EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 7 OCTOBER 2016 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-017-2014

(Dossier evaluation – Compliance check of a registration – Pre-natal developmental toxicity study – Read-across adaption – Duties of the Agency)

Factual background

Following a compliance check of a registration dossier for prop-2-yn-1-ol (hereinafter the 'Substance') submitted by BASF SE (hereinafter the 'Appellant'), the European Chemicals Agency (hereinafter the 'Agency') sent a draft decision requiring the Appellant to submit a pre-natal developmental toxicity (hereinafter 'PNDT') study to fulfil the standard information requirement of Section 8.7.2 of Annex IX to the REACH Regulation. The Appellant had proposed to address the information requirement through a read-across based on the analogue substance 2-butyne-1,4-diol. However, the Agency rejected the Appellant's read–across proposal as the studies submitted in support of the read-across showed that the Substance might be more toxic than the read-across substance.

The Appellant submitted comments to the Agency and updated its registration dossier and sought in the process to further justify its read-across approach. The Agency revised the draft decision after considering the Appellant's comments and dossier update but maintained the requirement for a PNDT study. The Agency notified the modified draft decision to the competent authorities of the Member States (hereinafter the 'MSCAs') in accordance with Article 51(1) and received several proposals for amendment, one of which proposed to remove the request for the PNDT study on the basis that the read-across proposal should be accepted (hereinafter the 'PfA'). These were notified to the Appellant, who submitted new comments to the Agency and updated its registration dossier for a second time, bringing further elements to the justification of its read-across proposal.

The Member State Committee revised certain aspects of the modified draft decision but rejected the PfA and maintained the requirement to perform a PNDT study and the Agency subsequently adopted the Contested Decision.

The Appellant lodged an appeal seeking the annulment of the Contested Decision and the refund of the appeal fee.

Main findings of the Board of Appeal

In its Decision of 7 October 2016, the Board of Appeal found that, contrary to the Appellant's argument, the Agency had correctly fulfilled its obligations under Articles 50(1) and 51(5) by addressing and taking into account in a professional and scientific manner the first dossier update and the Appellant's comments. The Board of Appeal observed that Article 50(1) does not oblige the Agency to request comments from concerned registrants on all amended drafts following the first draft of a compliance check decision. Similarly, Article 51(5) only gives the

Appellant the opportunity to comment on any proposals for amendment to the draft decision and not once more on the draft decision. The Board of Appeal observed that if the Appellant's argument was accepted, it could potentially lead to the evaluation procedure developing into an endless commenting exercise.

The Board of Appeal furthermore found lawful the Agency's practice of not taking into account a registrant's comments and dossier updates after the referral of a draft decision to the MSCAs. The Board of Appeal noted that this practice can be justified by the need for stability in the information contained in the registration dossier under evaluation when it must be examined by the MSCAs. The Board of Appeal considered that the present case could be distinguished from Case A-001-2014, *CINIC Chemicals Europe* because the information referred to by the Appellant was not substantial or new since it was already contained in the original registration dossier or in the first dossier update.

In light of the above considerations, the Board of Appeal concluded that the Agency did not breach Articles 50(1) and 51(5) and that the Agency's cut-off point was lawful. Consequently, the Board of Appeal dismissed the appeal, decided that the appeal fee should not be refunded and upheld the Contested Decision.
