EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	22 August 2022
Case	A-005-2022
Appellant	ARKEMA France S.A., France
Appeal received on	7 June 2022
Subject matter	A decision taken by the European Chemicals Agency under Article 42(1) of the REACH Regulation[2]
Keywords	*Dossier evaluation – Follow-up to a compliance check – Rectification of a decision by the Executive Director*
Contested Decision	CCH-D-2114582354-45-01/F
Language of the case	English

Background and remedy sought by the Appellant

On 24 October 2017, the Agency adopted a decision (the 'Initial Decision') under Article 41 following the compliance check of the registration dossier for the substance 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid (EC No 500-130-2; CAS No 55818-57-0, the 'Substance'). In that decision, the Agency required the Appellant to submit information on an extended one-generation reproductive toxicity study ('EOGRTS'; Section 8.7.3. of Annex X; test method: EU B.56. or OECD TG 443) in Wistar rats, oral route.

On 9 March 2022, after the examination of the information submitted in consequence of the Initial Decision, the Agency adopted the Contested Decision under Article 42(1). The Agency concluded that the Appellant's registration dossier remains non-compliant with Section 8.7.3. of Annex X by reason of the inadequate dose-level selected by the Appellant to detect reproductive toxicants and developmental immunotoxicants, and therefore requested the Appellant to repeat the EOGRTS at the highest dose level.

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

[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.

[2] All references to Articles and Annexes concern the REACH Regulation unless stated otherwise.

Pleas in law and main arguments

The Appellant argues that the Agency breached Articles 41 and 42 and the principle of legal certainty by requiring the Appellant to repeat the EOGRTS at the '*highest possible dose level*' in accordance with guidelines which, according to the Appellant, were not applicable, as they were published only after the EOGRTS was conducted in consequence of the Initial Decision.

The Appellant also argues that the Agency breached the last resort principle as regards testing on vertebrate animals as well as the principles of proportionality, protection of legitimate expectations and good administration, and committed an error of assessment by failing to examine, carefully and impartially, all the relevant information on the Substance.

Rectification, withdrawal of the appeal and closure of the case

The Acting Executive Director of the Agency rectified the Contested Decision under Article 93(1) by withdrawing it entirely. Subsequently, the Appellant withdrew the appeal and the Chairman of the Board of Appeal closed the case on 22 August 2022.

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