

**SUMMARY OF DECISION OF 29 MAY 2018 OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

Case number: A-007-2016

(Biocidal products – Data sharing dispute – Every effort – Cost calculation method – Value of studies)

Factual background

The European Chemicals Agency denied the Appellant permission to refer to certain studies owned by another company (the 'data owner') for the biocidal active substance alpha-cypermethrin (the 'active substance'), in accordance with Article 63(3) of the Biocidal Products Regulation (the 'BPR').

The Appellant wanted access to certain studies, so that it could be included in the list of suppliers of non-approved biocidal products and substances, which the Agency publishes pursuant to Article 95 of the BPR.

The Appellant disagreed with the price the data owner asked for these studies and with the cost calculation method of the final price. The Appellant considered in particular that the data owner had neither sufficiently itemised its offer nor justified the cost calculation method.

The Appellant proposed to move away from a negotiation on the value of the studies and to agree on a business deal consisting of a fixed price for the requested studies. The Appellant and the data owner continued to negotiate and in this context, the data owner suggested submitting the calculation of the value of the studies to a third party. The Appellant considered that this proposal meant that the negotiations were regressing by going back to the value of the studies when the negotiations had in fact moved on to a discussion on the business deal. At this point the Appellant submitted a data sharing dispute to the Agency.

The Agency adopted the Contested Decision and found that the Appellant failed to make every effort by rejecting the data owner's proposal for a third party to calculate the value of the studies.

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 stated that the Agency's assessment of whether every effort has been made should consider the negotiations as a whole and the actions of the parties throughout those negotiations.

The Agency had given disproportionate importance in the Contested Decision to the data owner's proposal for a third party valuation of the studies. The Contested Decision focussed only on the data owner's proposal to get the value of the studies assessed by a third party and ignored that the fact that the data owner had not transparently explained the different elements of the cost calculation method. As the Appellant and the data owner still disagreed on the cost calculation method, the data owner's proposal for a third party valuation of the studies would likely not have helped to find an agreement on data sharing.

Finally, the Agency had not recognised in the Contested Decision that the Appellant had made a major effort by proposing a business deal to unblock the negotiations thereby moving them away from a study by study approach.

As the Agency had failed to take sufficiently into account in the Contested Decision the Appellant's efforts throughout the whole negotiations, the Board of Appeal concluded that the Agency did not consider all the facts of the case in arriving at its decision and made an error of assessment.

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>*