European Parliament
2024-2029

Committee on the Environment, Climate and Food Safety

2025/2653(RSP)

6.5.2025

DRAFT MOTION FOR A RESOLUTION

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

on the draft Commission implementing regulation approving 2,2-Dibromo-2-cyanoacetamide (DBNPA) as an existing 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
(D105905/02 – 2025/2653(RSP))

Committee on the Environment, Climate and Food Safety

Members responsible: Christophe Clergeau, Sirpa Pietikäinen, Michal Wiezik, Jutta Paulus, Anja Hazekamp

B10-0000/2025

European Parliament resolution on the draft Commission implementing regulation approving 2,2-Dibromo-2-cyanoacetamide (DBNPA) as an existing 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
(D105905/02 – 2025/2653(RSP))

The European Parliament,

– having regard to the draft Commission implementing regulation approving 2,2-Dibromo-2-cyanoacetamide (DBNPA) as an existing 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 (D105905/02),

– 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 the opinions delivered on 30 November 2021 and 12 September 2023, respectively, by the Biocidal Products Committee (BPC) referred to in Article 75 of Regulation (EU) No 528/2012[2],

– 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[3],

– 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 DBNPA as an existing active substance for use in biocidal products of product-type 6 (PT6) (in-can preservatives) for a period of five years; whereas, in particular, DBNPA in PT6 is intended for short-term preservation of mineral slurries and other additives for use in paper production, for short-term preservation of paints and coatings and of raw materials used for their production, and for short-term preservation of polymer dispersions;

B. whereas DBNPA is a fast-acting biocide and exerts its biocidal action directly after its application via bromine, which inactivates enzymes by converting functional –SH groups

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

2 Opinion of the Biocidal Products Committee of 30 November 2021 on the application for approval of the active substance 2,2-Dibromo-2-cyanoacetamide (DBNPA); Product-type: 4; ECHA/BPC/300/2021, https://echa.europa.eu/documents/10162/085a4896-b067-bdbc-e38c-8f794e60e4f3, and the opinion of the Biocidal Products Committee of 12 September 2023 on the application for approval of the active substance 2,2-Dibromo-2-cyanoacetamide (DBNPA); Product-type: 6; ECHA/BPC/388/2023, https://echa.europa.eu/documents/10162/829c25ac-d37e-e5ab-aca4-0672374a547b.

3 OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj.

to the oxidised S-S form; whereas this reaction irreversibly disrupts the function of cell-surface components, interrupting transport across cell membranes and inhibiting key biological functions;

C. whereas, although the scenario of primary exposure to DBNPA and DBNPA-derived bromide used in PT6 only concerns industrial users requiring personal protection equipment, the scenario of secondary exposure to DBNPA-derived bromide concerning the general public is possible as a result of dietary exposure via treated paper used for food packaging;

D. whereas, in its communication of 14 October 2020 entitled 'Chemical Strategy for Sustainability - Towards a Toxic-Free Environment', the Commission committed to a zero-pollution ambition to attain a toxic-free environment to help to protect citizens and the environment better against hazardous chemicals and encourage innovation for the development of safe and sustainable alternatives;

Endocrine-disrupting properties for human health

E. whereas DBNPA is considered as having endocrine-disrupting properties that may cause adverse effects in humans, and therefore meets the exclusion criterion set out in Article 5(1), point (d), of Regulation (EU) No 528/2012;

F. whereas, in its opinion of 12 September 2023, the BPC therefore concluded that DBNPA should normally not be approved unless one of the conditions in Article 5(2) of Regulation (EU) No 528/2012 is met;

G. whereas Article 5(2), point (c), of Regulation (EU) No 528/2012 provides that active substances meeting the exclusion criteria may be approved if 'not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance';

H. whereas the Commission has concluded that the non-approval of DBNPA as an active substance for use in biocidal products of PT6 would have a disproportionate negative impact on society in comparison to the risks arising from the proposed uses of the substance; whereas the Commission thus considers the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied for those uses;

