

Announcement of appeal¹

Case	A-015-2015
Appellants	Evonik Degussa GmbH and Others ²
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 – Request for information</i>
Contested Decision	Decision on substance evaluation for silicon dioxide of 11 March 2015
Language of the case	English

Remedy sought by the Appellants

The Appellants request the Board of Appeal to:

- declare the appeal admissible;
- set aside the Agency's decision to include silicon dioxide on the Community Rolling Action Plan (hereinafter 'CoRAP');
- annul the Contested Decision in its entirety;
- order the refund of the appeal fee;
- take such other or further measures as justice may require.

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 SAS form;

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 See Annex for a full list of Appellants.

- (b) a sub-chronic toxicity study (90 day; OECD 413) in rats via the inhalation route using four specific forms of SAS;
- (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.

On 29 February 2012, silicon dioxide was included on the CoRAP due to initial grounds for concern relating to 'the substance characterisation, nanoparticles and toxicity of different forms of the substance'. The Appellants claim, however, that none of those alleged grounds for concern are criteria for inclusion of a substance on the CoRAP. The Appellants argue that as a result the Agency's decision to include the substance on the CoRAP was adopted in breach of Article 44 of the REACH Regulation and must be set aside.

The Appellants claim further that, since the decision to include the substance on the CoRAP was illegal and must be set aside, the Contested Decision lacks legal basis as only substances appearing on the CoRAP can be evaluated.

The Appellants argue that the Agency acted unlawfully in requesting it to generate and submit information on 'forms' of SAS as:

- (a) The Agency has no competence under the REACH Regulation to request information on 'forms' of substances;
- (b) In attempting to identify a concern the Agency misquoted several documents and therefore infringed its duty to state adequate reasons;
- (c) The Agency erred in its assessment that the information already provided by the Appellants is insufficient to identify 'forms' of SAS adequately under the REACH Regulation; and
- (d) The Agency breached the principle of legal certainty by imposing obligations that are expressed through undefined and uncertain terms.

The Appellants claim that the mere fact that the substance meets the non-legally binding definition of 'nanomaterials' in Commission Recommendation 2011/696/EU on the definition of nanomaterial is not sufficient to justify the requests for information in the Contested Decision. By requesting information on the substance on the grounds that the substance meets the non-legally binding definition of 'nanomaterials' in the Commission Recommendation, the Agency failed to identify a valid concern that needs to be addressed through the substance evaluation procedure.

The Appellants claim that the Agency erred in its assessment of its own 'Frequently Asked Questions on REACH registration' regarding chemically surface-treated substances that it used to demonstrate that a concern existed that must be addressed through new data. As a result, according to the Appellants, the Agency failed to apply its own guidance thereby frustrating the Appellants' legitimate expectations.

The Appellants claim that the Agency committed an error of assessment by considering that the results of a study relied on in the Contested Decision raise concerns that must be addressed by new studies. The Appellants also argue that the Agency breached the duty of good administration because it does not rely on the full study report available to it and did not

apply a weight of evidence approach considering all the information available to it. The Appellants claim further that the Agency breached the principle of proportionality by requesting information which is not necessary.

The Appellants argue that the requirement to submit information on each 'form' of SAS that is 'manufactured, imported and/or placed on the market' is unlawful as:

- there is no legal basis for such a request and the Agency therefore exceeded its competence;
- it discriminates against the Appellants where they only act as a distributor;
- it is disproportionate because the information would be provided by several Appellants since each of the Appellants have to fulfil the information requirements individually.

The Appellants claim that, by requesting information per individual 'form' and differentiating between surface treated and non-surfaced treated SAS, the Contested Decision discriminates against SAS as other substances have not been the subject-matter of such detailed and untargeted requests.

In addition, the Appellants argue that the Contested Decision is disproportionate and breaches the principles of legal certainty and legitimate expectations by containing information requests that are untargeted, broadly and ill-defined, and unsupported by the evidence available to the Agency, or by the relevant Agency guidance. The Appellants claim further that the Contested Decision was adopted in breach of the duty of good administration, by failing to provide adequate reasons for the requests for further information.

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>

Annex

List of Appellants

Evonik Degussa GmbH, Germany
Evonik Industries AG, Germany
Evonik Aerosil France Sarl, France
Evonik Silquilmica SA, Spain
Evonik Degussa Antwerpen NV, Belgium
Akzo Nobel Pulp and Performance Chemicals AB, Sweden
Akzo Nobel Finland OY, Finland
Akzo Nobel Chemicals GmbH, Germany
Albemarle Europe Sprl, Belgium
Albermarle Catalysts Company B.V., the Netherlands
BASF SE, Germany
Cabot Aerogel GmbH, Germany
Cabot Carbon Limited, the United Kingdom
Cabot GmbH, Germany
Clariant Production (France) S.A.S., France
Clariant Produkte (Deutschland) GmbH, Germany
Deltagran Europe srl, Italy
Grace Silica GmbH, Germany
Hellenic Petroleum SA, Greece
IQESIL S.A., Spain
Instituto Suizo Para el Fomento de la Seguridad Swissi-España, S.L.U, Spain
J.M. Huber Finland OY, Finland
Johnson Matthey Chemicals GmbH, Germany
LSR Associates Ltd., the United Kingdom
Merck KGaA, Germany
Merck Performance Materials SAS, France
PPG Industries Chemicals BV, the Netherlands
Rhodia Operations SAS, France
SCAS Europe S.A./N.V., Belgium
Silysiamont SpA, Italy
Specialty Chemicals Coordination Center SA/NV, Belgium
Solvay Solutions Italia SpA, Italy
Wacker Chemie AG, Germany
PQ Silicas UK Ltd., the United Kingdom
PPG CENTRAL (UK) Ltd., the United Kingdom