EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving 2,2-Dibromo-2-cyanoacetamide (DBNPA) as an existing active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

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(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 a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes 2,2-Dibromo-2-cyanoacetamide (DBNPA) (EC No: 233-539-7; CAS No: 10222-01-2).

(2) DBNPA has been evaluated for use in biocidal products of product-type 4, food and feed area, as described in Annex V to Regulation (EU) No 528/2012.

(3) Denmark 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 27 December 2016. After the submission of the assessment report, discussions took place in technical meetings organised by the Agency.

(4) In accordance with Article 75(1), point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee is responsible for preparing the opinion of the Agency regarding applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency on 25 June 2019 ("the opinion of 25 June 2019")[3], having regard to the conclusions of the evaluating competent authority.

(5) According to the opinion of 25 June 2019, DBNPA 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

[1] OJ L 167, 27.6.2012, p. 1.

[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).

[3] Biocidal Products Committee Opinion on the application for approval of the active substance: 2,2-Dibromo-2-cyanoacetamide (DBNPA), Product type: 4, ECHA/BPC/225/2019, adopted on 25 June 2019.

(EU) 2017/2100[4]. DBNPA therefore meets the exclusion criteria set out in Article 5(1), point (d), of Regulation (EU) No 528/2012. The opinion of 25 June 2019 also considered that the risks to human health and the environment of using the representative biocidal product presented in the application for approval of DBNPA for product-type 4 were acceptable subject to appropriate risk mitigation measures, but also concluded that, given the exposure of humans and the environment to DBNPA, a risk related to endocrine-disrupting properties cannot be excluded.

(6) Pursuant to Article 5(2) of Regulation (EU) No 528/2012, an active substance meeting the exclusion criteria may only be approved if it is shown that at least one of the conditions for derogation set out in that Article is met. When deciding whether an active substance may be approved on that basis, the availability of suitable and sufficient alternative substances or technologies is to be a key consideration.

(7) The Commission, with the support of the Agency, carried out a public consultation between 11 October 2019 and 10 December 2019 ("the public consultation") in order to gather information as to whether the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied.

(8) The opinion of 25 June 2019 and the contributions to the public consultation were discussed by the Commission with the Member States representatives in the meeting of the Standing Committee on Biocidal Products of February 2020. The Commission asked the Member States to indicate whether they consider that at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 would be met in their respective territory, and to provide justification. It was concluded that there was a need to further analyse the information provided by the applicant during the consultation to assess whether the condition in Article 5(2), point (a), could be considered met. On 8 July 2020, pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency[5] to revise its opinion and clarify whether a safe threshold may be derived in relation to the endocrine-disrupting properties of DBNPA, to assess the contribution of the use of DBNPA as a biocidal active substance to the average daily bromide consumption and to the environmental background, and to conclude whether the risks for human health and for the environment could be considered acceptable or not.

(9) The Biocidal Products Committee adopted the revised opinion of the Agency on 30 November 2021 ("the opinion of 30 November 2021")[6], having regard to the conclusions of the evaluating competent authority.

(10) According to the opinion of 30 November 2021, the risks associated with the exposure to DBNPA-derived bromide use in product-type 4, including the risks resulting from its endocrine-disrupting effects, are considered acceptable for humans and the environment for the representative biocidal product presented in the application for approval, subject to appropriate risk mitigation measures. Therefore, without prejudice to the provisions of Article 5(2) of Regulation (EU) No 528/2012, biocidal products of

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4 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).

5 Mandate requesting ECHA an opinion under Article 75(1)(g) of the BPR, "Evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4"

6 Biocidal Products Committee Opinion on the application for approval of the active substance: 2,2-Dibromo-2-cyanoacetamide (DBNPA), Product type: 4, ECHA/BPC/300/2021, adopted on 30 November 2021.

product-type 4 containing DBNPA may be expected to satisfy the requirements laid down in Article 19(1), point (b), of that Regulation.

(11) The opinion of 30 November 2021 and the contributions to the public consultation were discussed by the Commission with the Member States representatives in the meetings of the Standing Committee on Biocidal Products of March 2022 and June 2022. The Commission again asked the Member States to indicate whether they consider that at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 would be met in their respective territory, and to provide justification. No Member State indicated that those conditions would be met in its territory, in the light of the availability of alternatives, which is a key consideration in the context of Article 5(2) of Regulation (EU) No 528/2012.

