazol-3-one ('DCOIT'), copper pyrithione, copper flakes, copper thiocyanate, dicopper oxide, tolylfluanid, dichlofluanid, and tralopyril. In addition, the opinion concluded that there are 3 non-chemical alternatives to medetomidine for commercial craft (non-biocidal hard coatings, silicon-based coatings and in-water proactive cleaning) and 6 non-chemical alternatives for pleasure craft (non-biocidal hard coating, silicon-based coatings, ultrasonic systems, antifouling films/wraps, in water reactive cleaning, and in-water proactive cleaning).

(11) Between 6 September and 6 November 2024, the Commission, with the support of the Agency, carried out a third parties consultation in order to contribute to gathering information as to whether the conditions set out in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 were satisfied.

([6]) Biocidal Products Committee, 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.

([7]) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1, ELI: http://data.europa.eu/eli/reg_del/2017/2100/oj).

([8]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

(12) The opinion of the Agency and the contributions to the third parties consultation have been discussed with Member State representatives in the Standing Committee on Biocidal Products. Member State representatives have also been requested to indicate whether their Member States considered that at least one of the conditions set out in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 would be met, and to provide justifications for that position.

(13) During the meetings of 19 March, 20 June and 24 September 2025 of the Standing Committee on Biocidal Products ([9]), Member State representatives discussed the conclusions of the Agency's opinion on the availability of suitable and sufficient alternative substances or technologies to medetomidine, taking into account the contributions of the third parties consultation and the comments of the applicant. The majority of Member State representatives of the Standing Committee on Biocidal Products considered the non-chemical alternatives to medetomidine identified by the Agency's opinion for use in commercial and pleasure craft as an integral part for fouling protection, but they recognized that these methods might have availability or technical limitation issues, preventing them to cover the full range of applications or craft. Therefore, Member State representatives could not conclude whether non-chemical alternatives could act as suitable and sufficient alternatives to medetomidine for commercial and pleasure craft.

(14) In addition, Member State representatives did not consider as suitable alternatives to medetomidine, for both commercial and pleasure craft, the active substances copper flakes, tolylfluanid and dichlofluanid, because no application for their renewal of approval had been submitted by the deadline of 30 June 2024 in accordance with Article 13(1) of Regulation (EU) No 528/2012 and their approval expired on 31 December 2025. Moreover, Member State representatives could not conclude whether copper pyrithione could act as a suitable and sufficient alternative to medetomidine, for both commercial and pleasure craft, due to uncertainties on its efficacy against the organisms targeted by medetomidine. However, the majority of Member State representatives of the Standing Committee on Biocidal Products recognized as suitable and sufficient alternatives to medetomidine, for use in both commercial and pleasure craft, the active substances DCOIT, copper thiocyanate, dicopper oxide and tralopyril, which all have currently a less hazardous toxicological profile than medetomidine, and are not meeting the exclusion criteria set out in Article 5(1) of Regulation (EU) No 528/2012. Therefore, it is concluded that there are sufficient and suitable alternatives to medetomidine for use in biocidal products of product-type 21.

(15) Member State representatives in the Standing Committee on Biocidal Products also discussed the arguments of the applicant and of several contributors in the third parties consultation, who supported that a non-renewal of approval of medetomidine would trigger substantial costs due to higher fuel consumption and maintenance. However, in the absence of authorized biocidal products containing medetomidine under product-type 21 in the Union market in accordance with Article 17(1) of Regulation (EU) No 528/2012, and considering that suitable and sufficient alternative active substances to medetomidine are available (DCOIT, copper thiocyanate, dicopper oxide and tralopyril, for both commercial and pleasure craft), the views expressed by Member States show that a non-renewal of approval of medetomidine as an active substance for use in biocidal products of product-type 21 is not expected to have a disproportionate negative impact on society in comparison to the risk to human health, animal health or the environment arising from the use of the substance in antifouling biocidal products. Therefore, the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is not met.

(16) Furthermore, having in regard that drawing any conclusion on the level of risks of using medetomidine to human health and the environment considering its endocrine-disrupting properties was considered by the Agency as not being possible, and because the representative biocidal product presented by the applicant is not a product used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment, and considering the views of the Member State representatives in the Standing Committee on Biocidal Products on the matter, it is not concluded that the risk to humans, animals or the environment from exposure to medetomidine in a biocidal product, under realistic worst case conditions of use, is negligible. The condition set out in Article 5(2), first subparagraph, point (a), of Regulation (EU) No 528/2012 is therefore not met.

([9]) https://health.ec.europa.eu/biocides/events_en?f%5B0%5D=topic_topic%3A25&f%5B1%5D=topic_topic%3A114&f%5B2%5D=topic_topic%3A115.

(17) The applicant together with several contributors in the third parties consultation argued that the renewal of approval of medetomidine for use in biocidal products of product-type 21 would be essential to prevent or control a serious danger to the environment because medetomidine can contribute to the reduction of transfer of marine invasive species, it can support addressing the increasing resistance of marine organisms to antifouling biocidal products containing copper, and because medetomidine can contribute to the reduction of the greenhouse gas emissions (CO_2) through reduced fuel consumption of craft. However, in the presence of other suitable and sufficient alternative antifouling active substances to medetomidine, and considering the views of the Member State representatives in the Standing Committee on Biocidal Products on the matter, it is not concluded that medetomidine is essential to prevent or control a serious danger to the environment. The condition set out in Article 5(2), first subparagraph, point (b), of Regulation (EU) No 528/2012 is therefore not met.

(18) Consequently, taking into account the analysis of all data collected and the views expressed by Member State representatives in the Standing Committee on Biocidal Products, none of the conditions set out in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is met for medetomidine for its use in biocidal products of product-type 21.

(19) Since it is not possible to determine whether medetomidine still meets the conditions of approval laid down in Article 4(1) of Regulation (EU) No 528/2012, and because none of the conditions set out in Article 5(2), first subparagraph, of that Regulation is met, the conditions for renewal of the approval of an active substance set out in Article 12(1) of Regulation (EU) No 528/2012 are not fulfilled.

(20) It is therefore appropriate not to renew the approval of medetomidine for use in biocidal products of product-type 21.

(21) In order to allow sufficient time for economic operators to adapt, treated articles treated with or incorporating medetomidine for use in biocidal products of product-type 21 may be placed on the market for a period of 180 days after the entry into force of this Decision.

(22) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The approval of medetomidine as an active substance for use in biocidal products of product-type 21 is not renewed.

Article 2

Treated articles treated with or intentionally incorporating medetomidine for use in biocidal products of product-type 21 shall no longer be placed on the market from 8 June 2027.

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, 19 November 2026.

For the Commission
The President
Ursula VON DER LEYEN