

Announcement of appeal¹

Case	A-019-2013
Appellant	Solutia Europe sprl/bvba, Zaventem, Belgium
Appeal received on	25 October 2013
Subject matter	Statement of non-compliance following a dossier evaluation decision under Regulation (EC) No 1907/2006 (the 'REACH Regulation')
Keywords	<i>Notified new substance – Statement of non-compliance – Procedure under Article 51 of the REACH Regulation - Manifest error of assessment - Proportionality</i>
Contested Decision	SEV-C-0000003764-69-01/F of 25 July 2013
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision and order the Agency to pay the costs of the proceedings.

Pleas in law and main arguments

The Appellant submitted a notification for the substance N-(1,1-dimethylethyl)bis(2-benzothiazolesulfen)amide ('TBSI') to the Belgian competent authority in accordance with Directive 67/548/EEC². Pursuant to Article 24(1) of the REACH Regulation, a notification in accordance with Directive 67/548/EEC shall be regarded as a registration for the purposes of the REACH Regulation.

On 30 January 2008, the Belgian competent authority requested further information from the Appellant in accordance with the national legislation implementing Article 7(2) of Directive 67/548/EEC. The requested information consisted of a toxicokinetic study (OECD test guideline 417) and a mutagenicity study, specifically an in-vitro mammalian cell genotoxicity test (chromosomal aberration test or mouse lymphoma assay).

On 2 January 2012, the Appellant submitted an updated registration dossier to the Agency. Following an examination of the dossier, the Agency concluded that the Appellant's dossier did not contain the information requested by the Belgian competent authority. The Contested Decision, which was addressed to the Belgian competent authority, states that the Appellant's

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.

² Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

registration dossier was therefore non-compliant with Articles 5 and 41(4) of the REACH Regulation. The Contested Decision concludes that the Appellant therefore 'may be subject to enforcement actions by the national authorities of the Member States' and asks the Belgian competent authority '... to address the non-compliance in your own competence by means of enforcement.'

The Appellant claims that the Contested Decision is unlawful as it was taken in violation of the procedure foreseen in Article 51 of the REACH Regulation, in particular since the Appellant, the Member State Competent Authorities and the Member State Committee were not consulted. In this respect, the Appellant states that Article 135(1) of the REACH Regulation provides that requests to a notifier to provide further information to a competent authority in accordance with Directive 67/548/EEC shall be considered as a decision adopted in accordance with Article 51 of the REACH Regulation.

The Appellant claims further that the toxicokinetic study requested in the Contested Decision is not required under the REACH Regulation. According to the Appellant, in requesting the study the Agency therefore went beyond the limits of its discretion under Article 41 of the REACH Regulation and committed a manifest error of assessment. In addition, the Appellant claims that the Agency should have explained why such a study was needed.

With regards to the requirement to provide a mutagenicity study, the Appellant had submitted a read-across proposal which was rejected by the Agency. The Appellant claims, however, that the read-across approach should have been assessed only during substance evaluation under Article 46 of the REACH Regulation, and not during dossier evaluation under Article 41 of the REACH Regulation. The Appellant claims that as a result the Agency had infringed Article 41 of the REACH Regulation and committed a manifest error of assessment. In addition, the Appellant claims that the Agency had incorrectly assessed the substance of the read-across proposal.

The Appellant also claims that the Contested Decision is disproportionate and was adopted prematurely. In particular, the Appellant claims that the Agency had a choice of measures at its disposal, for example the Agency could have requested the Appellant to submit additional information to bring its dossier into compliance with the REACH Regulation. However, in issuing a statement of non-compliance, the Agency had selected the most restrictive of those measures as it triggered enforcement action and created other practical and commercial disadvantages which are excessive in relation to the aim pursued.

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>