EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-005-2016
Appellant	Cheminova A/S, Denmark
Appeal received on	25 July 2016
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 40 of the REACH Regulation
Keywords	*Testing proposal – Read-across – Analogue substance*
Contested Decision	TPE-D-2114328778-35-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision, order the refund of the appeal fee and take such other or further measures as justice may require.

Pleas in law and main arguments

The Contested Decision, regarding a testing proposal, was adopted on 26 April 2016 on the basis of Article 40 of the REACH Regulation in relation to the Appellant's registration dossier for sodium O,O-diethyl dithiophosphate (CAS No 3338-24-7, EC No 222-079-2; hereinafter the 'Substance'). The Contested Decision requires the Appellant to provide the following information using the Substance by 3 May 2018:

- a sub-chronic toxicity study (90-day), oral route (Section 8.6.2 of Annex IX to the REACH Regulation; test method: EU B.26/OECD 408) in rats; and
- a pre-natal developmental toxicity study (Section 8.7.2 of Annex IX to the REACH Regulation; test method: EU B.31/OECD 414) in rats or rabbits, oral route.

According to the Contested Decision, the Appellant's proposals for the abovementioned tests to be carried out using the analogue substance sodium O,O-diisobutyl dithiophosphate (EC No 258-508-5; hereinafter the 'analogue substance') and then applied to the Substance using a read-across approach were rejected by the Agency pursuant to Article 40(3)(d) of the REACH Regulation. The Agency rejected the Appellant's read-across proposal on the grounds that the requirements of Section 1.5 of Annex XI to the REACH Regulation had not been met and stated that it is therefore necessary to perform the tests on the Substance.

[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 claims that the Contested Decision was adopted on the wrong legal basis since the Agency used Article 40 of the REACH Regulation as the legal basis despite the fact that the registration dossier did not contain testing proposals for Sections 8.6.2 and 8.7.2 of Annex IX to the REACH Regulation for the Substance. The Appellant claims that instead of submitting testing proposals for the Substance, it had chosen to submit adaptations to information requirements by reference to testing on the analogue substance. The Appellant also claims that the Agency exceeded its powers by assessing, and rejecting, the Appellant's read-across justifications under Article 40 rather than Article 41 of the REACH Regulation.

The Appellant argues that the adaptations it included in its registration dossier comply with the requirements of Sections 1.2, 1.3 and 1.5 of Annex XI to the REACH Regulation. The Appellant claims that by deciding that the adaptations do not comply with those requirements the Contested Decision infringes Annex XI. The Appellant adds that the testing on the analogue substance could not have been available because the Agency was required to first carry out a testing proposal examination for the analogue substance pursuant to Article 40 of the REACH Regulation. The Appellant argues that Annex XI, read in accordance with the principles of the REACH Regulation and the overriding principles of European Union law, allows the Agency to accept a legitimate delay in the availability of the studies on the analogue substance before deciding to request testing on the Substance.

The Appellant also claims that the Agency breached its duty of good administration by conducting the testing proposal examination on the Substance without considering the parallel examination of testing proposals for the analogue substance.

The Appellant argues that the Agency failed to take into account all relevant information as it did not take into account a registration dossier update submitted by the Appellant before the deadline set by the Agency for such updates.

The Appellant claims that the Agency also breached Article 25 of the REACH Regulation by failing to consider alternatives to animal testing, the duty to state reasons, as well as the principles of proportionality, legal certainty and legitimate expectations.

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