

Announcement of appeal¹

Case	A-005-2015
Appellant	THOR GmbH, Germany
Appeal received on	3 March 2015
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 63(3) of the Biocidal Product Regulation (hereinafter 'the BPR')
Keywords	<i>Data sharing dispute – Permission to refer - Every effort – Precautionary principle- Right to be heard</i>
Contested Decision	[CONFIDENTIAL]
Language of the case	English

Remedy sought by the appellant

The Appellant requests the Board of Appeal to

- annul the Contested Decision and,
- order the Agency to refund the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted by the Agency on 26 January 2015. By this decision and pursuant to Article 63(3) of the BPR, the Agency granted a company (hereinafter 'the Prospective Applicant') a permission to refer to studies owned by the Appellant. This is in the context of a data sharing dispute in particular for the purpose of an application from the Prospective Applicant to be included on the Article 95 list of the BPR as a supplier of the active substance CIT/MIT (hereinafter 'the active substance'). As the active substance has not been approved, the BPR requires the Prospective Applicant to be on the Article 95 list in order to be allowed to be on the market after 1 September 2015.

The Appellant submits that the Agency breached Article 62 of the BPR in that the granting of the rights of reference to the Appellant's data was for a purpose which does not fall within the scope of Articles 62 and 63 of the BPR. The Appellant argues that the Prospective Applicant is already in possession of an in-vivo genotoxicity study with a positive result. The

¹ Announcement published in accordance with Article 6(6) of Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency.

Appellant submits that the Prospective Applicant was seeking to build a weight of evidence paper to neglect the results of their positive study. According to the Appellant, this is against the purpose of Articles 62 and 63 of the BPR.

The Appellant submits that the Prospective Applicant did not follow the procedure laid down in Article 63(3) of the BPR as he did not inform the Appellant that this procedure had been initiated and that the Agency did not respect the deadlines laid down in this article.

The Appellant submits that its right to be heard had been infringed as the Agency did not take into account certain documents relating to the data sharing dispute with the Prospective Applicant. The Appellant also submits that it was not given the opportunity to view all the information on which the Agency based the Contested Decision.

The Contested Decision stated that the Appellant, as a data owner, insisted on discussing technical equivalence on the basis of a test that they carried out unilaterally and the details of which they did not disclose. The Contested Decision stated that there was a lack of consistency and reliability in the data owner's behaviour that constituted a lack of effort on his part. The Appellant argues that the Agency made an error in the assessment of the Appellant's every effort.

The Appellant also claims that the Agency failed to take into account the precautionary principle in issuing the Contested Decision.

Further information

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

<http://echa.europa.eu/web/guest/regulations/appeals>