I. whereas the conclusion of the Commission that the impact of a non-approval of DBNPA would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of DBNPA stems from the opinion of the BPC of 30 November 2021 that bromide is naturally occurring and essential for human life and that, therefore, a threshold of adversity must exist for the thyroid-disturbing effects of bromide;

J. whereas, the BPC, in its opinion of 30 November 2021, however specifies that a quantifiable threshold level cannot be set due to multiple uncertainties, and, in addition it concludes that the already established acceptable daily intake reference values derived by the World Health Organization and the European Medicines Agency cannot be used as safe reference values against the thyroid-disturbing effects of bromide;

K. whereas the exposure to DBNPA-derived bromide from use in biocidal products of PT6 has been evaluated against the reference values from the 2019 European Union report on pesticide residues in food; whereas, based on this assessment, no endocrine disruptive effects in humans would be expected from exposure to DBNPA-derived bromide from the use in biocidal products of PT6, as the contribution of the exposure to DBNPA-derived bromide from use in biocidal products of PT6 to the overall exposure of the population to bromide would be within the natural range of what the European population is already exposed to through the diet;

L. whereas the BPC concluded on this basis that no unacceptable risks of endocrine-disrupting effects would be associated with exposure to DBNPA-derived bromide from use in biocidal products of PT6;

M. whereas, as raised by Sweden in its minority opinion[4], whether a threshold of adversity for endocrine effects exists for bromide because it is naturally occurring and essential for humans should be discussed broadly, that is to say as a principle, and such discussion should not be restricted to DBNPA in order to avoid setting a precedent;

N. whereas the European Food Safety Authority (EFSA) recommended in its scientific opinion[5] adopted on 20 November 2024 and published on 28 January 2025 that, for a complete risk assessment of bromide, further studies should be performed for a robust dietary exposure assessment and a more accurate risk assessment; whereas this raises a doubt as to whether exposure of humans to DBNPA-derived bromide from the use in PT6 is within the natural range of what the European population is already exposed to through the diet;

O. whereas endocrine-related effects frequently occur at low-dose levels and endocrine disruptor substances often do not have a safe threshold[6] and can act at low doses and display non-monotonic dose response curves without evidence of thresholds below which no effect occurs[7];

Endocrine-disrupting properties for the environment

P. whereas DBNPA is considered as having endocrine-disrupting properties that may cause adverse effects in non-target organisms, and therefore it is a candidate for substitution in accordance with Article 10(1), point (e), of Regulation (EU) No 528/2012;

Q. whereas the BPC opinion of 12 September 2023 states that bromide is a naturally occurring substance in the environment, and therefore it must be assumed that a threshold for the endocrine-disrupting effects of bromide exists; whereas with respect to the environment, and unlike in the case of human health, the BPC opinion does not contain information on whether bromide is essential in animals; whereas the assumption of the

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4 https://echa.europa.eu/documents/10162/36b14553-a794-13bc-fe10-b21689c8931c.

5 Scientific opinion of the EFSA Scientific Committee on 'Risks to human and animal health from the presence of bromide in food and feed', EFSA Journal 2025;23(1):e9121, https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2025.9121.

6 Scientific report of the Endocrine Active Substances Task Force. EFSA Journal 2010;8(11):1932,https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2010.1932.

7 Solecki, R., Kortenkamp, A., Bergman, Å., Chahoud, I., Degen, G.H., et al, 'Scientific principles for the identification of endocrine-disrupting chemicals: a consensus statement', *Archives of Toxicology*, February 2017; 91, pp. 1001-1006, https://link.springer.com/article/10.1007/s00204-016-1866-9.

existence of a threshold in the environment therefore appears to rely solely on the fact that the substance is naturally occurring;

R. whereas the BPC opinion of 12 September 2023 underlines that there can be large disparities in the background concentrations of bromide in the aquatic environment from one area to another, as the background concentrations of bromide are influenced by natural factors and anthropogenic sources, with a clear indication that concentrations of bromide are higher in areas of industrial activity;

S. whereas, therefore, it cannot be excluded that the background concentration of bromide in the exposed areas could be exceeded due to releases from DBNPA for use in biocidal products of PT6 and the DBNPA-derived bromide may increase the concentration of bromide in the environment;

