

SUMMARY OF THE DECISION OF 21 MAY 2024 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case A-011-2022

(Biocidal Products Regulation – Data-sharing – Every effort to reach an agreement on fair, transparent and non-discriminatory terms – Allegation of a breach of Article 95 – Error of assessment – Right to property)

Background

The appeal concerned the sharing of data and costs relating to the substance silicium dioxide/kieselguhr (the **Substance**)¹ under the Biocidal Products Regulation (**BPR**)².

The Appellant, Biofa GmbH, is the sole authorised supplier of the Substance currently included in the list under Article 95 of the BPR (the **Article 95 list**). Another company, Armosa Tech SA (the **Intervener**), submitted to the Agency an application for permission to refer to data submitted to the Agency by the Appellant.

By the Contested Decision, the Agency granted the Intervener permission to refer to the data at issue, subject to the payment to the Appellant of a share of the costs. The Appellant requested the Board of Appeal, amongst other things, to annul the Contested Decision.

Main findings of the Board of Appeal

Article 63(3) of the BPR provides that where the prospective applicant seeks permission to refer to protected data from the Agency, the Agency must grant the prospective applicant permission to refer if (i) every effort has been made to reach an agreement, and (ii) the prospective applicant has paid the data owner a share of the cost of the data.

It follows from a combined reading of Articles 63(3) and (4) of the BPR that the first of the conditions referred to in the previous paragraph is fulfilled if every effort has been made to reach an agreement on the sharing of data and costs on transparent, fair and non-discriminatory terms.

In the present case, there was no substantive disagreement between the Appellant and the Intervener on the terms for sharing data and costs. The Appellant and the Intervener failed to reach an agreement because the Appellant demanded, as a pre-condition for the sharing of data and costs, the compensation of damages allegedly caused by a potential infringement of Article 95 of the BPR on the part of the Intervener.

Article 63 of the BPR does not require a prospective applicant to compensate such damages. It follows from the second sentence of Article 63(4) of the BPR, and from the repeated use of the term 'cost' in the legal text, that, to obtain permission to refer to protected data, a prospective applicant is not required by law to pay for anything other than a share of the actual cost of generating, gathering, and submitting the data to which it needs to refer. The damages alleged

¹ CAS No 61790-53-2

² Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

by the Appellant were not a cost in that sense, and therefore fell outside the scope of Agency's assessment.

Furthermore, a data owner and a prospective applicant may conclude an agreement to make the sharing of data and costs subject to the fulfilment of additional conditions, such as the prior compensation of alleged damages. However, there was no such agreement between the Appellant and the Intervener.

The Agency was consequently entitled to conclude that every effort had been made to reach an agreement on the sharing of data and costs on transparent, fair and non-discriminatory terms. It also did not infringe the Appellant's fundamental right to the protection of property, fail to take into account the principle of good faith, or commit other errors alleged by the Appellant.

The Board of Appeal therefore dismissed the appeal. The appeal fee was not refunded

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>