Official Journal
of the European Union

EN
L series

2026/2576

24.11.2026

COMMISSION IMPLEMENTING DECISION (EU) 2026/2576

of 20 November 2026

on the non-approval of 1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH) as an existing active substance for use in biocidal products of product-types 6 and 13 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 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes in its Annex II a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes 1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione ('DMDMH') for product-types 6 and 13.

(2) DMDMH has been evaluated for use in biocidal products of product-types 6 (in-can preservatives) and 13 (metalworking-fluid preservatives), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond to product-types 6 (preservatives for products during storage) and 13 (working or cutting fluid preservatives), as described in Annex V to Regulation (EU) No 528/2012.

(3) Poland was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment reports together with its conclusions to the Commission on 25 August and 22 September 2010 for product-types 6 and 13, respectively. After the submission of those assessment reports, discussions took place in technical meetings organised by the European Chemicals Agency ('the Agency').

(4) It follows from Article 90(2), first subparagraph, of Regulation (EU) No 528/2012, that active substances for which the Member States' evaluation has been completed by 1 September 2013 are to be evaluated in accordance with the substantive conditions for approval laid down in Directive 98/8/EC.

(5) On 29 October 2024, the participant of DMDMH for product-types 6 and 13 informed the Agency of its decision to withdraw its support for DMDMH for both product-types in the review programme in accordance with Article 11(1), point (a), of Delegated Regulation (EU) No 1062/2014. Pursuant to Article 11(2) of that Regulation, that withdrawal is not to be considered as timely since it occurred after the date when the evaluating competent authority submitted its reports to the applicant for providing comments. Consequently, the examination of DMDMH had to be finalized.

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

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1, ELI: http://data.europa.eu/eli/reg_del/2014/1062/oj).

([3]) 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) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee is to prepare the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinions of the Agency on 24 February 2026 ([4]) ([5]), having regard to the conclusions of the evaluating competent authority.

(7) According to the opinions of the Agency, sufficient efficacy has not been demonstrated for any of the uses of the representative biocidal products for the assessed product-types since the efficacy data provided by the applicant were not sufficient.

(8) Furthermore, it was not possible to confirm that the ecotoxicological studies provided by the participant cover the specification of DMDMH and to conclude on the relevance of the impurities. As a result, the Agency could not conclude on the acceptability of the risks concerning the environment related with any of the uses of the representative biocidal products containing DMDMH included in the application dossiers for the assessed product-types, and on any safe use for the environment.

(9) Therefore, biocidal products of product-types 6 and 13 containing DMDMH are not expected to satisfy the criteria set out in Article 5(1), point (b), (i) and (iv), of Directive 98/8/EC read in conjunction with Article 10(1) of that Directive.

(10) It is therefore appropriate not to approve DMDMH for use in biocidal products of product-types 6 and 13.

(11) 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

1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH) is not approved as an active substance for use in biocidal products of product-types 6 and 13.

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, 20 November 2026.

For the Commission
The President
Ursula VON DER LEYEN

([4]) Biocidal Products Committee, Opinion on the application for the approval of the active substance: 1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH); Product-type: 6; ECHA/BPC/521/2026, adopted on 24 February 2026.

([5]) Biocidal Products Committee, Opinion on the application for the approval of the active substance: 1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH); Product-type: 13; ECHA/BPC/522/2026, adopted on 24 February 2026.