T. whereas, due to the many factors influencing the background concentration of bromide in the environment, the BPC concluded in its opinion of 12 September 2023 that a threshold for the endocrine-disrupting effects of bromide on the environment could not be established;

U. whereas the information presented in the opinion of the BPC of 12 September 2023 is insufficient to be able to conclude whether the additional exposure from the use of biocidal products of PT6 use poses no unacceptable risk to organisms;

Appropriateness of risk mitigation measures

V. whereas the draft implementing regulation provides for specific risk mitigation measures for the placing on the market of biocidal products containing DBNPA as an active substance and of treated articles;

W. whereas, the risk mitigation measures provided for in the draft 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 DBNPA, and to 'pay particular attention' to industrial users without further specification as to the nature of those requirements;

X. whereas, in its decision in case 12/2013/MDC of 18 February 2016 on the practices of the European Commission regarding the authorisation and placing on the market of plant protection products (pesticides)[8], 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;

Y. whereas the risk mitigation measures described in the draft implementing regulation therefore cannot be considered to be of a binding nature or sufficient to ensure a high

[8] https://www.ombudsman.europa.eu/en/case/en/40760.

level of protection of human health and the environment, considering that a threshold for the endocrine-disrupting effects of bromide on the environment could not be established;

Trade of treated articles within the Union

Z. whereas biocidal products of PT6 containing DBNPA may only be authorised for use in Member States where the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is met as DBNPA meets the exclusion criteria of Article 5 of that Regulation with regard to its endocrine-disrupting properties related to humans;

AA. whereas, while the use of biocidal products containing DBNPA will only be authorised 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 articles treated with such biocidal products from or between any Member States, even those Member States that do not consider the conditions of Article 5(2) as being met;

AB. whereas, under the draft implementing regulation, only a label providing the limited information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012 will be required for treated articles and that information will not be subject to regulatory scrutiny before the article is placed on the market; whereas, since the placing on the market of treated articles is not subject to any restriction, it will not be possible to control the use of an active substance in treated articles through any other provision if appropriate conditions are not specified in the approval decision for the active substance in accordance with Article 58(2) of Regulation (EU) No 528/2012;

AC. whereas, in Commission Implementing Regulation (EU) 2022/1950[9], the Commission decided for the first time, as part of the risk mitigation measures to be applied in accordance with Article 58 of Regulation (EU) No 528/2012 and adopted at the active substance approval stage, to restrict the placing on the market of treated articles unless Member States proactively decide to authorise them on their territory; whereas the Commission has not applied similar measures to the approval of DBNPA as an existing active substance for use in biocidal products of PT6;

AD. 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;

AE. 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 the Commission not to approve DBNPA as an existing active substance for use in biocidal products of PT6;

AF. whereas the approval of DBNPA is therefore inappropriate, demonstrates non-observance of the precautionary principle, and constitutes a violation of the legal obligation of the Commission to ensure a high level of protection of both human health and the

[9] Commission Implementing Regulation (EU) 2022/1950 of 14 October 2022 renewing the approval of creosote as an active substance for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 269, 17.10.2022, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2022/1950/oj).

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 DBNPA as an existing active substance for use in biocidal products of PT6 for a period of five years is not proportionate in light of the unacceptable risks DBNPA poses to human health and the environment, in view of:

   (a) the available information and considering the lack of scientific consensus on the methodology for setting thresholds for humans and animals in the environment, making it not possible currently to conclude whether risks from use of DBNPA-derived bromide in PT6 are acceptable or not,

   (b) the inappropriateness of the risk mitigation measures and their non-binding character given that no threshold for the endocrine-disrupting effects of bromide in humans and in the environment could be established, and given the lack of protection against risks arising from the trade of treated articles on the internal market;

4. Calls on the Commission to withdraw its draft implementing regulation and to submit a new draft to the committee, which proposes non-approval of DBNPA, as approving DBNPA, 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;

5. Reiterates that approving an active substance which has endocrine-disrupting properties poses unacceptable risks to human health in relation to uses such as those proposed for approval in the Commission draft implementing regulation;

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