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COMMISSION IMPLEMENTING DECISION (EU) 2026/599

of 19 March 2026

not approving formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) as an active substance for use in biocidal products of product-type 6 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) Annex II to Commission Delegated Regulation (EU) No 1062/2014 [2] establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) ('HPT') for product-type 6.

(2) HPT has been evaluated for use in biocidal products of product-type 6 (in-can preservatives) as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council [3], which corresponds to product-type 6 (preservatives for products during storage) as described in Annex V to Regulation (EU) No 528/2012.

(3) On 1 August 2007, an application was submitted to request the inclusion of HPT for use in biocidal products of product-type 6 ('the application') into Annex I to Directive 98/8/EC. In the application, the applicant submitted a sole representative biocidal product supported for the preservation of fuels which are prone to bacterial decay.

(4) Austria was designated as the rapporteur Member State, and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 29 September 2016. After the submission of the assessment report, discussions took place in technical meetings organised by the Agency.

(5) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares 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 opinion of the Agency on 29 June 2017 ('the opinion of 29 June 2017') [4], having regard to the conclusions of the evaluating competent authority.

[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).

[4] Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product-type: 6; ECHA/BPC/162/2017, adopted on 29 June 2017.

(6) According to the opinion of 29 June 2017, HPT is classified as carcinogenic category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([5]), and therefore meets the exclusion criterion set out in Article 5(1), point (a), of Regulation (EU) No 528/2012.

(7) According to the opinion of 29 June 2017, HPT did not meet the criteria to be classified as toxic for reproduction category 2 in accordance with Regulation (EC) No 1272/2008, and therefore it was not considered as having endocrine-disrupting properties in accordance with Article 5(3), second subparagraph, of Regulation (EU) No 528/2012, pending the adoption of delegated acts specifying the scientific criteria for the determination of endocrine-disrupting properties.

(8) Commission Delegated Regulation (EU) 2017/2100 ([6]) setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 entered into force on 7 December 2017 and applies as of 7 June 2018.

(9) In anticipation of the application of the new scientific criteria set out in Delegated Regulation (EU) 2017/2100, and in order to provide clarity as regards the hazard properties and the risks resulting from the use of HPT, on 26 April 2018, pursuant to Article 75(1), second subparagraph, point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([7]) to revise its opinion of 29 June 2017 and to clarify whether HPT also has endocrine-disrupting properties on the basis of the scientific criteria laid down in that Delegated Regulation.

(10) The Agency adopted its revised opinion on 8 June 2022 ('the opinion of 8 June 2022') ([8]). According to the opinion of 8 June 2022, no conclusion could be drawn based on the available data as to whether HPT has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms) on the basis of the criteria laid down in Delegated Regulation (EU) 2017/2100. However, considering the known severe hazard properties of this substance, meeting already the exclusion criterion set out in Article 5(1), point (a), of Regulation (EU) No 528/2012, and based on scientific reasons, further data were not requested by the Agency.

(11) The Agency concluded in its opinion of 8 June 2022 that there are no unacceptable risks to human health and the environment from the use of biocidal products containing HPT for product-type 6, when leaving aside the absence of conclusion on whether HPT has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms) on the basis of the criteria laid down in Delegated Regulation (EU) 2017/2100, and when risk mitigation measures are applied to limit the exposure of humans, animals and the environment to HPT as much as possible. However, the Agency did not reach a conclusion on the level of risks of using HPT to human health and the environment considering its endocrine-disrupting properties due to the lack of available information with regard to these properties.

([5]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

([6]) 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).

([7]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Evaluation of the Endocrine disrupting properties of certain biocidal actives substances according to the scientific criteria' (https://echa.europa.eu/documents/10162/2166576/Mandate+Opinion+Request+Evaluation+of+ED+properties_April+2018.pdf/7b66f04c-04a1-4af6-9f62-cc05e37528db?t=1612430315069).

([8]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product-type: 6; ECHA/BPC/331/2022, adopted on 8 June 2022.

(12) On 18 July 2023, pursuant to Article 75(1), second subparagraph, point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([9]) to revise its opinion of 8 June 2022 as the efficacy of the representative biocidal product had not been appropriately assessed in accordance with the applicable guidance document on efficacy ([10]), and this issue had not been adequately identified by the evaluating competent authority during the evaluation nor during the peer review by the Agency. Tier 2 data representing real-life conditions should have been requested and assessed. The Biocidal Products Committee adopted the revised opinion of the Agency for product-type 6 on 29 May 2024 ([11]).

(13) 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.

(14) Between 5 September and 4 November 2017, the Commission, with the support of the Agency, carried out a public consultation in order to gather information as to whether the conditions set out in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 were satisfied.

(15) On 17 February 2023, pursuant to Article 75(1), second subparagraph, point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([12]) to provide an opinion on the evaluation of the availability and suitability of alternatives to HPT, including product-type 6. The Biocidal Products Committee adopted the related opinion of the Agency on 23 November 2023 ('the opinion of 23 November 2023') ([13]). In that opinion, the Agency made the decision to rename HPT to formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) ('RP 1:1'). That opinion found that no suitable and sufficient alternative substances or technologies exist for RP 1:1 for the use supported in the application.

(16) The opinion of 23 November 2023 and the contributions to the public consultation were discussed with Member State representatives in the Standing Committee on Biocidal Products. Member State representatives were requested to indicate whether their respective Member State 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.

