

## SUMMARY OF DECISION OF 3 NOVEMBER 2020 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-009-2019

(Biocidal Products Regulation – Data and cost-sharing – Right to be heard –
Every effort – Contractual agreement making the sharing of data conditional on the prior
establishment of chemical similarity – Payment of a share of the cost –
Manifestly unreasonable amount)

## Factual background

The appeal concerned the sharing of data and costs relating to the active substance tetrakis(hydroxymethyl)phosphonium sulphate (2:1) (EC No 259-709-0; 'THPS').

Solvay Solutions UK Limited (the 'Appellant') is the data owner for several studies on THPS within the meaning of Article 59 of the Biocidal Products Regulation.

On 14 November 2016, the Agency adopted a decision grainting another company, Dow Benelux B.V., permission to refer to the studies pursuant to the second subparagraph of Article 63(3) of the Biocidal Products Regulation.

On 7 March 2018, the Board of Appeal annulled that decision.

On 6 May 2019, the Agency adopted the contested decision which again granted Dow Benelux B.V. permission to refer to the studies.

The Appellant requested the Board of Appeal to annul the contested decision.

Main findings of the Board of Appeal

The Board of Appeal found that the Agency had breached the Appellant's right to be heard, as it did not give the Appellant a possibility to make observations on the implications of the first decision of the Board of Appeal before adopting its second decision. The Board of Appeal therefore annulled the Contested Decision and examined whether the conditions for granting Dow Benelux B.V. permission to refer had been fulfilled.

The Board of Appeal found that Dow Benelux B.V. had failed to comply with the two conditions for obtaining permission to refer, set out in the second subparagraph of Article 63(3) of the Biocidal Products Regulation.

First, the Appellant and Dow Benelux B.V. had signed a contractual agreement according to which the they agreed to stop negotiating a permission to refer to the studies if chemical similarity between their sources of THPS could not be established. Neither the Agency nor the Board of Appeal are competent to declare such an agreement invalid, that power being reserved to the competent national bodies, such as national courts. Dow Benelux B.V. pursued the negotiations despite the fact that chemical similarity between the two sources of THPS could not be established, without seeking a declaration of invalidity of the agreement by a competent body. Therefore, the first confition set out in the second subparagraph of Article 63(3) of the Biocidal Products Regulation was not fulfilled as Dow Benelux B.V. had not made every effort to reach an agreement on data and cost-sharing.

Second, the payment made by Dow Benelux B.V. to the Appellant as a share of the cost of the studies was manifestly unreasonable in the circumstances of the case. Therefore, the second condition set out in the second subparagraph of Article 63(3) of the Biocidal Products Regulation was not fulfilled.

As result, the Board of Appeal upheld the appeal and denied the application of Dow Benelux B.V. for permission to refer to the studies.

**NOTE:** The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 91(1) of the REACH Regulation. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.

Unofficial document, not binding on the Board of Appeal

The full text of the decision is available on the Board of Appeal's section of ECHA's website: <a href="http://echa.europa.eu/about-us/who-we-are/board-of-appeal">http://echa.europa.eu/about-us/who-we-are/board-of-appeal</a>