EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-004-2015
Appellant	Polynt S.p.A, Italy
Appeal received on	27 February 2015
Subject matter	A decision taken by the European Chemicals Agency (the Agency') pursuant to Article 41(3) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	*Evaluation – Compliance check – Request for further information*
Contested Decision	CCH-D-2114289309-36-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

- Declare the appeal admissible and well-founded;
- Partially annul the Contested Decision insofar as it requires the submission of data from testing on vertebrate animals, and;
- Order the Agency to pay the costs of these proceedings.

Pleas in law and main arguments

The Contested Decision was adopted on 28 November 2014 following a compliance check under the dossier evaluation procedure of the registration submitted by the Appellant for hexahydro-4-methylphthalic anhydride ('4-MHHPA').

The Contested Decision requests the Appellant to submit *inter alia* (i) a sub-chronic toxicity study (90-day), oral route in rats, and; (ii) a pre-natal developmental toxicity study in rats or rabbits, oral route.

[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 challenges the Contested Decision firstly on the ground that it was adopted in violation of the procedural requirements and safeguards set out in Articles 50 and 51 of the REACH Regulation. According to the Appellant, in contravention of those Articles and the Appellant's rights of defence, the Appellant's comments were not duly considered, and are not reflected in the Contested Decision. In addition, the Appellant was never given a proper opportunity to respond to the new issues raised by the Agency in respect of the comments submitted by the Appellant.

Secondly, the Appellant claims that the Contested Decision infringes substantive requirements under the REACH Regulation whereby the pre-natal developmental toxicity study may be waived in relation to a substance that is deemed to be of equivalent concern to a carcinogen, mutagen or reprotoxic substance.

Thirdly, the Appellant contends that the Contested Decision infringes the legal requirements under the REACH Regulation relating to animal welfare, in that it requires the Appellant to undertake an oral sub-chronic toxicity study despite the fact that the study would not address the property of concern, which is respiratory sensitisation.

Fourthly, the Appellant alleges that the Contested Decision infringes well-established principles of EU law: (i) it is disproportionate, in that vertebrate data should only be provided as a last resort, in particular where read-across provides a valid alternative; and (ii) it infringes the principle of legitimate expectations, in that the Agency does not accept the Appellant's proposed use of read-across despite having itself relied on read-across in a parallel assessment of the substance.

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