EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 19 OCTOBER 2016 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-004-2015

(Compliance check – Read-across – Right to be heard – Animal welfare – Proportionality – Legitimate expectations)

Background

Following the compliance check of the registration dossier submitted by Polynt S.p.A. (hereinafter the 'Appellant') for the substance hexahydro-4-methylphthalic anhydride (hereinafter '4-MHHPA'), the Agency rejected a proposed read-across of data from other cyclic anhydrides to the Substance. ECHA therefore adopted the Contested Decision requiring the Appellant to provide certain standard information, including a sub-chronic toxicity study (90-day) and a pre-natal developmental toxicity study on 4-MHHPA.

The Appellant sought the annulment of the Contested Decision concerning these two information requests.

Main findings of the Board of Appeal

With regard to the Appellant's claims concerning breaches of procedural requirements, the Board of Appeal found that the procedural provisions in the REACH Regulation (Articles 50 and 51) do not oblige the Agency to request a registrant's comments on every revised version of a draft compliance check decision, but only on the initial draft decision. Nevertheless, the Board of Appeal considered that in certain circumstances it is possible that the addressees of a decision should be given the opportunity to comment beyond the opportunities foreseen in Articles 50 and 51. However, in the present case the Contested Decision was not based on any matters of fact or law on which the Appellant had not had sufficient opportunities to make known its views effectively. The Appellant's right to be heard had therefore been respected.

Concerning an argument that the Appellant was not required to submit the standard information at issue because the Substance was already classified as a respiratory sensitiser and stringent risk management measures were in place, the Board of Appeal found that the REACH Regulation makes no provision for such an adaptation.

The Board of Appeal furthermore found that the Agency did not commit an error in rejecting the Appellant's proposed read-across of data from other cyclic anhydrides to 4-MHHPA. In particular, the Appellant had not explained variabilities in No Observed Adverse Effect Levels between the various substances. It had also failed to explain why studies performed on one of the substances in the read-across group showed renal effects which were absent in studies on the other substances in that group. The Board of Appeal therefore considered that the Appellant had not established that the structural differences between the cyclic anhydrides did not lead to different toxicological effects. Having rejected the read-across, ECHA had to ask for relevant standard information. Since it has no discretion is this regard, ECHA could not have breached the principle of proportionality or the animal welfare provisions by adopting the Contested Decision.

Finally, the Board of Appeal rejected the Appellant's arguments concerning its alleged legitimate expectation that the proposed read-across would be accepted because the Agency had relied on data relating to other cyclic anhydrides for the purposes of identifying 4-MHHPA as a Substance of Very High Concern. The Board of Appeal found, in essence, that the Appellant's argument was factually incorrect.

The appeal was dismissed.

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.
