ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 8 AUGUST 2018
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-009-2016

(Substance evaluation – Right to be heard)

Background

The Appellant is the only registrant of the substance climbazole (EC No 253-775-4, CAS No 38083-17-9).

Following an evaluation by the competent authority of the United Kingdom, the Appellant was required to provide the following information:

- an extended one-generation reproductive toxicity study (EOGRTS) in rats, oral route, with the registered substance,
- an aerobic sludge treatment simulation test,
- *in vitro* endocrine disruption screening studies, and
- further information on worker exposure.

The Appellant argued, amongst other things, that the Agency had breached procedural rules and the right to be heard.

Main findings of the Board of Appeal

The Board of Appeal found that the Appellant's right to be heard was breached with regards to the EOGRTS and the *in vitro* endocrine disruption screening studies.

First, the Board of Appeal found that the Appellant had all the opportunities to comment on the draft decision and on the proposals for amendment expressly foreseen in Articles 50 to 52 of the REACH Regulation (paragraphs 45 to 52 of the Decision of the Board of Appeal).

However, the Board of Appeal noted that there are circumstances in which, in order to comply with the right to be heard, registrants must be given an opportunity to make known their views beyond the procedural rules set out in Articles 50 to 52.

As regards the EOGRTS, the decision had been substantially modified in the closed session of the Member State Committee meeting, which is the final stage of the decision-making procedure. The decision-making procedure had therefore taken place in such a way that the Appellant had no opportunity to comment on the specific combination of the requested study (EOGRTS) and the potential concern (reproductive toxicity) (paragraphs 74 to 84 of the Decision of the Board of Appeal).

As regards the *in vitro* endocrine disruption screening studies, the evaluating Member State Competent Authority had included in the decision references to new information after the Appellant commented on the draft decision. The Appellant had no opportunity to comment on this information (paragraphs 95 to 108 of the Decision of the Board of Appeal).

The Board of Appeal therefore concluded that the Appellant's right to be heard had been breached with regards to the EOGRTS and the *in vitro* endocrine disruption screening studies, and annulled the Contested Decision to this extent.

NOTE: The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 91(1) of the REACH Regulation. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.
