

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

**Case** A-007-2017

**Appellant** Infineum UK Ltd, United Kingdom

**Appeal received on** 19 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** Substance evaluation – Compliance check – Standard information

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 Appellant

The Appellant requests the Board of Appeal to annul Part II, Section 1 and Part III, Section 1 of the Contested Decision regarding 'Concerns on endocrine disruption and reproductive toxicity', which require the Appellant to conduct an Extended One Generation Reproduction Toxicity Study (OECD test guideline 443; 'EOGRTS') in rats (oral route).

The Appellant also requests the Board of Appeal to refund the appeal fee.

## Pleas in law and main arguments

The Appellant states that it registered 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol (hereinafter the 'Substance') at the 10 to 100 tonnes per year tonnage band. The Appellant adds that it is part of a joint submission for the Substance and that other registrants have registered the Substance at the 100 to 1 000 tonnes per year tonnage band.

The Appellant argues that, pursuant to Annexes IX and X to the REACH Regulation, an EOGRTS is a standard information requirement for registrants of a substance in quantities above 1 000 tonnes per year and, subject to certain conditions, above 100 tonnes per year. The Appellant claims that as a result an EOGRTS is not a standard information requirement for its registration dossier.

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The Appellant claims that by requiring it to submit information that is a standard information requirement for some of the registrants but not for the Appellant, and which would have been more adequately obtained through a prior compliance check, the Agency has identified and pursued an illegitimate objective for the substance evaluation it conducted, namely the need to fill alleged data gaps in the registration dossiers.

The Appellant argues that by requiring it to provide information that it would have not been required to provide if a compliance check of its registration had been conducted, and by not justifying why standard information was requested under substance evaluation rather than dossier evaluation, the Agency breached Articles 41(1), 42(2) and 47(1) of the REACH Regulation as well as the proportionality principle.

## **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