

**DECISION OF THE CHAIRMAN OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

31 May 2018

(Withdrawal of appeal by appellant)

Case number	A-009-2017
Language of the case	English
Appellant	Celanese Production Germany GmbH & Co. KG, Germany
Representatives	Scott Megregian and Zanda Romata K&L Gates LLP, United Kingdom
Contested Decision	CCH-D-2114355769-31-01/F of 30 March 2017, adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 41 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation')

THE CHAIRMAN OF THE BOARD OF APPEAL

gives the following

Decision

1. The Appellant is a registrant of vinyl acetate (EC No 203-545-4, CAS No 108-05-4).
2. 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 required it to perform and submit:
 - an *in vivo* mammalian comet assay study (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*'; and
 - a pre-natal developmental toxicity study in a second species (OECD TG 414) in accordance with Section 8.7.2. of Annex X of the REACH Regulation.
3. On 30 June 2017, the Appellant filed this appeal contesting the request for the *in vivo* mammalian comet assay study.
4. Between 25 August 2017 and 17 March 2018, at the Parties' request, the proceedings were stayed by the Board of Appeal pursuant to Article 25 of Commission Regulation

(EC) No 771/2001 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5), as amended by Commission Implementing Regulation (EU) 2016/823 (OJ L 137, 26.5.2016, p. 4; the 'Rules of Procedure').

5. 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'*. As a consequence, the Executive Director of the Agency rectified the Contested Decision by withdrawing the request for the *in vivo* mammalian comet assay study.
6. On 27 March 2018, the Appellant stated that it wished to withdraw this appeal.
7. In accordance with Article 1b of the Rules of Procedure, where an appeal is withdrawn, the Chairman closes the proceedings.
8. Pursuant to Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.4.2008, p. 6) the appeal fee is refunded if a contested decision is rectified. As the Agency has rectified the Contested Decision by withdrawing it to the extent it was challenged by the Appellant, the appeal fee must be refunded.

On those grounds,

THE CHAIRMAN OF THE BOARD OF APPEAL

hereby:

- 1. Closes appeal case A-009-2017.**
- 2. Decides that the appeal fee shall be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal