WORLD TRADE ORGANIZATION

G/TBT/N/EU/1221

8 July 2026

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Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** EUROPEAN UNION **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** European Commission EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu Website: https://technical-barriers-trade.ec.europa.eu/en/home
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], Other:**
4.	**Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable):** Biocidal products
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Draft Commission Implementing Decision (EU) repealing Implementing Decision (EU) 2026/1089 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; (3 page(s), in English) **Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:** https://members.wto.org/crnattachments/2026/TBT/EEC/26_03533_00_e.pdf European Commission EU-TBT Enquiry Point Fax: + (32) 2 299 80 43 E-mail: grow-eu-tbt@ec.europa.eu The text is available on the Website: https://technical-barriers-trade.ec.europa.eu/en/home
6.	**Description of content:** This draft Commission Implementing Decision repeals the postponement of the expiry date of the approval of medetomidine for use in biocidal products of product type (PT) 21. 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. On 28 May 2024 the Agency adopted its opinion on medetomidine for PT21, having regard to the conclusions of the evaluating competent authority. Given the opinion of Agency, medetomidine has endocrine disrupting properties that may cause adverse effects in humans in accordance with the criteria laid down in Commission Delegated Regulation (EU) 2017/2100. Medetomidine therefore meets the exclusion criterion set out in Article 5(1), point (d), of Regulation (EU) No 528/2012. Alternatives

	are available for its use in biocidal products of product-type 21. None of the derogation criteria under Article 5(2) of the BPR are considered met. Consequently, a draft Decision is being prepared to not renew the approval of medetomidine for PT 21. Further to that Decision, it is necessary to repeal the postponement of the expiry date of the approval of medetomidine for PT21. The present draft Decision therefore intends to repeal Decision (EU) 2026/1089 postponing the expiry date of the approval of medetomidine for PT21.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of public health. Harmonisation of the EU market on biocidal products.; Protection of the environment
8.	**Relevant documents:** 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 (OJ L 167, 27.6.2012, p. 1.). Available in all EU languages. EUR-Lex - 32012R0528 - EN - EUR-Lex (europa.eu)
9.	**Proposed date of adoption:** November 2026 **Proposed date of entry into force:** 20 days from publication in the Official Journal of the EU
10.	**Provision of comments** **Final date for comments:** 6 September 2026 **[X] 60 days from notification** **Contact details of agency or authority designated to handle comments regarding the notification:** European Commission, EU-TBT Enquiry Point, Fax: + (32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu