

Announcement of appeal¹

Case A-008-2016

Appellants Emerald Kalama Chemical B.V., the Netherlands

Lanxess Deutschland GmbH, Germany; and Ineos Chloro Toluenes Belgium NV, Belgium

Appeal received on 13 September 2016

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

pursuant to Article 41(3) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH

Regulation

Keywords Dossier evaluation – Compliance check – Right to be heard

Contested Decision CCH-D-2114332899-33-01/F

Language of the case English

Remedy sought by the Appellants

The Appellants request the Board of Appeal to:

- annul the Contested Decision;
- remit the case to the Agency for re-evaluation of the registration dossier as updated by the lead registrant; and
- order the refund of the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted on 13 June 2016 following a compliance check, under the dossier evaluation procedure, of the registration submitted by the lead registrant for benzaldehyde (hereinafter the 'Substance'). The Contested Decision required the lead registrant to provide information on several additional studies, including tests on animals.

The Appellants claim that the Contested Decision, which is addressed to the lead registrant only, breaches Article 50(1) of the REACH Regulation. In particular, the Appellants argue that, pursuant to Article 50(1), the draft of the Contested Decision (hereinafter the 'draft decision') should have been notified to all co-registrants of the Substance and not only to the lead registrant.

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 Appellants argue that by failing to notify the draft decision to all co-registrants of the Substance, and therefore denying them the opportunity to provide comments, the Agency breached the co-registrants' right to be heard and their right to good administration.

The Appellants also claim that the Agency committed an error of assessment by failing to take into consideration all relevant data. The Appellants argue that as a result the Agency also breached the Appellants' right to good administration, right to be heard and right to legal certainty.

The Appellants claim that the Agency did not take any additional steps, beyond its established practice, to determine whether more information was available on the endpoints identified in the Contested Decision. In particular, the Appellants claim that the lead registrant became aware of the draft decision only after the deadline to provide comments as the responsible person had been on medical leave at the time the draft decision was notified. The Appellants state that as soon as they became aware of the draft decision they contacted the Agency and requested the opportunity to discuss the draft decision and provide further justifications for the read-across approach provided in the registration dossier. The Appellants state that they also provided explanations as to why the requirements in the draft decision had already been met at the Member State Committee meeting at which the Substance was discussed. The Appellants add that, prior to the adoption of the Contested Decision, the lead registrant updated its registration dossier with additional justifications for the adaptations proposed in its registration dossier. The Appellants consider that the Agency's refusal to deviate from its established practice in the extenuating circumstances of the case lead to unnecessary information requests.

In addition, for the same reasons, the Appellants claim that the Contested Decision breaches the principle of proportionality, is contrary to the letter and spirit of the REACH Regulation with regard to animal welfare, and is not tailored to real information needs.

Other information

Pursuant to Article 93(1) of the REACH Regulation, the Executive Director of the Agency rectified the Contested Decision by Decision of 12 October 2016. The appeal was subsequently withdrawn by the Appellants and the case was closed by the Chairman of the Board of Appeal on 14 November 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