(17) During the discussion with Member State representatives at the meeting of 25 September 2024 of the Standing Committee on Biocidal Products it was indicated that the Agency opinion of 23 November 2023 did not examine in the course of the analysis of alternatives the active substance formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) ('RP 3:2') as a potential alternative active substance to RP 1:1 for the use supported in the application. The Commission initiated a further consultation of Member State representatives on the matter in the meetings of the Standing Committee on Biocidal Products of 6 December 2024, 19 March 2025, 20 June 2025, and 24 September 2025. At each of these meetings, the respective additional information provided by the applicant on 15 November 2024, 28 February 2025 and 27 June 2025, were brought to the attention of Member State representatives. Based on that information, the applicant did not consider RP 3:2 as a suitable alternative to RP 1:1, although it mentioned that RP 3:2 is the most valid biocidal solution for fuel preservation and that the preservation of a diesel fuel with RP 1:1 containing approximately 20 % water would be counterproductive. However, the majority of Member State representatives in the Standing Committee on Biocidal

([9]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Examination of efficacy tier 2 data on specific active substances acting as preservatives (product-types 6-13)'.

([10]) Technical notes for guidance in support of Annex VI of Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market; Common principles and practical procedures for the authorization and registration of products; short title: TNsG on Product Evaluation; February 2008.

([11]) Biocidal Products Committee Opinion on the application for approval of the active substance: Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product type: 6; ECHA/BPC/426/2024, adopted on 29 May 2024.

([12]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)'.

([13]) Biocidal Products Committee Opinion on a request according to Article 75(1)(g) on the evaluation of the availability and suitability of alternatives to Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) and (ratio 3:2), short: RP 1:1 and RP 3:2 for PT 2, 6, 11, 12 (only RP 3:2) and 13; ECHA/BPC/405/2023, adopted on 23 November 2023.

Products considered that RP 3:2 is more technically compatible than RP 1:1 for fuel preservation prone to bacterial decay. Therefore, despite recognising the same hazardous properties of RP 3:2 as those of RP 1:1, the majority of Member State representatives of the Standing Committee on Biocidal Products recognised RP 3:2 as a suitable and sufficient alternative substance to RP 1:1 for the use supported in the application of RP 1:1, thus not agreeing with the conclusions of the Agency opinion of 23 November 2023 that no suitable and sufficient alternative substances or technologies exist for RP 1:1. Therefore, considering the analysis of all data collected and the views expressed by Member States, a non-approval of RP 1:1 as an active substance for use in biocidal products of product-type 6 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 for the preservation of fuels which are prone to bacterial decay. The condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is thus not satisfied for such use.

(18) Furthermore, taking into account that no conclusion can be drawn by the Agency on the level of risks of using RP 1:1 to human health and the environment considering its endocrine-disrupting properties, and because possible release of RP 1:1 into the environment cannot be excluded according to the views of the Member State representatives in the Standing Committee on Biocidal Products, it cannot be concluded that the risk to humans, animals or the environment from exposure to RP 1:1 in a biocidal product, under realistic worst case conditions of use, is negligible. Therefore, the condition in Article 5(2), first subparagraph, point (a), of Regulation (EU) No 528/2012 is not met.

(19) No relevant information or justification has been submitted by the applicant or through the public consultation to demonstrate that RP 1:1 would be essential to prevent or control a serious danger to human health, animal health or the environment. The condition in Article 5(2), first subparagraph, point (b), of Regulation (EU) No 528/2012 is therefore not met.

(20) On 28 February 2025 and on 27 June 2025, the applicant indicated its intention to support representative biocidal products for the examination of the application of RP 1:1 linked to uses other than preservation of fuels prone to bacterial decay, such as the use of RP 1:1 for the preservation of mold (casting) release agents, paints, adhesives, sealants, cleaners, abrasives materials, polishing pastes and technical emulsions. However, the application for approval of RP 1:1 for product-type 6 has been under evaluation since its submission on 1 August 2007 and the applicant has had several opportunities in the past to provide sufficient evidence to assess whether the conditions in Article 5(2) of Regulation (EU) No 528/2012 would be met for that active substance. In addition, authorities are not required to accept any further study or additional data submitted by an applicant on its own initiative after the submission of the assessment report by the evaluating competent authority to the Agency and the adoption of the Agency's Opinion, as this would entitle an applicant to extend the evaluation procedure indefinitely and delay the adoption of a decision on the active substance. This would run counter to the objective of Regulation (EU) No 528/2012 to ensure a high level of protection of human, animal health and of the environment.

(21) Moreover, even if the additional information submitted late by the applicant (on 28 February 2025 and on 27 June 2025, supporting uses other than preservation of fuels prone to bacterial decay) had been taken into account in the examination of the active substance, the Commission considers that none of the conditions in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 would be met.

(22) 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 in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 are met.

(23) In addition, since no conclusion on the level of risks from using RP 1:1 to human health and the environment considering its potential endocrine-disrupting properties was drawn by the Agency, it has not been demonstrated based on the data available in the application that the representative biocidal product containing RP 1:1 for product-type 6 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.

(24) Therefore, the conditions laid down in Article 4(1) of Regulation (EU) No 528/2012 for approval of RP 1:1 for use in biocidal products of product-type 6 are also not met.

(25) It is therefore appropriate not to approve RP 1:1 as an active substance for use in biocidal products of product-type 6.

(26) 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

Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) is not approved as an active substance for use in biocidal products of product-type 6.

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, 19 March 2026.

For the Commission
The President
Ursula VON DER LEYEN