

Announcement of appeal¹

Case A-004-2017

Appellant 3v Sigma S.p.A., Italy

Appeal received on 20 March 2017

Subject matter A decision adopted by the European Chemicals Agency

(hereinafter the 'Agency') pursuant to Article 46 of the REACH

Regulation

Keywords Substance evaluation – Ultra vires – Infringement of the REACH

Regulation - Proportionality - Error of assessment

Contested Decision Decision of 20 December 2017 on the substance evaluation of

bis(2-ethylhexyl) 4,4'-{6-[4-tert-butylcarbamoyl) anilino]-1,3,5-triazine-2,4-diyldiimino}dibenzoate (CAS No 154702-15-5, EC No 421-450-8; hereinafter the 'Substance'), notified to the Appellant through the annotation number SEV-D-2114351702-55-01/F

Language of the case English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision in its entirety or in so far as it requires it to submit the following information on the Substance:

- sediment simulation testing (aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD Test Guideline 308) at 20°C, and
- further information on uses and environmental emissions.

The Appellant further requests reimbursement of the appeal fee and of all legal costs incurred.

Pleas in law and main arguments

The Substance is an effective ultra violet sunscreen used in cosmetic products. The Contested Decision requests further information on the Substance on the ground that, in essence, some of its metabolites could be persistent, bioaccumulative and toxic ('PBT') within the meaning of Annex XIII to the REACH Regulation.

The Appellant claims that the Contested Decision was adopted *ultra vires*, breaches the REACH Regulation and the principle of proportionality, and is based on a manifest error of assessment in several respects.

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.



First, the Appellant claims that it has been established that the Substance itself is not PBT. Further testing is therefore unnecessary.

Second, the Appellant argues that the testing conditions prescribed by the Contested Decision are not realistic in normal environmental conditions. The requested temperature of 20°C is intended to maximise the probability of formation of metabolites and, as such, not tailored to real information needs.

Third, the Appellant claims, in essence, that the information requirements in the Contested Decision go beyond what is necessary to achieve the objective pursued because the required test is onerous, the Substance itself is not PBT, and any metabolites that may be formed would be in such low quantities that it is improbable that they could cause environmental damage.

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