ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

**Announcement of appeal**[1]

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| **Case** | A-006-2012 |
| **Appellant** | Momentive Specialty Chemicals B.V., Pernis-Rotterdam, Netherlands |
| **Appeal received on** | 20 September 2012 |
| **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** | *Evaluation – Compliance check – Request to submit further information – Use of read-across data* |
| **Contested decision** | CCH-D-0000002304-84-04/F |
| **Language of the case** | English |

## Remedy sought by the Appellant

The Appellant seeks annulment of the part of the contested decision that requires the Appellant to submit:

(i) information on skin sensitisation, performed with the registered substance, using test method B.42 according to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation, and to update the technical dossier and the Chemical Safety Report ('CSR') with the relevant information;

(ii) information on *in vitro* gene mutation in mammalian cells, performed with the registered substance, using the test method B.17 according to Regulation (EC) No 440/2008, and to update the the technical dossier and the CSR with the relevant information; and

(iii) information on *in vitro* cytogenicity study in mammalian cells or the *in vitro* micronucleus study, performed with the registered substance, using test method B.10 according to Regulation (EC) No 440/2008 or draft OECD guideline 487, and to update the technical dossier and the CSR with the relevant information.

The Appellant also seeks refund of the appeal fee.

## Pleas in law and main arguments

The contested decision was adopted on 21 June 2012 following a compliance check under the dossier evaluation procedure of the Appellant's registration submitted for the substance vinyl 2-ethylhexanoate.

The Appellant submits that it has provided and satisfied the information requirements set-out above by reference to relevant read-across data relating to two source substances (vinyl neononanoate and vinyl neodecanoate).

[1] Announcement published in accordance with Article 6(6) of Commission Regulation (EC) No 771/2008 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).

The Appellant contends that the contested decision was adopted in breach of REACH Regulation requirements, as well as general legal principles of EU law and is not scientifically justified.

The Appellant contends that it is legally and scientifically justified in relying upon the read-across data submitted in the registration dossier and therefore by submitting this data it has satisfied the data requirements. Furthermore, the Appellant claims that it is legally obliged to only submit and rely upon the read-across data in order to, amongst other things, avoid vertebrate animal testing which should only be undertaken as a last resort, as required under Article 25(1) of the REACH Regulation.

The Appellant claims that the question of whether a particular registrant can group substances and apply the read-across approach depends primarily on whether a substance is sufficiently similar in structure to another substance for read-across to apply. The Appellant submits that the registered, target substance is sufficiently similar in structure to the source substances to permit read-across.

The Appellant submits that ECHA has provided no valid or justifiable ground to deny read-across. The Appellant claims further that the substantive scientific grounds for not permitting read-across contained within the contested decision are inconsistent, illogical, and illegal. For example, it claims that ECHA permitted read-across from the source to the target substances for ecotoxicological and environmental fate data but not for the end-points listed in the contested part of the Decision. In addition, the Appellant submits that there is no legal provision preventing a registrant from applying read-across between a mono-constituent substance and a UVCB.

The Appellant claims further that the general approach adopted by ECHA as regards to read-across appears to be inconsistent and out-of-step with the OECD approach, with other academic and regulatory institutions, and with a general body of recognised academic experts on read-across.

The Appellant also submits that it has clearly stated the reasons for relying on read-across data and it is under no legal burden of proof to provide exhaustive arguments sufficiently justifying read-across.

The Appellant submits that it could not and was not able to attend the Member State Committee ('MSC') meeting at which the draft contested decision was adopted. It adds that it has a deep and thorough understanding of the registered substance and the source substances and that its opinion on read-across should have been fully understood and taken into account at the relevant MSC meeting.

The Appellant contends that adoption of the contested decision was illegal and in breach of, amongst other things, the REACH Regulation and broader EU requirements regarding animal testing and animal welfare, and Article 130 of the REACH Regulation regarding the duty to state reasons. The Appellant also contends that the contested decision is manifestly disproportionate.

**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