

Development of Legislation and Other Instruments

BPC-41: SE minority opinion on DBNPA, product type 4

Disclaimer: This minority opinion is made in reference to the draft opinion presented to the BPC (29 October 2021). Since the final opinion was not available at the time of writing this minority opinion, we cannot take into account possible changes or amendments made to the wording of the final opinion.

Sweden's principal concern over the opinion¹ 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. With respect to the environment, the opinion does not contain information on whether bromide is essential in animals. 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 4 are within the background concentrations in the environment, although in the high end of the large range reported in literature. The opinion suggests that the risk from DBNPA in PT4 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 likely not 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 industrial applications like breweries and dairies, the opinion suggests that the exposure from this use is

¹ 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.

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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 is insufficient to be able to conclude whether or not the additional exposure from the PT4 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 PT4 are acceptable or not.

Finally, we would like to remark that at this stage, there is no need to answer the question whether risks are acceptable or not, due to the primary need to clarify whether the risk to humans, animals or the environment from exposure to the active substance is negligible. This is needed in order to decide whether the active substance DBNPA is eligible for derogation in accordance with Article 5.2.a). If the risk is found to be negligible, then it is also acceptable. We believe that derogations 5.2.b) or c) are not applicable for this substance in PT4. However, for other product types or other substances with ED properties the question of “acceptable risk” might be meaningful.

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