

Announcement of appeal¹

Case A-025-2015

Appellant Rütgers Novares GmbH, Germany

Appeal received on 18 December 2015

Subject matter A decision taken by the European Chemicals Agency (the 'Agency')

pursuant to Article 46(1) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 52 of the REACH

Regulation

Keywords Substance evaluation – Intermediate – Proportionality

Contested Decision Decision on substance evaluation for biphenyl (CAS No 92-52-4, EC

No 202-163-5) of 1 October 2015

Language of the case English

Remedy sought by the Appellant

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

Pleas in law and main arguments

The Contested Decision was adopted by the Agency on 1 October 2015 following a substance evaluation of biphenyl (hereinafter the 'Substance') carried out by the Competent Authority of Portugal.

The Contested Decision, which is addressed to four registrants of the Substance, requests the addressees to provide information on the following by 8 April 2018:

- (i) Ready biodegradability (test method: Closed bottle test, OECD 301D);
- (ii) Sediment simulation testing (test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24./OECD 308) at a temperature of 12 °C, using Carbon 14 ring-labelled test substance, including identification of degradation products; this study shall be conducted only if results of the ready biodegradability test indicate that the registered substance screens as persistent/very persistent;
- (iii) Extended one-generation reproductive toxicity study in rats, oral route (test method: OECD 443, including Cohort 2A and 2B, and Cohort 3).

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.



The Appellant claims that the Agency breached Articles 41(1), 42(2) and 47(1) of the REACH Regulation. The Appellant argues that by not conducting a compliance check prior to the evaluation of the Substance and not adequately justifying in the Contested Decision requests for information that are standard information requirements which would have been more adequately obtained through a prior compliance check, the Agency has identified and pursued an illegitimate objective for the substance evaluation it conducted, namely the need to fill alleged data gaps under the REACH Regulation.

The Appellant also claims that the Agency breached the proportionality principle as the Agency failed to demonstrate the necessity of the information requested in the Contested Decision. More specifically, the Appellant claims that the Agency failed to demonstrate that there is a potential risk to human health or the environment, that the potential risk needs to be clarified and that the information requested has a realistic possibility of leading to improved risk management measures.

Other information

Pursuant to Article 93(1) of the REACH Regulation, the Executive Director of the Agency rectified the Contested Decision by Decision of 11 February 2016. The appeal was subsequently withdrawn by the Appellant and the case was closed by the Board of Appeal on 7 March 2016.

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

The CoRAP list of substances is available at the following:

http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances