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EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	21 June 2023
Case	A-008-2023
Appellant	Shell Chemicals Europe B.V., the Netherlands
Appeal received on	9 May 2023
Subject matter	A decision taken by the European Chemicals Agency under Article 40 of the REACH Regulation[2]
Keywords	*Dossier evaluation – Testing proposal – Rectification of a decision by the Executive Director*
Contested Decision	TPE-D-2114627230-63-01/F
Language of the case	English

Background and remedy sought by the Appellant

On 9 February 2023, the Agency adopted a decision under Article 40 following the examination of a testing proposal submitted by the Appellant for the substance p-xylene[3]. By 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./OECD TG 443) by oral route, in rats, specified as follows:

- Ten weeks premating exposure duration for the parental (P0) generation;
- The highest dose level in P0 animals must be determined based on clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals, or follow the limit dose concept;
- Cohort 1A and 1B (reproductive toxicity);
- Cohorts 2A and 2B (developmental neurotoxicity); and
- Investigations on learning and memory function.

[1] Announcement published in accordance with Article 6(6) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5).

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1). All references to Articles and Annexes concern the REACH Regulation unless stated otherwise.

[3] EC no 203-396-5; CAS no 106-42-3 (the **Substance**).

The Appellant requests that the Board of Appeal:

- Annuls the Contested Decision in its entirety or, in the alternative, to the extent that it requires the extension of the EOGRTS to Cohorts 2A and 2B, as well as investigations on learning and memory function; and
- Refunds the appeal fee.

Pleas in law and main arguments

The Appellant argues that the Agency:

- breached Article 40 and Annex X by failing to review the testing proposal submitted by the Appellant,
- incorrectly exercised its discretion under Article 40, failed in its duty to state reasons, and breached the principle of good administration in relying in the Contested Decision on information related to other substances; and
- failed to demonstrate a particular concern that would justify the request for information on Cohorts 2A and 2B under Column 2 of Section 8.7.3. of Annex X.

The Appellant argues that the requirement to carry out investigations on learning and memory function lacks a valid legal basis, and, in any case, does not meet the conditions for such a request as set out by the Agency in the Contested Decision.

Rectification, withdrawal of the appeal and closure of the case

The 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 21 June 2023.

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