SUMMARY OF DECISION OF 1 AUGUST 2016 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-003-2015

(Compliance check – Weight of evidence adaption – Column 2 of Section 8.7 of Annex IX adaption – Pre-natal developmental toxicity study)

Factual background

Following a compliance check of the registration dossier for antimony nickel titanium oxide yellow (the 'Substance') submitted by BASF Pigment GmbH (the 'Appellant'), the European Chemicals Agency (the 'Agency') sent a draft decision to the Appellant requiring it to submit a pre-natal developmental toxicity ('PNDT') study to fulfil the information requirements of Section 8.7.2 of Annex IX of the REACH Regulation (the 'PNDT endpoint'). The Appellant sought to fulfil these requirements in its registration dossier through an adaptation listed at the third indent of Column 2 to the PNDT endpoint.

The Appellant failed to provide any comments on the draft decision, but updated its registration dossier on 7 August 2013 to further justify how it met the information requirements for the PNDT endpoint.

On 1 September 2014, the Member State Committee unanimously adopted the Contested Decision and notified it to the Appellant on 26 November 2014. The Agency concluded in the Contested Decision that the Appellant had not documented that the three cumulative conditions of the Column 2 adaptation for the PNDT endpoint were met. The Contested Decision noted that although the Appellant had provided some evidence of low toxicity it had not documented either lack of absorption or of human exposure.

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 on 1 August 2016, the Board of Appeal examined inter alia whether the Agency had made an error of assessment in the Contested Decision. The Appellant claimed that it provided sufficient information to satisfy the PNDT endpoint and that it had employed a weight of evidence.

The Board of Appeal first concluded that the Agency was correct in finding that the Appellant had documented neither lack of absorption nor lack of human exposure. Specifically, the Agency had rejected the Appellant's claimed adaptation on the basis of objective arguments and observable results. Furthermore the Appellant had not substantied its argument that the Substance's migration was below the limit of detection.

The Appellant had also incorrectly considered that the condition of lack of absorption could be satisfied in this case through evidence of low bioavailability. Similarly, the Appellant could not

use the cut-off criteria for the classification of mixtures under the CLP Regulation to demonstrate that the conditions of the Column 2 adaptation were met as these criteria only demonstrated low absorption rather than lack of absorption. The Appellant had also failed to address the Agency's concerns regarding the use by consumers of products containing the Substance.

The Board of Appeal then considered whether the Agency correctly concluded that the Appellant's weight of evidence approach could not fulfil the cumulative conditions of the Column 2 adaption. The Board of Appeal noted that for such an approach to succeed, the Appellant would need to provide information showing by weight of evidence that the Column 2 conditions were met. However, the Board of Appeal had already found that the data submitted by the Appellant was not sufficient for the second and third adaptation conditions for the PNDT endpoint to be met. Therefore, the Board of Appeal concluded that the Appellant had not demonstrated that the Column 2 adaptation was met through a weight of evidence approach.

In response to the Appellant's argument that a webinar given by the Agency gave rise to legitimate expectations that the Appellant's weight of evidence approach would be accepted by the Agency, the Board of Appeal considered that it was not clear from the webinar's slides that the Agency had indicated how to use a weight of evidence approach to satisfy the Column 2 adaptation conditions.

The Board of Appeal analysed whether the Agency made an error in the assessment of the Appellant's weight of evidence approach in light of the requirements in Section 1.2 of Annex XI. The Appellant had not explicitly claimed a weight of evidence adaption in its registration dossier and the Board of Appeal considered it was not the task of the Agency to develop, justify or improve a weight of evidence adaption on a registrant's behalf and concluded therefore that the Agency did not err in that regard.

In light of the above considerations, the Board of Appeal concluded that the Agency did not commit an error of assessment. Consequently, the Board of Appeal dismissed the appeal, decided that the appeal fee shall not be refunded and upheld the Contested Decision.
