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

Case number: A-014-2014

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

Factual Background

Following a compliance check of the registration dossier for chrome antimony titanium buff rutile (hereinafter the 'Substance') submitted by BASF Pigment GmbH (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 (hereinafter the 'PNDT endpoint'). Although the Appellant had proposed to satisfy the PNDT endpoint by application of the adaptation possibility set out in the third indent of Column 2 of Section 8.7 of Annex IX (hereinafter the 'Column 2 adaptation'), the Agency concluded that this proposal did not meet the three cumulative conditions for that adaptation (namely, low toxicity, lack of absorption by relevant routes and lack of human exposure).

The Appellant submitted comments on the draft decision and updated its registration dossier to further justify how it fulfilled the conditions of the Column 2 adaptation. The Agency revised its draft decision, concluding that the Appellant still failed to demonstrate how the conditions of the Column 2 adaptation were met. The Agency noted, concerning the first condition, that the Appellant had provided evidence of low toxicity. However, when it came to the second and third conditions, the Appellant had neither provided evidence on the lack of absorption by relevant routes nor on the lack of human exposure.

The Agency notified its revised draft decision to the competent authorities of the Member States and, having received no proposals for amendment, adopted its final decision (hereinafter the 'Contested Decision') and notified it to the Appellant.

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 1 August 2016, the Board of Appeal noted that the Appellant was arguing in its appeal, in essence, that the Agency made an error of assessment. In particular, the Appellant claimed that it provided sufficient information to satisfy the PNDT endpoint through a weight of evidence approach. The Board of Appeal, in order to decide whether there was an error of assessment on the part of the Agency, examined the latter's assessment of the information contained in the Appellant's dossier in three steps. First, it examined the Agency's assessment of the three cumulative conditions for a Column 2 adaptation. Second, it considered whether the Agency had correctly assessed the approach claimed by the Appellant that it used a weight of evidence approach to fulfil the cumulative conditions of the Column 2 adaptation. And, third, the Board of Appeal analysed the Agency's assessment of the

Appellant's dossier in light of the rules governing weight of evidence adaptations for standard information requirements in Section 1.2 of Annex XI.

The Board of Appeal first concluded that the Agency had correctly found that the second and third conditions of the Column 2 adaptation, namely the lack of systemic absorption and no or no significant human exposure to the Substance, were not fulfilled by the Appellant. The Agency had advanced objective arguments to justify that the information submitted by the Appellant was insufficient. More specifically, the Agency had correctly concluded, based on the information submitted in the Appellant's dossier, that the substance was bioavailable. Furthermore, the Agency was correct in concluding that the Appellant had failed to substantiate its claim that there was no or no significant human exposure to the Substance.

The Board of Appeal then found that the Agency correctly assessed the Appellant's proposed weight of evidence approach as applied to the cumulative conditions of the Column 2 adaptation. In order for the weight of evidence approach to succeed, the Appellant would have needed to provide information showing, by weight of evidence, that the conditions for the Column 2 adaptation were met. However the Board of Appeal had already found that the second and third conditions were not met through the information provided by the Appellant. Therefore, the Agency had not committed an error of assessment in this regard. The Board of Appeal also found that a webinar given by the Agency did not, contrary to the Appellant's claim, give rise to legitimate expectations that its weight of evidence approach to the Column 2 adaptation would be valid. In particular the webinar's slides did not indicate how a weight of evidence approach could be used to satisfy the conditions of the Column 2 adaptation.

Finally, the Board of Appeal found that the Agency did not make an error of assessment regarding the Appellant's claimed weight of evidence adaptation for the PNDT endpoint pursuant to Section 1.2 of Annex XI. The Board of Appeal observed that the Appellant did not explicitly claim a weight of evidence adaptation but rather argued that the data it had submitted would be sufficient in its own right. The Board of Appeal found, however, that it is not the task of the Agency to develop, justify or improve a weight of evidence adaptation on a registrant's behalf. The Board of Appeal added that even if the Agency had done so, the conditions for a weight of evidence adaptation for the PNDT endpoint for the Substance would not have been fulfilled by the Appellant's data.

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.
