

Announcement of appeal¹

Case	A-009-2016
Appellant	Symrise AG, Germany
Appeal received on	29 September 2016
Subject matter	A decision adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 46(1) and in accordance with the procedure set out in Articles 50 and 51 of the REACH Regulation
Keywords	<i>Substance evaluation – Procedural requirements – Error of assessment – Proportionality – Breach of Article 25</i>
Contested Decision	Substance evaluation decision of 30 June 2016 requesting further information on the substance climbazole (CAS No 38083-17-9, EC No 253-775-4), notified to the Appellant through the annotation number SEV-D-2114340660-58-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision, order the refund of the appeal fee and take such other or further measures as justice may require.

Pleas in law and main arguments

Climbazole is an inorganic chemical substance used in cosmetic products for its antifungal properties. The Contested Decision, adopted pursuant to the substance evaluation procedure, requires the Appellant to submit further information on this substance, and in particular:

- An Extended One-Generation Reproductive Toxicity Study ('EOGRTS') in accordance with OECD Test Guideline ('TG') 443 in rats, oral route;
- A simulation test – aerobic sludge treatment, A: activated sludge units, B: biofilms, in accordance with OECD TG 303A or B;
- In vitro endocrine disruption screening studies; and
- Further information on worker exposure.

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 Appellant claims, first, that the Agency breached the Appellant's right to be heard, the procedural provisions in Articles 50 and 51 of the REACH Regulation, the principle of good administration and the Appellant's legitimate expectations. The Appellant argues, in this regard, that it was denied the opportunity to comment on the revised draft of the decision which was referred to the Member State Committee, and that it was not allowed to speak at the meeting of the Member State Committee in which climbazole was discussed.

Second, the Appellant claims with regard to the request for the EOGRTS that the Agency committed an error of assessment because it did not take all relevant information into account, and breached the duty to state reasons. The Appellant claims, moreover, that this request is disproportionate and breaches the animal welfare requirements of Article 25 of the REACH Regulation.

Third, the Appellant claims that the request for the aerobic sludge treatment simulation test was adopted in breach of the right to be heard and the duty to state reasons.

Fourth, the Appellant claims that the request for *in vitro* endocrine disruption screening studies was based on an error of assessment, and that the Agency breached its obligation to take all relevant information into account as well as the principle of legal certainty.

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>