EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

Mandate requesting ECHA opinions 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"

1. Background

(1) During its 31st meeting in June 2019, the Biocidal Products Committee of ECHA adopted its final opinion[1] on the application for approval of the active substance DBNPA for use in biocidal products of product type 4.

(2) The review of DBNPA took place in a specific context where the scientific criteria for the determination of endocrine-disrupting (ED) properties came into application while the assessment of the active substance was almost finalised. This situation required the BPC to update its draft opinion to assess DBNPA in the light of these ED criteria. The BPC concluded that: "*The risk assessment showed no unacceptable risks for DBNPA for humans and for the environment including the environmental relevant metabolite CAM. For the endocrine disrupting properties of this substance a potential exposure threshold cannot be identified, therefore no safe exposure level can be demonstrated for DBNPA in regard to its ED properties. DBNPA is considered to have endocrine disrupting properties relevant for both humans and non-target organisms in the environment*."

(3) This statement however lacks clarity as the committee concludes that the risk assessment showed no unacceptable risks for this substance although it does not provide a clear conclusion on the level of risks of using DBPNA considering its ED properties.

(4) Quantitative risk assessment builds on the fact that, for a given substance, a biological threshold exists for a given toxicological effect, below which exposure does not exert any adverse effect in organisms. Quantitative risk assessment is feasible, when such a threshold can be derived using the (eco)toxicological data available. It is not clear from the opinion whether the existence of a threshold for ED properties was considered by the BPC, and if considered, on which data and scientific considerations it was based and which conclusions were drawn.

(5) DBNPA meets the criteria for the identification of endocrine disruptors for human health and should not normally be approved unless it can be shown that at least one of the conditions of Article 5(2) of the BPR is met. This

[1] The opinions of ECHA are available here

active substance is also recognised as having ED properties for non-target animals, which is important information to take into account to assess whether the risks to the environment is negligible as required under Article (5)(2)(a) of the BPR.

(6) In order to collect information for the assessment of whether one or more of the conditions of Article 5(2) of the BPR are met, the Commission organised a public consultation from 11 October to 10 December 2019[2].

(7) During the 67th meeting of the Standing Committee on Biocidal Products (SCBP) on 7 February 2020, the Commission presented the outcome of this consultation and its preliminary conclusions to the Member States as whether or not one of the conditions of Article 5(2) is met for DBNPA.

(8) During the discussions in the SCBP, it was concluded that there is a need to further analyse the information provided by the applicant during the consultation to assess whether the condition (a) of Article 5(2) could be considered met.

2. The questions referred to ECHA

(9) Following the background information mentioned above and the lack of clarity of the opinion adopted at BPC-33, an opinion of ECHA is required on the risks for human health and for the environment from the use of DBNPA that integrates the risks from the ED properties of DBNPA.

(10) As regards to the risks for human health, ECHA is required to :

(a) Based on available information, clarify whether a safe level (threshold) can be determined for the ED properties of DBNPA-derived bromide for human health, and if such threshold can be established, what would be this level.

(b) Clarify the level of the risks for humans by:

1. Considering the acceptable daily intake for bromide derived by WHO and the European Medicines Agency for bromide salts used as anti-epileptics in humans, and considering them in the risk assessment if relevant.

2. Taking into account the levels of bromide that are considered essential for human life.

3. Assessing the contribution of the use of DBNPA as a biocide to the average daily bromide consumption.

4. Assessing the level of risk for human health, either by a quantitative assessment or a qualitative assessment

[2] https://echa.europa.eu/fr/derogation-to-the-exclusion-criteria-previous-consultations/-/substance-rev/24101/term

5. Providing an opinion whether the risks can be considered acceptable or not.

(11) As regards to the risks for the environment, ECHA is required to:

(a) Based on available information, clarify whether a safe level (threshold) can be determined for the ED properties of DBNPA-derived bromide for the environment, and if such threshold can be established, what would be this level.

(b) Determine the background level of bromide in the environment

(c) Determine the exposure of non-target organisms to DBNPA-derived bromide.

(d) Clarify the level of the risks to the environment by:

1. Assessing the level of risk for the environment, either by a quantitative assessment or by a qualitative assessment by considering among others the DBNPA-derived bromide concentration and the background level of bromide.

2. Providing its opinion whether the risks can be considered acceptable or not.

(12) Based on the outcomes of this assessment for the human health and the environment, the BPC should revise its current opinion in order to provide an updated consolidated version of its opinion on DBNPA.

(13) The opinion should summarise the information used for developing the opinion and the adequateness of this information for the opinion.

3. Elements to be considered by ECHA when addressing this question

(14) ECHA is invited to take into account in particular:

(a) All the data submitted in the application, as well as the conclusions of the discussions in the BPC and its Working Groups.

(b) Any further information submitted by the applicant or other interested parties during the development of this opinion.

(c) The data submitted during the public consultation on this substance organised from 11 October to 10 December 2019, including those submitted by the applicant.

(d) The comments submitted by the Member States following the discussion in the 63rd meeting of the SCBP on the presence on their national markets of possible alternatives to DBNPA and their comments about the level of risks for human health and the environment. A summary of these comments is available in the annex to this mandate.

4. Deadline for the ECHA opinions

(15) ECHA shall adopt its opinion by 31 December 2021 at the latest.

Annex I

Summary Comments from the Member States following the discussions in the 67th meeting of the Standing Committee on Biocidal Products on the existence of PT4 products containing DBNPA on their territory and the availability of alternatives

Member State	**Are there DBNPA products on the MS market?**	**What are the alternative to DBNPA products on the MS market?**	**Has the MS assessed and have a preliminary view whether one or the conditions for derogation under Article 5(2) can be considered met or not?**
MS1	1 PT 4 product containing DBNPA	375 PT4 products with different active substance(s)	Not assessed
MS2	No PT 4 product with DBNPA on the market	Alternative products are available on the market	A derogation under article 5(2)(a) should be investigated
MS3	1 PT 4 product containing DBNPA	No data	Not assessed
MS4	6 PT 4 products containing DBNPA registered. Only 3 regularly placed on the market	Alternative products are available on the market	Not assessed
MS5	No PT 4 product with DBNPA on the market	Alternative products are available on the market	Not assessed
MS6	No PT 4 product with DBNPA on the market	470 PT4 products with different active substance(s) 9 products for disinfection of pipelines	Not assessed
MS7	No PT 4 product with DBNPA on the market	Alternative products are available on the market	Not assessed
MS8	No PT 4 product with DBNPA on the market	332 PT 4 products with different active substance(s)	Not assessed
MS9	No PT 4 product with DBNPA on the market. No need for the substance on their	382 PT4 products registered under the transitional regime and containing 15 different active substances but not	Conditions are not met even for the negligible risks.

	market	DBNPA. However, impossible to verify whether the uses of these products match the uses for DBNPA.	Reasoning: Negligible exposure = a Margin of Expose of e.g. 1000 between the no-observed adverse effect level (NOAEL) for the critical effect and the exposure. In this case, the critical NOAEL seem to be 1.4 mg DBNPA/kg bw/day, based on hyperplasia of the thyroid follicular cells in a two-year rat study. To have a Margin of Expose of 1000, the exposure should not exceed 0.0014 mg DBNPA/kg bw/day. According to applicant data, the secondary exposure for both adults and toddlers is below 0.0014 mg DBNPA/kg bw/day. However, the mixing and loading scenario exceeds 0.0014 mg DBNPA/kg bw/day. Due to this fact, we do not consider the exposure negligible and, on the basis of the hazard assessment of DBNPA, this means that the risk cannot be considered negligible