ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 15 APRIL 2019 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-010-2017

(Data-sharing dispute – Article 30 – Assessment of 'every effort' – Requirements for data and cost sharing to be fair, transparent and non-discriminatory)

Factual background

The case concerned a data-sharing decision adopted by the Agency pursuant to Article 30(3) of the REACH Regulation. The contested decision granted four potential registrants of a substance, Acid Orange 7, permission to refer to certain studies which one of the Appellants had submitted in its own registration dossier for that substance.

The Appellants requested the Board of Appeal to annul the contested decision. They argued primarily that the Agency is not competent to assess whether the terms proposed by the parties to share data and costs are fair, transparent and non-discriminatory, and that the Agency made several errors of assessment.

Main findings of the Board of Appeal

1. *Competence of the Agency (paragraphs 51-60 of the decision of the Board of Appeal)*

The Board of Appeal found that – pursuant to Articles 2, 4 and 5(1) of Implementing Regulation 2016/9,[1] which implement Article 30 of the REACH Regulation – the Agency is competent to assess whether the terms proposed by the parties to share data and costs are fair, transparent and non-discriminatory.

2. *Requirements for data and cost sharing to be fair, transparent and non-discriminatory (paragraphs 76-83 of the decision of the Board of Appeal)*

The Board of Appeal examined the requirements for data and cost sharing to be fair, transparent and non-discriminatory, as set out in Articles 2 and 4 of Implementing Regulation 2016/9 and Article 30(1) of the REACH Regulation.

First, as regards the requirement for data and cost-sharing to be transparent, the Board of Appeal found that a previous registrant and data owner must provide clear and comprehensible explanations as to:

- which information is to be shared ('itemisation of data'),
- how the cost of generating the information is determined,
- how administrative costs are determined, and
- how costs are to be shared among registrants.

Second, as regards the requirement for data and cost-sharing to be fair, the Board of Appeal found that a potential registrant can only be required to pay a share of the costs

[1] Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with the REACH Regulation (OJ L 3, 6.1.2016, p. 41)

of generating, gathering and submitting to the Agency the information that it requires for the purposes of its own registration. These costs must moreover be actual in the sense that they can be determined either by proof or by approximation.

Finally, as regards the requirement for data and cost-sharing to be non-discriminatory, the Board of Appeal found that registrants that are in comparable situations must not be treated differently and registrants who are in different situations must not be treated in the same way unless such treatment is objectively justified.

3. *Assessment of the efforts of the parties by the Agency (paragraphs 84 to 90 of the decision of the Board of Appeal)*

The Board of Appeal examined how the Agency should assess a data-sharing dispute. The Board of Appeal found that the Agency's assessment is to determine whether the potential registrant who filed the dispute has made every effort. The Agency's assessment is not to determine whether the previous registrant or data owner has made every effort.

The Agency's assessment should primarily focus on those elements on which the parties could not agree during their negotiations, and which therefore led to the filing of the dispute.

The Agency's assessment should be carried out in a logical sequence. It is only if the previous registrant and data owner has been transparent, and the terms it proposes are therefore clear and comprehensible, that the Agency is in a position to examine whether those terms are also fair and non-discriminatory.

The Agency's assessment must be balanced in the sense that it must take into account the negotiations as a whole, taking into account the actions of both parties and all other relevant circumstances. The Agency must have regard to the development of the negotiations over time.

4. *The Board of Appeal's assessment of the case (paragraphs 91 to 173 of the decision of the Board of Appeal)*

The data-sharing negotiations between the Appellants (including the previous registrant and data owner) and the potential registrants had been unsuccessful because the potential registrants disagreed with the Appellants on four issues:

a. the identification of the studies to which access was being negotiated (i.e. whether studies must be listed by author and title),
b. the calculation of administrative costs,
c. the 8% annual surcharge on the price of a letter of access, and
d. the one-off 15% surcharge.

For each of these four issues, the Board of Appeal examined whether the Appellants had complied with the requirements for data and cost-sharing to be fair, transparent and non-discriminatory.

a. The identification of the studies to which access was being negotiated

The Board of Appeal found that the Appellants had failed to comply with the requirement of transparency. This was because the Appellants should have provided the potential registrants with the titles and authors of those studies and did not do so.

b. The calculation of administrative costs

The Board of Appeal found that the Appellants had complied with the requirement of transparency but failed to comply with the requirement of fairness. This was because the Appellants included in their calculation administrative costs which the potential registrants are not required to share.

c. The 8% annual surcharge on the price of a letter of access

The Board of Appeal found that the Appellants had complied with the requirement of transparency but failed to comply with the requirements of fairness and non-discrimination. The 8% annual surcharge was unfair because the Appellants had set it without regard to the actual costs of generating, gathering and submitting to the Agency the information required for the registration of Acid Orange 7. The 8% annual surcharge was also discriminatory because, by increasing the price in real terms of the same letter of access over time, it treated registrants who are in the same situation differently without an objective justification.

d. The one-off 15% surcharge

The Board of Appeal found that the Appellants had complied with the requirement of transparency but failed to comply with the requirement of fairness. This was because the Appellants failed to establish that the 15% surcharge had been set to cover actual costs of generating, gathering and submitting to the Agency the information required for the registration of Acid Orange 7.

5. Conclusion

The Board of Appeal concluded that the potential registrants had made every effort by consistently challenging the Appellants on the identification of the studies to which access was being negotiated, the calculation of administrative costs, the 8% annual surcharge and the 15% surcharge. Whilst the Appellants did respond to the Interveners' questions, this did not lead to any changes to the proposed terms, which were not found to be transparent, fair and non-discriminatory.

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.
