European Parliament
2024-2029

Committee on the Environment, Climate and Food Safety

2026/2550(RSP)

13.2.2026

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 115(2) and (3) of the Rules of Procedure

on the draft Commission implementing regulation approving formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) as an existing active substance for use in biocidal products of product-types 2, 11 and 13 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (D111760/02 – 2026/2550(RSP))

Committee on the Environment, Climate and Food Safety

Members responsible: Christophe Clergeau, Anja Hazekamp

B10-0000/2026

European Parliament resolution on the draft Commission implementing regulation approving formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) as an existing active substance for use in biocidal products of product-types 2, 11 and 13 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council
(D111760/02 – 2026/2550(RSP))

The European Parliament,

– having regard to the draft Commission implementing regulation approving formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) as an existing active substance for use in biocidal products of product-types 2, 11 and 13 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (D111760/02),

– 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,

– having regard to Article 11 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[2],

– having regard to Rule 115(2) and (3) of its Rules of Procedure,

– having regard to the motion for a resolution of the Committee on the Environment, Climate and Food Safety,

A. whereas the draft Commission implementing regulation proposes to approve formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) ('RP 1:1') as an existing active substance for use in biocidal products of product-types 2 (private area and public health area disinfectants and other biocidal products), 11 (preservatives for liquid-cooling and processing systems) and 13 (working or cutting fluid preservatives) for a period of five years;

Carcinogenicity and endocrine-disrupting properties

B. whereas RP 1:1 is classified as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[3], and therefore meets the exclusion criterion set out in Article 5(1), point (a), of Regulation (EU) No 528/2012;

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1 OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
2 OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj.
3 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).

C. whereas the Biocidal Products Committee adopted opinions on 8 June 2022[4] stating that no conclusion could be drawn based on the available data whether RP 1:1 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 Commission Delegated Regulation (EU) 2017/2100[5];

D. whereas, as set out in recital 20 of the draft Commission implementing regulation, the Biocidal Products Committee concluded that there are no unacceptable risks to human health and the environment from the use of biocidal products containing RP 1:1 for product-types 2, 11 and 13, but only 'when leaving aside the absence of conclusion on whether RP 1:1 has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms)' and 'when risk mitigation measures are applied to limit the exposure of humans, animals and the environment to RP 1:1 as far as possible'; whereas the Biocidal Products Committee further found that no conclusion could be drawn on the level of risks of using RP 1:1 to human health and the environment considering its endocrine-disrupting properties due to the missing information;

E. whereas RP 1:1 is a candidate for substitution in accordance with Article 10(1), point (a), of Regulation (EU) No 528/2012;

F. whereas, based on the data available in the applications, it has ultimately not been demonstrated that the representative biocidal products containing RP 1:1 for product-types 2, 11 and 13 may be expected not to have unacceptable effects themselves, or as a result of their residues, on human health and on the environment, and that they may be expected to satisfy the criteria set out in Article 19(1), point (b)(iii) and (iv), of Regulation (EU) No 528/2012;

G. whereas the Biocidal Products Committee identified unacceptable risks for the Sewage Treatment Plant, surface water and the terrestrial compartment from the use of biocidal products containing RP 1:1;

H. whereas according to the draft Commission implementing decision (D111762/01) not approving RP 1:1 for product-type 6, possible release of RP 1:1 into the environment

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4 Biocidal Products Committee opinions of 8 June 2022:
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: 2; ECHA/BPC/330/2022, https://echa.europa.eu/documents/10162/2a1ce589-23a1-ea92-9b3e-35f2590a13df,
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: 11; ECHA/BPC/332/2022, https://echa.europa.eu/documents/10162/cfd588d4-d25e-b07c-0de2-6e989cccff1f,
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: 13; ECHA/BPC/333/2022
https://echa.europa.eu/documents/10162/92955c77-3105-3095-8acf-b58b55019d34.

5 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).

cannot be excluded according to the views of the Member State representatives in the Biocidal Products Committee; whereas this consideration led to the conclusion that the condition in Article 5(2), first subparagraph, point (a), of Regulation (EU) No 528/2012 is not met; whereas based on the assessment report, such release into the environment cannot be excluded as well for considered uses for product-types 2, 11 and 13;

I. whereas proposing to approve an existing active substance classified as carcinogen category 1B, and failing to take into account the endocrine-disrupting properties of RP 1:1 in its evaluation is a manifest failure by the Commission to uphold its duty of ensuring a high level of protection of both human health and the environment; whereas unacceptable risks to human health and the environment would therefore result from the use of biocidal products containing RP 1:1;

Consideration of available alternatives

J. whereas in accordance with Article 19(5) of Regulation (EU) No 528/2012, and notwithstanding paragraphs 1 and 4 of that Article, a biocidal product may be authorised when the conditions laid down in paragraph 1, point (b)(iii) and (iv), of that Article are not fully met where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation;

K. whereas, based on the opinion of the Biocidal Products Committee, the Commission concluded that RP 1:1 meets the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 as the Commission considered that not approving the active substance RP 1:1 would have a disproportionate negative impact on society when compared with the risk to human health and the environment arising from the use of that substance, in particular because of the lack of alternatives for the proposed uses;

L. where, according to the European Chemicals Agency (ECHA) Guidance[6], a suitable alternative to a biocidal active substance under Regulation (EU) No 528/2012 needs to fulfil three criteria, namely being available, technically and economically feasible, and safer, meaning that it reduces the risk to human health, animal health and the environment;

M. whereas assessing and comparing the risks of a substance with potential chemical alternatives entails examining the hazard profiles of the alternative substances and comparing them to the hazard profile of the candidate for substitution to assess whether it is possible to determine with sufficient certainty that the alternative would result in a lower level of risk;

