EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-017-2014
Appellant	BASF SE, Germany
Appeal received on	17 December 2014
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency'), pursuant to Article 41(3) of the REACH Regulation, in accordance with Articles 50 and 51 of the REACH Regulation.
Keywords	*Dossier evaluation - Compliance check – Pre-natal development toxicity study*
Contested Decision	CCH-D-0000004930-75-04/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

- annul the Contested Decision (part II.A.2), and
- order the Agency to refund the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted on 19 September 2014 following a compliance check under the dossier evaluation procedure of the Appellant's registration submitted for the substance prop-2-yn-1-ol, CAS No 107-19-7 (EC-No 203-471-2). By the Contested Decision, in Part II.A.2, the Agency requested the Appellant to conduct and submit a pre-natal development toxicity study in order to cover the endpoint of Annex IX, Section 8.7.2 of the REACH Regulation. As part of the registration dossier, the Appellant had submitted information that it claims satisfied the requirements for read-across according to Annex XI, Section 1.5 of the REACH Regulation. However, in the Contested Decision, the Agency did not consider the information submitted by the registrant to satisfy these requirements.

[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.

The Appellant submits that it provided all data necessary for the assessment of the read-across approach but that the Agency failed to take it into account. Notably, the Appellant submitted an OECD 421 study on the registered substance and an OECD 414 study on substance 2-butyne-1,4-diol (another substance than the one registered by the Appellant). The Appellant submits that the similar structure of the substances justifies its read-across approach.

The Appellant further submits that the Agency breached the procedure of Articles 50(1) and 51(5) of the REACH Regulation in its assessment of a proposal for amendment by a Member State. The Appellant claims that this proposal supported its arguments for read-across. The Appellant further submits that the Agency did not take its comments into account in the decision-making process.

The Appellant also submits that the Contested Decision lacks a legal basis and that the registration dossier covers the pre-natal development toxicity in accordance with the provisions of the REACH Regulation.

The Appellant further submits that the contested part of the Decision violates the principle of proportionality by imposing substantial testing burden on the Appellant.

Finally, the Appellant also submits that the requested tests breach the principle of animal welfare with regards to the requirements of Article 25(1) of the REACH Regulation, which sets out that testing on vertebrate animals shall be undertaken only as a last resort.

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