

Development of Legislation and Other Instruments

## **BPC-48: SE minority opinion on DBNPA, product-type 6**

Sweden has two concerns over the opinion, related to 1) the lack of proposals for restriction of the use in treated articles and 2) definition of a threshold and the conclusions of the risk assessment with respect to endocrine disrupting properties.

### *Treated articles*

DBNPA meets the exclusion criteria of Article 5 of Regulation (EU) No 528/2012 with regard to its endocrine disrupting properties related to humans. Consequently, the opinion proposes that DBNPA should normally not be approved unless one of the conditions for derogation set in Article 5(2) of BPR is met. Sweden is of the opinion that similar restrictions must be set on the placing of the market of treated articles. In other words, the placing on the market of treated articles should be restricted to uses for which member states identify that at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is applicable. We emphasise that 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 the Biocidal Products Regulation. Since the committee decided not to include restrictions on treated articles in the opinion, Sweden submits this minority opinion.

Swedish Chemicals Agency

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**Mailing address**

Box 2  
SE-172 13 Sundbyberg

**Visit & delivery**

Vasagatan 12 D  
172 67 Sundbyberg

**Invoicing address**

PEPPOL-ID:  
0007:2021003880

**Phone & mail**

+46 8 519 41 100  
kemi@kemi.se

**Web site**

[www.kemi.se](http://www.kemi.se)

**VAT no**

202100-3880

*Threshold and the conclusions of the risk assessment with respect to endocrine disrupting properties*

Sweden's concern over the opinion<sup>1</sup> is that we believe that it is too early to make a general statement, as the opinion in effect does, that a threshold of adversity for endocrine effects must exist because bromide is naturally occurring and essential for humans. The issue should be discussed first as a principal and not be restricted to the present substance in order to avoid setting a precedent. With respect to the environment, the opinion does not contain information on whether bromide is essential in animals. Thus, the assumption of the existence of a threshold in the environment appears to rely solely on the fact that the substance is naturally occurring. We doubt that it is appropriate to make such a generalised statement.

The environmental levels of bromide resulting from the representative use in product type 6 is within the background concentrations in the environment. The opinion suggests therefore that the risk from DBNPA in PT 6 can be considered acceptable. However, we note that a large part of the variation is due to the large regional variation in bromide levels in the environment (mainly due to distance from the sea). Therefore, there will be places where the input of bromide from DBNPA might exceed the natural background considerably. The species forming the ecosystems in such regions are unlikely to be adapted to high background levels. Any possible endocrine disrupting (ED) effects resulting from the background concentration are not known, as currently no threshold can be derived for the ED properties of DBNPA-derived bromide.

Considering that the representative use of this product is in paper mills, the opinion suggests that the exposure from this use is minor compared to the bromide exposure from other anthropogenic sources. This might be true for certain industrialised regions, but the information as presented in the opinion

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<sup>1</sup> We would like to clarify that there are certain aspects of the BPC opinion that Sweden can agree with. We agree that, based on available information, a threshold cannot be determined due to multiple uncertainties (which are listed in an annex to the BPC opinion). We agree with the opinion that previously established reference values from other institutions are not appropriate for use when assessing the level of risk against the endocrine disruptive properties of bromide. Furthermore, we also agree that based on available information it is not currently possible to determine the minimum systemic levels of bromide essential for human life. We note that it could not be established whether the current average daily intake of bromide is safe or not.

is insufficient to be able to conclude whether or not the additional exposure from the PT6 use poses an acceptable risk to environmental organisms.

Based on the available information and considering the lack of broader agreement on the methodology for setting thresholds in humans and animals in the environment, it is, in our view, currently not possible to conclude whether risks from use of DBNPA in PT6 are acceptable or not.

Since the majority of the committee members decided to support the opinion, Sweden submits this minority opinion.