EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	11 November 2019
Case	A-014-2019
Appellant	LG Chem Europe GmbH, Germany
Appeal received on	4 October 2019
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 40 of the REACH Regulation
Keywords	*Testing proposal – Multi-constituent substance – Animal welfare – Proportionality*
Contested Decision	TPE-D-2114465664-40-01/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 a pre-natal developmental toxicity ('PNDT') study (Annex X, Section 8.7.2. of the REACH Regulation; test method: OECD TG 414) in a second species (rabbit), oral route and an extended one-generation reproductive study ('EOGRTS') (Annex X, Section 8.7.3. of the REACH Regulation; test method: OECD TG 443) in rats, oral route.

In the alternative, the Appellant requests partial annulment of the Contested Decision insofar as it requires that the EOGRTS is conducted with additional parameters.

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

Pleas in law and main arguments

The Appellant submitted a registration dossier for substance 1,4-Benzenedicarboxylic acid, mixed Bu and 2-ethylhexyl diesters (EC No 946-149-3, CAS No 1571954-81-8, the 'Substance') at the tonnage band of 1000 tonnes or more per year.

The Appellant claims, in essence, that when adopting the Contested Decision the Agency failed to take into account the available information demonstrating that the Substance is not toxic to reproduction.

[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 conditions set out in Sections 8.7.2. of Annexes IX and X for triggering the need for the PNDT study in a second species are not met in the present case. Therefore the Agency breached the REACH Regulation when it required the Appellant to carry out the PNDT study in a second species.

In its registration dossier the Appellant had proposed to conduct the PNDT study in a second species and the EOGRTS. However, in its comments to the Agency's draft decision, the Appellant seeked to fulfil the PNDT and EOGRTS endpoints, amongst other information, by read-across from the constituents of the Substance. The Appellant also claimed that in any case the additional cohorts required for the EOGRTS are unnecessary.

The Appellant argues that the Agency breached Article 40(1), (3) and (4) of the REACH Regulation as it failed to adequately consider the Appellant's comments on the draft decision and did not provide the Appellant an opportunity to address any inaccuracies in the registration dossier.

The Appellant also argues that the Agency breached Article 40(2) of the REACH Regulation by ignoring the information submitted by a third party in a public consultation on the Appellant's EOGRTS testing proposal.

The Appellant claims that, by failing to consider the alternatives to animal testing, the Agency breached Article 25 of the REACH Regulation and the principle of proportionality.

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