(12) In fact, based on the information collected and the views expressed by Member States, suitable and sufficient alternative substances or technologies are available. The representative biocidal product presented by the applicant in the application for approval is a product used for the disinfection of food processing vessels by professional/industrial users (such as industrial mayonnaise or yogurt producing facilities, fermenters for beer or other fermented products). The opinion of 30 November 2021 lists several active substances as potential alternatives[7]. 26 active substances are already approved for use in biocidal products of product-type 4, while another 37 active substances are still under examination within the work programme for the systematic examination of existing active substances pursuant to Article 89 of Regulation (EU) No 528/2012. Moreover, other active substances have been approved under Regulation (EU) No 528/2012 following the assessment of representative biocidal products similar to the representative biocidal product presented in the application for the approval of DBNPA[8]. No evidence has been submitted by the applicant showing that any of those active substances could not be used for the same purpose as DBNPA. Lastly, several Member States representatives indicated during the discussions in the Standing Committee on Biocidal Products that no biocidal products containing DBNPA for product-type 4 were registered under their national rules or placed on their market despite the presence of food processing industries on their territory, and that alternative active substances and biocidal products were available on their territory for the same or similar use, like biocidal products containing peracetic acid or hydrogen peroxide.

(13) Furthermore, the representative biocidal product presented by the applicant cannot be considered as a product used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment, as, according to the opinion of 30 November 2021, its use may lead to the presence of residues in disinfected bottles even after rinsing and may lead to releases into the environment via waste water. Although the opinion of 30 November 2021 concludes that the risks to humans and to the environment could be considered acceptable, in view of the positions expressed by Member States representatives in the Standing Committee on

[7] Biocidal Products Committee Opinion on the application for approval of the active substance: 2,2-Dibromo-2-cyanoacetamide (DBNPA), Product type: 4, ECHA/BPC/300/2021, adopted on 30 November 2021, on page 16: 2-phenoxy ethanol, Active chlorine (generated from sodium chloride by electrolysis or released from hypochlorous acid), Active chlorine (released from calcium hypochlorite), Active chlorine (released from sodium hypochlorite), Bromoacetic acid, C(M)IT/MIT, Decanoic acid, Glutaraldehyde, Hydrogen peroxide, Iodine, L(+) lactic acid, Octanoic acid, Peracetic acid, Peracetic acid generated from tetraacetylethylenediamine (TAED) and sodium percarbonate, PHMB (1415;4.7), PHMB (1600;1.8), Polyvinyl-pyrrolidone iodine, Propan-1-ol, Propan-2-ol, Salicylic acid.

[8] For instance: lactic acid, octanoic acid, decanoic acid, peracetic acid or glutaraldehyde.

Biocidal Products, it is not concluded that the risks could be considered negligible. Considering in addition that suitable and sufficient alternative substances or technologies are available, the condition in Article 5(2), point (a), of Regulation (EU) No 528/2012 is therefore not met.

(14) No specific information or justification has been submitted by the applicant to demonstrate that DBNPA would be essential to prevent or control a serious danger to human health, animal health or the environment. Considering in addition that suitable and sufficient alternative substances or technologies are available, the condition in Article 5(2), point (b), of Regulation (EU) No 528/2012 is therefore not met.

(15) No information has been submitted by the applicant that demonstrates that the non-approval of DBNPA would have disproportionate negative impacts on society when compared to the risks to human health, animal health or the environment arising from the use of the substance. Considering in addition that suitable and sufficient alternative substances or technologies are available, the condition in Article 5(2), point (c), of Regulation (EU) No 528/2012 is therefore not met.

(16) Consequently, the applicant has not shown that any of the conditions in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is met. It is therefore appropriate not to approve DBNPA for use in biocidal products of product-type 4.

(17) 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

2,2-Dibromo-2-cyanoacetamide (DBNPA) (EC No: 233-539-7; CAS No: 10222-01-2) is not approved as an active substance for use in biocidal products of product-type 4.

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,

For the Commission
The President
Ursula VON DER LEYEN