

REACH REGULATION 2006: ECHA GRANT OF REGISTRATION TO AN INDIVIDUAL REGISTRANT SUCCESSFULLY CHALLENGED BY LEAD REGISTRANT

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This article considers the implications of a decision made in March 2016 by the Board of Appeal of the European Chemicals Agency (ECHA) to annul ECHA's earlier decision to grant a REACH registration to an individual company that was not part of a joint registration for that substance. The Board of Appeal considered that the earlier decision breaches several cornerstones of the REACH Regulation 2006, including data-sharing by registrants and the "one substance, one registration" principle.

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BACKGROUND

Under the REACH Regulation 2006, EU manufacturers and importers are required to share certain data for the purposes of registering REACH chemical substances with the European Chemicals Agency (ECHA), which is the European agency for the REACH regime. The lead registrant collates the studies and data to support the registration dossier. In other than exceptional cases, the lead registrant can usually expect to recoup and share some of the costs of the studies by selling Letters of Access to new entrants wanting to join the registration.

REACH stands for the Registration, Evaluation, Authorisation and Restriction of Chemicals. For more information on:

- *The REACH regime generally, see Practice note, REACH: EU chemicals regime (<http://uk.p02edi.practicallaw.com/7-205-3979>).*
- *REACH registration in particular, see Practice note, REACH: Registration (<http://uk.p02edi.practicallaw.com/8-504-5481>).*

FACTS

On 15 March 2016, the Board of Appeal of ECHA issued its decision on *Case A-022-2013* (<http://uk.p02edi.practicallaw.com/3-625-4862>). This was an appeal lodged by the lead registrant of a chemical substance because ECHA had granted a registration to an individual company for the same substance, outside of the existing joint submission for registration. The lead registrant argued that the individual company's registration dossier:

- Ignored data-sharing under REACH, with the expected cost sharing that goes with it.

RESOURCE INFORMATION

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JURISDICTION

England, European Union



- Was missing key information and data.
- Had not been properly checked by ECHA.

The lead registrant argued that, as a consequence, ECHA's decision to grant the registration gave the individual registrant an unfair market advantage.

DECISION

ECHA's Board of Appeal upheld the appeal, which means the case has been remitted back to ECHA for further examination.

COMMENT

Case A-022-2013 is highly significant as it underlines that, except in strictly limited cases, potential registrants cannot expect to "cut corners" and save costs by submitting an individual registration dossier when there is already a joint submission for the same substance.

The decision also subjects ECHA's completeness check procedures when granting registrations to critical scrutiny. In this case, the Board of Appeal held that the individual registrant's dossier was deficient and should not have been granted. ECHA's reliance upon an automated system for carrying out the "completeness check" on registration dossiers did not exonerate ECHA from its legal duties to ensure that all the key components of a registration dossier were present.

The decision in Case A-022-2013 is also consistent with the new Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH, which came into force on 26 January 2016. (See *Legal update, EU Regulation on improving data-sharing under REACH chemicals regime published in Official Journal* (<http://uk.p02edi.practicallaw.com/6-621-6595>).)

The new Implementing Regulation states that the principle of "one substance, one registration" should be "reinforced" and emphasises the role of ECHA in ensuring that, with limited exceptions, all submissions of information regarding the same substance are joined to the same registration. The Implementing Regulation also sets out specific requirements regarding the itemisation of costs and the inclusion of cost-sharing models within data-sharing agreements, subject to certain rights of waiver for pre-existing agreements.

Manufacturers and importers should consider the requirements of this Implementing Regulation, not least because the Implementing Regulation provides that parties' compliance with its provisions will be taken into account by ECHA when settling data-sharing disputes.