

Announcement of appeal¹

Case	A-014-2015
Appellants	Grace GmbH & Co. KG, Germany Advanced Refining Technologies GmbH, Germany
Appeal received on	10 June 2015
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 46(1) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 52 of the REACH Regulation
Keywords	<i>Substance evaluation – Nanomaterials - Proportionality</i>
Contested Decision	Decision on substance evaluation for silicon dioxide of 11 March 2015. The Decision was notified to the Appellants through the following annotation numbers: SEV-D-2114297922-36-01/F and SEV-D-2114297955-27-01/F
Language of the case	English

Remedy sought by the Appellants

The Appellants request the Board of Appeal in particular to annul the Contested Decision in its entirety, and order the Agency to refund the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted by the Agency on 11 March 2015 following a substance evaluation of silicon dioxide (CAS No 7631-86-9) carried out on behalf of the Ministry of Infrastructure and the Environment as the Competent Authority of the Netherlands (hereinafter the 'evaluating MSCA'). The evaluation by the evaluating MSCA was targeted to the characterisation of the substance, human health hazard assessment in relation to the inhalation route and exposure assessment of the registered synthetic amorphous silica (hereinafter 'SAS').

The Contested Decision requests the following information by 20 March 2017:

- (a) information on seven physicochemical properties of each individual form of SAS;
- (b) a sub-chronic toxicity study (90 day; OECD 413) in rats via the inhalation route using four specific forms of SAS;

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.

- (c) information on the uses of each individual form of SAS;
- (d) information on each of eight physicochemical properties of 'each individual surface treated SAS form'; and
- (e) 'all toxicological information on surface-treated SAS as manufactured, imported and/or placed on the market as available to the Registrant(s)', and a scientific justification that substantiates if and why the toxicological information on untreated SAS can be used for assessing the safety of surface-treated SAS.

The Appellants claim that there is no reliable evidence to substantiate the Agency's purported concern that SAS presents a risk of inhalation toxicity. The Appellants seek the annulment of the Contested Decision on the following grounds:

- (a) The Agency has materially erred in its assessment of the evidence underlying its decision, has misinterpreted available data and placed reliance almost exclusively on one flawed publication;
- (b) In reaching its decision, the Agency has failed to consider a number of important and relevant scientific studies brought to its attention by the Appellants and other registrants of SAS;
- (c) The Agency has based its decision very largely on its own classification of SAS as a nanomaterial, a classification that the Agency is not empowered to make and that in any event is irrelevant to the toxicity of SAS;
- (d) The Contested Decision is disproportionate in that it is not appropriate or necessary to achieve the objective of protecting human health, and places an unduly heavy burden on the Appellants; and
- (e) The Agency has misused its powers and/or acted ultra vires by requiring unnecessary, and unnecessarily extensive, testing on vertebrate animals in breach of Article 25(1) of the REACH Regulation.

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>

The CoRAP list of substances is available here:

<https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>