

Announcement of appeal¹

Case	A-008-2017
Appellants	SI Group-UK Ltd., United Kingdom Oxiris Chemicals S.A., Spain
Appeal received on	23 June 2017
Subject matter	A decision adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 46(1) of the REACH Regulation
Keywords	<i>Substance evaluation – Error of assessment – Statement of reasons – Proportionality – Animal welfare – Compliance check</i>
Contested Decision	Agency Decision of 23 March 2017 on the substance evaluation of 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol (EC No 204-279-1, CAS No 118-82-1)
Language of the case	English

Remedy sought by the Appellants

The Appellants request the Board of Appeal to annul the Contested Decision requiring them to conduct an Extended One Generation Reproduction Toxicity Study (OECD test guideline 443; 'EOGRTS') in rats (oral route) and a soil simulation test (test method: aerobic and anaerobic transformation in soil; EU C.23/OECD 307).

In the alternative, the Appellants request the partial annulment of the requirement to conduct the soil simulation test in so far as it sets out the study design for that study.

The Appellants also request the Board of Appeal to order the Agency to pay the costs of the proceedings.

Pleas in law and main arguments

The Appellants submit that the Agency failed to fulfil the conditions for imposing further information requirements under Article 46 of the REACH Regulation and failed to provide an adequate statement of reasons. In particular, the Appellants claim that the Agency provided no information or explanation regarding the potential risk perceived by the Agency. In addition, the Appellants claim that the Agency failed to provide information or explanations on how the information required in the Contested Decision will lead to an improvement of the risk management measures in place.

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, as amended by Commission Implementing Regulation (EU) 2016/823.

The Appellants also claim that the requirement to conduct an EOGRTS is based on an error of assessment. In particular, the Appellants claim that there is insufficient weight-of-evidence to justify the request for information. The Appellants argue that whilst two high quality and reliable studies showed either no adverse effects or reversible effects, the Agency chose to rely on four old studies of poor or unreliable quality to support its finding of the possibility of adverse effects.

The Appellants argue that, should the Board of Appeal not annul the Contested Decision in its entirety, the Contested Decision should be partially annulled in so far as it sets out the study design for the soil simulation study. In this regard the Appellants consider that the Agency committed an error of assessment regarding the requirement to conduct a soil simulation study with use of strong extraction techniques, detection of degraded metabolites at 0.1% w/w and parallel testing at different temperatures.

The Appellants also claim that the requirement to conduct an EOGRTS breaches the principles of proportionality and animal welfare. The Appellants claim that it would be more proportionate, and in accordance with the principle of animal welfare, to adopt a step-wise approach whereby the Appellants perform an enhanced OECD 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test and then submit the results to the Agency with proposals for further testing where appropriate.

The Appellants claim that the Contested Decision infringes the procedural requirements provided by the REACH Regulation by requiring the requested information under substance evaluation without first performing a compliance check on the Appellants' registration dossiers.

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>