

**SUMMARY OF DECISION OF 7 MARCH 2018 OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

Case number: A-014-2016

(Biocidal products – Data sharing dispute – Every effort – Permission to refer – Chemical similarity – Contractual freedom)

Factual background

The European Chemicals Agency granted a company (the 'prospective applicant') permission to refer to certain studies owned by the Appellant concerning the biocidal active substance tetrakis(hydroxymethyl)phosphonium sulphate (2:1) (the 'active substance'), in accordance with Article 63(3) of the Biocidal Products Regulation (the 'BPR').

The prospective applicant wanted access to the studies owned by the Appellant so that they could be used in an application for inclusion in the list of suppliers of biocidal products and substances which have not been approved and which the Agency publishes pursuant to Article 95 of the BPR.

The prospective applicant and the Appellant agreed contractually that chemical similarity between their sources of the active substance had to be established by a third party. The contract included a clause according to which the parties would have to stop negotiating a data sharing agreement if no chemical similarity could be established.

After a third party consultant concluded that chemical similarity was inconclusive, the Appellant and the prospective applicant disagreed as to whether data sharing negotiations should continue. The Appellant considered that the negotiations had to stop as the prospective applicant had not proven chemical similarity. The prospective applicant considered that the negotiations should continue. The prospective applicant then requested the Agency to perform a second chemical similarity assessment. After this assessment yielded a negative result, the Appellant and the prospective applicant still disagreed as to whether they should continue negotiating.

In the Contested Decision, the Agency found that the Appellant failed to make every effort in the data sharing negotiations because it refused to continue the data sharing discussions and required that chemical similarity had to be established.

The Appellant lodged an appeal before the Board of Appeal seeking the annulment of the Contested Decision.

Main findings of the Board of Appeal

The Board of Appeal recalled that the Appellant and the prospective applicant had the contractual freedom to insert a clause relating to chemical similarity in their agreement.

As the result of the chemical similarity assessment performed by the third party consultant was inconclusive, chemical similarity had not been established. Therefore following the terms of the contract mutually agreed by the Appellant and the prospective applicant, data sharing negotiations had to stop. As the Board of Appeal established that the contract mutually agreed by the Appellant and the prospective applicant applied, the assessment of the Appellant's and the prospective applicant's conduct in the negotiations had to be examined in this context.

The Board of Appeal considered that the circumstances of the case demonstrated that the Appellant was open to resolving the chemical similarity issue irrespective of the findings of the consultant. It also considered that by insisting on the continuation of the negotiations without having established chemical similarity, the prospective applicant acted contrary to the mutually agreed contract terms.

The Board of Appeal therefore concluded that the Agency made an error because it had not assessed the efforts of both parties to the data sharing dispute in a balanced manner ignoring the Appellant's efforts and focussing its assessment primarily on the prospective applicant's efforts. The Board of Appeal annulled the Contested Decision.

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 77 of the BPR. 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:
<http://echa.europa.eu/about-us/who-we-are/board-of-appeal>