

## **SUMMARY OF THE DECISION OF 27 OCTOBER 2020 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

**Case number: A-024-2018**

*(Data and cost-sharing dispute – Opt-out – Access to the joint submission – Error of assessment – Requirements for data and cost-sharing – Every effort)*

### *Factual background*

The Appellant, Symrise AG, is the lead registrant of 3-phenylpropan-1-ol (EC No 204-587-6; the 'Substance'). Since the Appellant and a potential registrant (the 'Data Claimant') did not reach an agreement on the sharing of data and costs for the Substance, the Data Claimant submitted to the Agency an application for permission to refer to certain studies contained in the Appellant's registration dossier for the Substance.

The contested decision was based on Articles 30(3) and 11 of the REACH Regulation, as well as Article 5 of Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing. The contested decision, in effect, consisted of three separate decisions:

- (i) The decision granting the Data Claimant access to the joint submission;
- (ii) The decision setting the Data Claimant a time limit to submit the information necessary to complete its registration dossier; and
- (iii) The decision granting the Data Claimant permission to refer to certain studies which the Appellant had submitted in its registration dossier for the Substance.

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

### *Main findings of the Board of Appeal*

In its Decision of 27 October 2020, the Board of Appeal dismissed the appeal in relation to each of the three separate decisions contained in the Contested Decision.

#### *1. The decision on access to the joint submission*

The Board of Appeal decided that it was not competent to decide on the appeal against the decision on access to the joint submission. This is because such decisions are adopted on the basis of Article 11 of the REACH Regulation which does not fall within the list of appealable decisions set out in Article 91(1) of the REACH Regulation.

#### *2. The decision setting the Data Claimant a time limit to submit the information necessary to complete its registration dossier*

The Board of Appeal decided that the appeal against the part of the contested decision granting the Data Claimant a time limit to update its registration dossier was inadmissible. This is because that part of the decision was not of direct and individual concern to the Appellant as required by Article 92(1) of the REACH Regulation.

### *3. The decision granting the Data Claimant permission to refer*

The data and cost-sharing negotiations between the Appellant and the Data Claimant focused on an agreement concerning the right for the Data Claimant to refer in its registration dossier to information available in the Appellant's registration dossier (a 'letter of access agreement'). The parties also discussed the possibility of the Data Claimant purchasing certain data and submitting that information separately (an 'opt-out agreement') pursuant to Article 11(3) of the REACH Regulation.

The Board of Appeal rejected the Appellant's arguments that the Agency had acted outside the scope of its powers by assessing and deciding on the efforts made by the parties to agree on the sharing of data and costs, including as part of an opt-out.

The Board of Appeal also decided that the Agency did not make an error of assessment in finding that the Appellant had not made every effort to reach an agreement that would be fair, transparent and non-discriminatory.

In relation to the opt-out agreement, the Board of Appeal decided that, contrary to the Appellant's claims, a reimbursement mechanism must be included in a cost-sharing model, unless the parties agree otherwise. As a result, the Agency did not make an error in concluding that, in refusing to discuss the inclusion of a reimbursement mechanism, the Appellant had not made every effort to reach an agreement.

In relation to the letter of access agreement, the Board of Appeal decided that the Appellant had failed to comply with the requirement of transparency as it did not provide the Data Claimant with sufficient itemisation or proof of the administrative costs incurred by the Appellant. The Appellant also abused its position by requesting the Data Claimant to pay a fee to continue negotiations.

The Board of Appeal also decided that a clause in the Appellant's cost-sharing model according to which registrants who are affiliates of a previous registrant are not required to bear a share of costs if they submit their own registration dossier was discriminatory.

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**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 and Article 77(1) of the Biocidal Products 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.

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*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>*