ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	13 January 2020
Case	A-015-2019
Appellant	Polynt S.p.A., Italy
Appeal received on	4 December 2019
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 40 of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	*Testing proposal – Extended one-generation reproductive toxicity study – Error of assessment – Animal welfare – Proportionality*
Contested Decision	TPE-D-2114483466-38-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision which requires the Appellant to conduct an extended one-generation reproductive toxicity study ('EOGRTS') (Section 8.7.3. of Annex X to the REACH Regulation; test method: OECD TG 443) in rats, oral route.

In the alternative, the Appellant requests the partial annulment of the Contested Decision insofar as it requires the EOGRTS to include Cohort 3 (developmental immunotoxicity).

The Appellant requests the Board of Appeal to order the Agency to pay the costs of the appeal proceedings.

Pleas in law and main arguments

The Agency adopted the Contested Decision following an examination of the Appellant's testing proposal for the substance hexahydro-4-methylphthalic anhydride (EC number 243-072-0, CAS number 19438-60-9; the 'Substance').

The Appellant argues that the Contested Decision infringes Section 8.7. of Annex X to the REACH Regulation. This is because there is no need to conduct the EOGRTS as the Substance is of equivalent concern to carcinogen, mutagen and reproductive toxic ('CMR') substances.

[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 as amended by Commission Implementing Regulation (EU) 2016/823.

The Appellant argues that the Agency committed an error of assessment by requiring Cohort 3 (developmental immunotoxicity) to be included in the EOGRTS. This is because the studies submitted by the Appellant show that there is no particular concern on developmental immunotoxicity justified by any of the criteria in Column 2 of Section 8.7.3. of Annex X to the REACH Regulation.

The Appellant argues that the Agency breached Article 40(2) of the REACH Regulation by ignoring or improperly disregarding information submitted by a third party following a public consultation on the Appellant's testing proposal. The Agency also breached Article 40(2) of the REACH Regulation by requiring that scientific information submitted by third parties '*proves'* or '*fulfils*' information requirements in a registration dossier.

The Appellant argues that the Agency failed to consider alternatives to animal testing and requested a study that is not necessary. As a result, the Agency breached Article 13 of the Treaty on the Functioning of the European Union and Article 25 of the REACH Regulation, as well as the principles of proportionality, animal welfare and sound administration.

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