

## Announcement of appeal<sup>1</sup>

<b>Published on</b>	23 April 2019
<b>Case</b>	A-001-2019
<b>Appellant</b>	Solvay Fluor GmbH, Hannover, Germany
<b>Appeal received on</b>	12 February 2019
<b>Subject matter</b>	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 42(1) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
<b>Keywords</b>	<i>Dossier evaluation – Follow-up to a compliance check – Legal basis – Error of assessment – Legal certainty – Right to be heard – Article 25</i>
<b>Contested Decision</b>	CCH-D-2114450985-37-01/F
<b>Language of the case</b>	English

### Background

On 5 February 2015, pursuant to Article 41(3) of the REACH Regulation, the Agency adopted a decision following a compliance check of the Appellant's dossier for the substance sulphur hexafluoride. In that decision, the Agency requested the Appellant to update its registration dossier by 12 August 2016 with information on a pre-natal developmental toxicity ('PNDT') study (Section 8.7.2. of Annex IX to the REACH Regulation), and a sub-chronic toxicity study (90 day), inhalation route (Section 8.6.2. of Annex IX to the REACH Regulation).

With regard to the PNDT study, the Appellant updated its registration dossier with a weight-of-evidence approach according to Section 1.2. of Annex XI to the REACH Regulation.

On 15 November 2018, after the follow-up evaluation of the Appellant's dossier update pursuant to Article 42(1) of the REACH Regulation, the Agency adopted the Contested Decision. In the Contested Decision, the Agency rejected the Appellant's weight-of-evidence approach. The Agency concluded that the Appellant's registration dossier still does not comply with Section 8.7.2. of Annex IX to the REACH Regulation.

According to the Contested Decision, '*the respective Member State competent authority (MSCA) and national enforcement authority (NEA) will be informed of [the Agency's] decision [...]. They may consider enforcement actions to secure the implementation of [the compliance check decision of 5 February 2015]*'.

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<sup>1</sup> 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.

### **Remedy sought by the Appellant**

The Appellant requests the Board of Appeal to:

- annul the Contested Decision,
- order the Agency to refund the appeal fee, and
- take such other or further measures as justice may require.

### **Pleas in law and main arguments**

The Appellant states that, under Article 42(1) of the REACH Regulation, the Agency was required to examine the information submitted by the Appellant following the compliance check decision of 5 February 2015. If necessary, the Agency was required to draft a decision in accordance with Article 41.

The Appellant argues that, contrary to Article 41(3) of the REACH Regulation, the Contested Decision does not require the Appellant to submit information to bring its registration dossier into compliance within an adequate time limit. The Contested Decision is limited to a statement of non-compliance. As a result, the Agency breached Article 42(1) of the REACH Regulation and exceeded the powers granted to it by that provision. The Agency also breached Article 41 of the REACH Regulation, as well as the principle of legal certainty and the principle of protection of legitimate expectations.

The Appellant argues that, in adopting the Contested Decision, the Agency breached the Appellant's right to be heard and its rights of defence. This is because the Agency inserted substantial new information in the Contested Decision and the Appellant did not have an opportunity to make its views known on that information.

The Appellant argues that, in rejecting the Appellant's weight-of-evidence approach, the Agency committed an error of assessment, failed to consider all relevant information and breached Annex XI of the REACH Regulation.

The Appellant argues that the Agency breached Article 25 of the REACH Regulation, as well as the principle of proportionality, in finding that a PNDT study was still required despite the fact that the Appellant had fulfilled the endpoint in question using a weight-of-evidence approach.

### **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>