N. whereas, according to the ECHA Guidance, the hazard endpoints related to the exclusion criteria should be considered when performing the analysis of alternatives; whereas in accordance with Article 10(1), point (a), of Regulation (EU) No 528/2012,

6 ECHA Guidance. Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance, January 2023, https://echa.europa.eu/documents/10162/1276600/guidance_analysis_alternatives_biocides_en.pdf/10646cd2-8ec9-36a8-2f00-201fcc49c43e?t=1675846602684

active substances having endocrine disrupting properties are considered as meeting the exclusion criteria;

O. whereas the Commission concludes therefore that there are no available alternatives to the use of RP 1:1 in biocidal products for the intended uses, and in particular that no alternative has a significant lower hazard profile, based on an incomplete hazard profile of RP 1:1 as, according to the opinion of the Biocidal Products Committee, no conclusion could be drawn based on the available data whether RP 1:1 has endocrine-disrupting properties that may cause adverse effects in humans and that further data were not requested by ECHA;

Appropriateness of risk mitigation measures

P. whereas the draft Commission implementing regulation provides for specific risk mitigation measures for the placing on the market of biocidal products containing RP 1:1 as an active substance and of treated articles;

Q. whereas, the risk mitigation measures provided for in the draft Commission implementing regulation are largely left to the Member States' discretion at the product assessment phase, and will merely require competent authorities to 'pay particular attention' to the exposure and risks linked to any of the proposed uses of the biocidal products containing RP 1:1, and to 'pay particular attention' to industrial users without further specification as to the nature of those requirements;

R. whereas, in view of the unacceptable risks identified for the Sewage Treatment Plant, surface water and the terrestrial compartment from the use of biocidal products containing RP 1:1, according to the draft Commission implementing regulation, those products may be approved provided that certain specifications and conditions concerning its use are complied with, in particular that the product assessment shall 'pay particular attention' to those aspects;

S. whereas, in the decision in case 12/2013/MDC of 18 February 2016 on the practices of the Commission regarding the authorisation and placing on the market of plant protection products (pesticides), the European Ombudsman called on the Commission to review its approach to the definition and implementation of mitigation measures (conditions and restrictions), so as to include further requirements aimed at ensuring that the Commission does not evade its responsibility to ensure the effective protection of human health, animal health and the environment by allowing Member States almost absolute discretion as regards the definition of mitigation measures for potentially unsafe substances, given that standard formulations are very open-ended and it can be doubted whether they can be legally described as requiring mitigation measures at all;

T. whereas the risk mitigation measures provided for in the draft Commission implementing regulation cannot be considered to be of a binding nature or sufficient to ensure a high level of protection of human health and the environment, considering that no conclusion on the risk derived from endocrine-disrupting properties could be established;

Trade of treated articles

U. whereas, while the authorisation of products to treat articles will be restricted for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation

(EU) No 528/2012 is met, it will still be possible to freely import or trade treated articles between any Member States, even those that do not consider the conditions of Article 5(2) of that Regulation as being met;

V. whereas, under the draft Commission implementing regulation, only a label providing the limited information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012 and a warning statement will be required on treated articles and that information and statement will not be subject to regulatory scrutiny before the article is placed on the market; whereas, since no product authorisation is necessary, there will also be no evaluation of whether efficacy of such articles matches the label claim;

W. whereas, therefore, the draft Commission implementing regulation does not provide a high enough level of protection of human health and the environment, and does not provide a level playing field for Union and non-Union companies;

X. whereas the Commission should have protected the Union's citizens and the environment on the basis of scientific information, using the obligation and the legal possibilities that Regulation (EU) No 528/2012 provides for, to ensure a high level of protection of both human health and the environment; whereas this should have led to the non-approval of RP 1:1 as an existing active substance for use in biocidal products of product-types 2, 11, and 13;

Y. whereas the renewal of the approval of RP 1:1 is therefore inappropriate, demonstrates non-observance of the precautionary principle, and constitutes a violation of the legal obligation on the Commission to ensure a high level of protection of both human health and the environment;

1. Considers that the draft Commission implementing regulation exceeds the implementing powers provided for in Regulation (EU) No 528/2012;

2. Considers that the draft Commission implementing regulation is not consistent with Union law, in that it is not compatible with the aim and content of Regulation (EU) No 528/2012;

3. Considers that the draft Commission implementing regulation approving RP 1:1 as an existing active substance for use in biocidal products of product-types 2, 11, and 13 is not proportionate in light of the unacceptable risks RP 1:1 poses to human health and the environment, in view of

   (a) the classification of RP 1:1 as carcinogen category 1B and the absence of conclusion regarding its endocrine-disrupting properties, as well as the unacceptable risk identified for the environment;

   (b) the analysis of available alternatives for some of the uses proposed for approval based on the incomplete hazard profile of RP 1:1;

   (c) the inappropriateness of the risk mitigation measures and their non-binding character, and the lack of protection regarding the trade of treated articles on the internal market;

4. Considers that the significant delay in completing the review programme for the

examination of existing biocidal active substances contained in biocidal products is seriously hampering the performance of a proper analysis of alternatives as not all active substances on the market have yet been evaluated in accordance with Regulation (EU) No 528/2012 and therefore not all products have been authorised in accordance with the same regulation, as pointed out by the Biocidal Products Committee in its opinion[7];

5. Calls on the Commission to withdraw its draft implementing regulation and to submit a new draft to the committee, proposing a non-approval of RP 1:1 for the considered uses, as granting this approval, despite its hazardous properties and the lack of adequate risk mitigation measures, would not be compatible with the aim and content of Regulation (EU) No 528/2012;

6. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.

[7] https://echa.europa.eu/documents/10162/9314ebdb-f82e-7ceb-1fc1-5d2e617f8902