EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	9 March 2020
Joined cases	A-016-2019 to A-029-2019
Appellants	Lubrizol France SAS, France (A-016-2019 to A-023-2019) Lanxess Deutschland GmbH, Germany (A-024-2019) Infineum Italia S.r.l., Italy (A-025-2019) Chevron Oronite SA M/I, France (A-026-2019 and A-027-2019) Afton Chemical S.P.R.L., Belgium (A-028-2019) Afton Chemical S.P.R.L. (Woluwe), Belgium (A-029-2019)
Appeal received on	24 December 2019
Subject matter	14 decisions 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 – Read-across approach – Sub-chronic toxicity study – Pre-natal developmental toxicity study – Error of assessment – Animal welfare – Proportionality*
Contested Decision	TPE-D-2114484217-44-01/F, TPE-D-2114483969-22-01/F TPE-D-2114484220-57-01/F, TPE-D-2114484222-53-01/F TPE-D-2114484207-45-01/F, TPE-D-2114484210-58-01/F TPE-D-2114484212-54-01/F, TPE-D-2114483966-28-01/F TPE-D-2114484215-48-01/F, TPE-D-2114484202-55-01/F TPE-D-2114484206-47-01/F, TPE-D-2114484204-51-01/F TPE-D-2114483975-29-01/F, TPE-D-2114484214-50-01/F
Language of the case	English

Background and remedy sought by the appellant

The Appellants are registrants of 14 different substances derived from zinc dialkyldithiophosphate (the 'ZDDP Substances'). The Appellants sought to fulfill the standard information requirements on sub-chronic toxicity and pre-natal developmental toxicity for all 14 substances by putting forward testing proposals on one of the substances and following a grouping approach for the others. Whilst the Agency accepted the grouping approach in case of four of the substances, it rejected the proposed read-across of the results for the other ZDDP Substances and required the Appelants to conduct, on each of those substances, a sub-chronic toxicity study (90-day), oral

[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.

route (Section 8.6.2. of Annex IX to the REACH Regulation; test method: OECD TG 408) in rats and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX to the REACH Regulation; test method: OECD TG 414) in a first species (rats or rabbits), oral route.

The Board of Appeal decided to join the 14 cases on 13 February 2020.

The Appellants request the Board of Appeal to annul the Contested Decisions.

Pleas in law and main arguments

The Appellants argue that, by not clarifying the alleged concerns related to substance identity of the 14 registered substances as well as the proposed category approach in a compliance checks, prior to reviewing the testing proposals, the Agency breached Articles 40 to 43, 50 and 51 of the REACH Regulation.

The Appellants argue that, by adopting the Contested Decisions, the Agency incorrectly exercised its margin of discretion and thereby breached the Appellants right to sound administration. Moreover, by requesting the conduct of unnecessary studies, the Agency breached the principle of proportionality and Article 25(1) of the REACH Regulation.

The Appellants also argue that, by addressing the draft and final decisions only to the lead registrants, and not to all registrants of each of the substances, the Agency breached several provisions of the REACH Regulation, including Articles 40 and 50. Moreover, the Appellants claim that the Agency breached the general principle of equal treatment and non-discrimination, and the principle of good 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