EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-016-2015
Appellant	AlzChem AG, Germany
Appeal received on	12 June 2015
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 40 of the REACH Regulation
Keywords	*Testing proposal – Pre-natal developmental toxicity study – Cessation of manufacture*
Contested Decision	TPE-D-2114296573-38-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision and to order the Agency to refund the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted on 16 March 2015 pursuant to Article 40 of the REACH Regulation and required the Appellant to carry out a pre-natal developmental toxicity study in rats or rabbits through the oral route on a substance for which the Appellant had submitted a registration dossier in the 100 to 1000 tonnes tonnage band.

The Appellant submits that it ceased manufacture of the registered substance as a result of the Contested Decision and will not continue placing it on the market. The Appellant indicates that it submitted a notice to the Agency through REACH-IT that it ceased manufacturing. The Appellant concludes that there is therefore no more exposure from the substance and, consequently, the animal testing on the substance would be unreasonable and in breach of Articles 13 and 25 of the REACH Regulation.

[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 further submits that it stopped being SIEF facilitator and deactivated its membership in the SIEF. Furthermore, the Appellant indicates that that there is no other registrant for the registered substance and no company therefore prepared to take over the role of a lead registrant in the SIEF.

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