EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-007-2015
Appellant	Celanese Chemicals Europe GmbH, Germany
Appeal received on	12 March 2015
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency'), pursuant to Article 41(3) of the REACH Regulation, in accordance with Articles 50 and 51 of the REACH Regulation
Keywords	*Dossier evaluation - Compliance check – Read-across*
Contested Decision	CCH-D-2114288751-40-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

- annul the Contested Decision; and
- order the refund of the fee paid by the Appellant in accordance with Article 10(4) of Regulation (EC) No 340/2008.

Pleas in law and main arguments

The Contested Decision was adopted on 12 December 2014 following a compliance check under the dossier evaluation procedure of the registration submitted by the Appellant for dibutyl maleate (hereinafter the 'Substance').

The Contested Decision requests the Appellant to provide information on a pre-natal development toxicity study in rats or rabbits by the oral route (test method: EU B. 31/OECD 414) for the purposes of Section 8.7.2 of Annex IX. According to the Contested Decision, the Agency rejected the proposed read-across on the grounds that it did not comply with the general rules on adaptation set out in Section 1.5 of Annex XI. The Agency concluded further in the Contested Decision that the Appellant had not provide documentation to demonstrate enzymatic hydrolysis of the Substance or that the metabolite n-butanol does not reveal any adverse effects on reproduction and development.

[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. All references to Articles and Annexes are to the REACH Regulation unless stated otherwise.

The Appellant contests the Agency's conclusion that the Appellant's read-across approach does not fulfil the requirements of Section 1.5 of Annex XI and the Agency's requirement to submit information on a pre-natal development toxicity study in rats or rabbits by the oral route.

The Appellant submits that the Contested Decision has no valid legal basis since the Appellant's registration dossier was compliant with the REACH Regulation, in particular Section 1.5 of Annex XI thereof, and the Agency's Guidance available at the relevant time on how read-across proposals should be presented.

The Appellant claims that the Contested Decision is contrary to the letter and spirit of the REACH Regulation with regard to the compliance check procedure, in particular Article 51(1) thereof, and to the principle of the right to be heard set out in particular in Article 41 of the Charter of Fundamental Rights of the European Union and Article 16 of the Code of Good Administrative behaviour for the Staff of the European Chemicals Agency. The Appellant claims that it had no opportunity to make its views known on the Agency's conclusions for rejecting the read-across as those conclusions were not included in the version of the draft decision on which it commented but were only added in a subsequent version of the draft decision.

The Appellant claims that the Contested Decision is contrary to the principle of proportionality. In particular, the Appellant claims that it had already provided relevant data in an updated dossier before the Contested Decision was adopted. The Appellant also argues that the Agency had relevant data in its possession by virtue of other registrants' dossiers and that relevant information regarding the hydrolysis of the Substance is already in the public domain. In addition, the Appellant argues that the Agency had refused to engage with the Appellant with a view to discussing the performance of a study to address certain of the concerns before the adoption of the Contested Decision. The Appellant claims that it would be disproportionate for the Agency to request vertebrate studies to provide information which already exists.

The Appellant claims that the Contested Decision is contrary to the letter and spirit of the REACH Regulation with regard to animal welfare. In particular, the Appellant claims that the requested study will not generate significantly different information to that already available from the read-across proposal it already submitted and the other information available to the Agency. As a result, the Contested Decision is, according to the Appellant, contrary to Article 25(1) which requires that testing on vertebrate animals shall be undertaken only as a last resort.

The Appellant also claims that the Contested Decision is contrary to the letter and spirit of the REACH Regulation in so far as it is not tailored to real information needs. The Appellant claims that since the requested study will not generate significantly different information to that already available from the read-across proposal submitted and the other information already available to the Agency, the Contested Decision promotes the duplication of animal testing contrary to the objective set out in Recital 63 and Article 25(1).

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