EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 17 DECEMBER 2014
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case Number: A-017-2013

(Data sharing – Every effort – Discrimination)

Factual Background

The European Chemicals Agency (hereinafter the 'Agency') granted FW Hempel Metallurgical GmbH (hereinafter the 'Data Claimant') permission to refer to data involving testing on vertebrate animals contained in the joint registration dossier for vanadium (hereinafter the 'Contested Decision'). The Data Claimant had previously submitted a claim to the Agency with a view to obtaining permission to refer to such data following an alleged failure of negotiations with Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein (hereinafter the 'Appellant'). The negotiations had focused primarily on the cost of the letter of access and in particular a 10 % annual cost increase which applied to any purchase of a letter of access after 2010.

In the Contested Decision the Agency concluded that the Appellant had not made every effort to reach an agreement on the sharing of data and their costs in a fair, transparent and non-discriminatory way, as required by Article 30(1) of the REACH Regulation[1]. In particular, the Agency concluded that by making an agreement to share data conditional upon a 10 % annual cost increase, which discriminated against all registrants who are obliged to register after 2010, the Appellant, '… did not contribute to finding a non-discriminatory agreement on data sharing.'

The Appellant requested the Board of Appeal to annul the Contested Decision.

Main findings of the Board of Appeal

In its Decision of 17 December 2014, the Board of Appeal considered that the Agency should not examine whether the actual and precise cost of a letter of access is reasonable and justified. The Board of Appeal observed however that the Agency is entitled to make an assessment of whether the parties to the data sharing dispute made, pursuant to Article 30(1), '… every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way'. The Board of Appeal observed that this requirement should be read as a whole and that the test for the Agency to apply is whether every effort was made bearing in mind the need for the cost sharing to be determined in a fair, transparent and non-discriminatory way. The Board of Appeal considered further that in the present case the Agency was obliged to examine the annual cost increase as this was repeatedly raised by the Data Claimant during the negotiations as a cause of concern and was the principle issue preventing an agreement from being reached.

Having regards to the facts of the present case, the Board of Appeal rejected the Appellant's claim that the Agency had exceeded its competence in its assessment of the data sharing terms. The Board of Appeal considered that the Agency did not examine whether the 10% annual cost increase was justifiable. The Agency rather only examined whether an increase

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p.1; corrected by OJ L 136, 29.5.2007, p. 3). All references to Articles hereinafter concern the REACH Regulation.

payable by future registrants based on the applicable registration deadline, irrespective of the specific amount, was justifiable based on the arguments presented during the data sharing negotiations between the parties.

The Board of Appeal considered that an additional charge which is paid only by registrants who purchase the letter of access after 2010 is de facto discriminatory unless there are legitimate and justifiable reasons for charging additional amounts to later registrants. The Board of Appeal also observed that any cost sharing arrangements must ensure that costs are shared fairly amongst all registrants of the same substance.

In that respect, the Board of Appeal found that the communications between the parties during the data sharing negotiations showed no evidence of a process such to ensure that all costs are ultimately shared fairly between registrants. The Board of Appeal also observed that the use of terms by the Appellant in relation to the 10% annual cost increase such as 'compensation' and the implication of a discount for early registrants were not consistent with costs being shared fairly amongst all registrants.

The Appellant claimed during the proceedings that a reconciliation of costs, including the 10 % annual cost increase, would take place after the 2013 registration deadline. The Board of Appeal concluded however that the Appellant had not made it clear during the negotiations that the reconciliation would include the 10 % annual cost increase. The Agency had therefore been justified, based on the information available from the negotiations between the parties to the data sharing dispute, in concluding that the Appellant '… did not contribute to finding a non-discriminatory agreement on data sharing.'

The Board of Appeal also rejected the Appellant's claim that the Agency should have rejected the data sharing dispute as inadmissible on the grounds that the Data Claimant had not identified the relevant studies to which permission to refer was sought. The Board of Appeal observed that it is the duty of the Agency to clarify the studies to which access is sought in order to ensure that access, if granted, is only given to the data required to cover a claimant's registration requirements, and not other data that may have been part of the initial negotiations. The Board of Appeal however observed that Article 30(1) and (3), and the related Guidance, do not provide that the provision of a precise list of the studies involving testing on vertebrate animals requested during the data sharing dispute is an admissibility criterion that must be satisfied before the Agency can commence its assessment of the data sharing dispute. The Board of Appeal also found that the provision of a complete list is not necessary for the Agency to be able to commence its examination of the data sharing dispute. The Board of Appeal therefore considered that the Agency did not act unlawfully in proceeding with its assessment of the data sharing dispute despite the absence of a precise and accurate list of studies for which permission to refer was sought. The Board of Appeal also found that the lack of an exact list of vertebrate animal studies had no bearing on the success or otherwise of the negotiations and was therefore not relevant in considering whether every effort had been made.

The Board of Appeal also rejected the Appellant's claim that the Agency breached its right to be heard and its rights of defence. The Board of Appeal found that the procedure for the Agency's examination of a data sharing dispute, in particular the opportunity for the parties to such a dispute to receive copies of the respective submissions, is not specifically foreseen in the REACH Regulation. The Board of Appeal, having considered the Charter of Fundamental Rights of the European Union and specifically the right to good administration that includes the right to be heard, found that this right did not include an automatic requirement for submissions to be cross-notified to the parties to a data sharing dispute for their observations or comments. The Board of Appeal observed that the Agency must consider, on a case-by-case basis, what measures need to be taken in order to comply with the fundamental right to be heard.

The Board of Appeal found that, during the data sharing dispute in the present case, only communications between the parties during the data sharing negotiations, and the claims made therein, were considered by the Agency in its assessment of whether every effort had been made. Furthermore, during the appeal proceedings, having received a copy of these documents and many opportunities to do it, the Appellant did not identify any documents, communications or claims concerning the data sharing negotiations between the parties that the Agency had considered as part of its assessment and of which it had not been aware during the negotiations. As a consequence, the Board of Appeal considered that the Appellant's right to be heard was fully respected.

The Board of Appeal also rejected the Appellant's plea alleging that the Agency had relied on evidence incapable of substantiating the conclusion reached in the Contested Decision and the plea alleging that the Agency failed to consider all available information in its evaluation of whether every effort had been made.

In view of the above, the Board of Appeal dismissed the appeal.
