EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-009-2017
Appellant	Celanese Production Germany GmbH & Co. KG, Germany
Appeal received on	30 June 2017
Subject matter	A decision adopted 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 – Section 8.4. of Annex X – Modified in vivo* mammalian comet assay
Contested Decision	CCH-D-2114355769-31-01/F
Language of the case	English

Background

The Appellant is a registrant of vinyl acetate (EC No 203-545-4, CAS No 108-05-4).

The Agency performed a compliance check of the Appellant's registration in accordance with Article 41 of the REACH Regulation. In the Contested Decision, the Agency found the Appellant's registration to be incomplete and requested, amongst other things, an *in vivo* mammalian comet assay (OECD TG 489) in accordance with Column 2 of Section 8.4. of Annex X of the REACH Regulation, including '*modified experimental conditions that enable the detection of DNA crosslinks*'.

Pleas in law and main arguments

The Appellant requested the Board of Appeal to annul the request for an *in vivo* mammalian comet assay.

The Appellant argued that the request for an *in vivo* mammalian comet assay was based on an error of assessment, breached the principle of proportionality, breached the animal welfare requirements in the REACH Regulation, and was vitiated by a procedural error.

[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 (OJ L 137, 26.5.2016, p. 4).

Other information

At the Parties' request, the Board of Appeal stayed the appeal proceedings between 25 August 2017 and 17 March 2018.

On 19 March 2018, the Agency informed the Board of Appeal that '*the Member State Committee […] reviewed the regulatory approach regarding comet-assay modifications for cross-linking agents. The [Member State Committee] concluded to request, for dossier evaluation cases, the comet assay in standard form (OECD TG 489) without a modified protocol to detect crosslinks and called on the ECHA secretariat to review its past decisions taken on this*'.

The Executive Director of the Agency consequently rectified the Contested Decision by withdrawing the request for the *in vivo* mammalian comet assay. The Appellant subsequently withdrew the appeal, and the Chairman of the Board of Appeal closed the case by decision of 31 May 2018.

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