

SUMMARY OF DECISION OF 4 APRIL 2017 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-001-2016

(Biocidal products – Data sharing costs – Revenues received under the Biocidal Products

Directive – Permission to refer)

Factual background

The European Chemicals Agency granted a company (the 'prospective applicant') permission to refer to certain studies owned by the Appellant concerning the biocidal active substance 3-iodo-2-propynylbutyl carbamate (the 'active substance'), in accordance with Article 63(3) of the Biocidal Products Regulation (the 'BPR').

The Appellant, a participant to a task force of four companies, had submitted studies to the authorities of the relevant Member State for the active substance under the Biocidal Products Directive¹ (the 'BPD').

The Appellant was included in the Article 95 list as a review programme participant for the active substance for six product types. The prospective applicant sought access to the Appellant's data in order to apply to be also included in the Article 95 list.

The negotiations had failed mainly because the prospective applicant and the Appellant disagreed on the method for the calculation of the costs to be shared. The prospective applicant considered that the number of participants to the task force was a relevant factor in the calculation. The Appellant contested this interpretation and suggested a division of the costs by two between itself and the prospective applicant.

In the Contested Decision, the Agency found that the Appellant had failed to make every effort in the data sharing negotiations and considered that the cost calculation method proposed by the Appellant was manifestly unfair to the prospective applicant. The Agency therefore granted the prospective applicant permission to refer to the Appellant's studies. The Agency in particular considered that the Appellant should have taken into account revenues received from the other task force participants under the BPD.

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 found that the Agency correctly applied Article 63(3) of the BPR when it gave the prospective applicant the permission to refer to data.

However, the Board of Appeal observed that the Agency was not entitled to examine whether cost calculation methods are in themselves fair, transparent and non-discriminatory. Nevertheless, the Board of Appeal recognised that an assessment of the fair, transparent and non-discriminatory nature of data sharing negotiations cannot be completely separated from

¹ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1) was repealed by Article 96 of the BPR on 1 September 2013.

the assessment of the negotiations on the cost sharing. Therefore, the Agency should consider whether the parties, when negotiating a calculation method did so in good faith, or in other words, with a real intention to find an agreement. In the present case, the Board of Appeal found that the prospective applicant had demonstrated such an intention and the Agency had therefore correctly concluded that the prospective applicant had made every effort in the negotiations.

The Board of Appeal also found that neither the wording, the context nor the objectives of Article 63(3) require that the payment of a share of the costs should be made before a data sharing dispute is lodged. However, the condition of paying a share of the costs cannot be construed as a simple formal requirement whereby the Agency would automatically grant access to studies by virtue of proof of any kind of payment once it has established that every effort has been made in the negotiations.

Consequently, the Board of Appeal dismissed the appeal.

NOTE: The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions adopted under BPR. 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