

SUMMARY OF DECISION OF 21 SEPTEMBER 2020 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-023-2018

*(Data-sharing dispute – Legal basis – Requirements for data and cost-sharing –
Transparency – Every effort – Sharing of costs – Duties of the Agency)*

Factual background

The Appellant, Oxiteno Europe SPRL, is the lead registrant of a substance, isopentyl acetate. Pursuant to Article 30(3) of the REACH Regulation, the Agency granted a potential registrant (the 'Data Claimant') permission to refer to certain studies which the Appellant had submitted in its registration dossier for that substance.

The Appellant requested the Board of Appeal to annul the contested decision. It argued that the Agency did not have competence to adopt the contested decision and that the Agency breached several legal provisions and made numerous errors of assessment.

Main findings of the Board of Appeal

1. Legal basis of the contested decision and competence of the Agency

The Board of Appeal found that even though the Substance Information Exchange Forums (SIEFs) ceased to be operational on 1 June 2018, the facts that are relevant in the data-sharing dispute between the Data Claimant and the Appellant took place prior to that date. The substantive data and cost-sharing rules set out in Article 30 of the REACH Regulation therefore applied to the present case.

Therefore, Article 30(3) of the REACH Regulation was a valid legal basis and the Agency had competence to grant the Data Claimant permission to refer to information in the Appellant's dossier.

The Board of Appeal found also that pursuant the fourth sentence of Article 30(3) of the REACH Regulation the Agency is empowered to grant or deny a potential registrant permission to refer to the information in a registration dossier that has been previously submitted to the Agency by a registrant of the same substance.

The Board of Appeal also found that it is for national courts, and not for the Agency, to decide how the costs should be shared between the Appellant and the Data Claimant.

2. Assessment of the efforts of the Appellant and the Data Claimant by the Agency

The Board of Appeal found that the Agency correctly based its assessment of the efforts made by the Appellant and the Data Claimant on the exchanges of information between them during the data and cost-sharing negotiations. Both the Appellant and the Data Claimant had a possibility to provide to the Agency all documentation related to the data-

sharing dispute. Therefore, the right to be heard of the Appellant was fully respected.

In light of Article 5 of Implementing Regulation 2016/9, the Agency is required to grant a potential registrant permission to refer if, despite the potential registrant's requests and objections, the previous registrant fails to comply with the requirements for data and cost-sharing to be transparent, fair and non-discriminatory.

The Board of Appeal found that the Appellant failed to provide an itemisation or proof of how the Appellant as a lead registrant and its external consultants incurred administrative costs. The basis for, and the level of, these costs were repeatedly challenged by the Data Claimant in the course of the data and cost-sharing negotiations.

As the Appellant provided neither itemisation nor proof of the challenged costs, it failed to provide the Data Claimant with clear and comprehensible explanations as to how the cost of gathering and submitting the information to the Agency were determined. The Appellant therefore failed to comply with the requirement of transparency.

3. Outcome

The Board of Appeal concluded that the Agency did not make an error of assessment when it found that the Appellant had not made every effort to reach an agreement with the Data Claimant on the sharing of data and costs.

The Board of Appeal therefore dismissed the appeal.

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