ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 9 NOVEMBER 2021
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-009-2020

(Follow-up to dossier evaluation – Article 42(1) of the REACH Regulation – Cessation of manufacture – Legal certainty – Proportionality – Read-across)

Factual background

The Appellant sought the annulment of a decision taken by the Agency under Article 42(1) of the REACH Regulation in follow-up to an initial compliance check decision concerning the Appellant's registration dossier for substance esterification products of 1,3-dioxo-2-benzofuran-5-carboxylic acid with nonan-1-ol (EC Number 941-303-6; the 'Substance').

By its initial compliance check decision taken under Article 41 of the REACH Regulation, the Agency rejected amongst others the read-across adaptation with which the Appellant had sought to fulfil the standard information requirement for a sub-chronic toxicity study under Section 8.6.2. of Annex IX to the REACH Regulation.

In response to the initial compliance check decision the Appellant submitted an updated read-across adaptation for the sub-chronic toxicity study endpoint. Subsequently, it informed the Agency that it had ceased manufacturing the Substance.

By the contested decision the Agency rejected the updated read-across adaptation and found that the Appellant's registration dossier still does not comply with Section 8.6.2. of Annex IX to the REACH Regulation. The Appellant requested the Board of Appeal to annul the contested decision on two main grounds. First, the Appellant argued that the Agency should not have addressed to it the contested decision after it had lawfully ceased to manufacture the Substance. Second, the Appellant argued that the Agency committed an error of assessment in rejecting its read-across adaptation.

Main findings of the Board of Appeal

In its Decision of 9 November 2021, the Board of Appeal dismissed the appeal.

The Board of Appeal held that the Appellant continued to be bound to provide the information requested in the initial compliance check decision even if it had ceased manufacturing the Substance after the adoption of that decision. Article 50(2) of the REACH Regulation only prevented the Appellant from being subject to a new request concerning other information that was not requested in the initial compliance check decision.

The Board of Appeal held that the contested decision did not contain any request for further information within the meaning of Article 50(2). In the contested decision the Agency merely concluded that the Appellant's registration dossier still contained a data-gap regarding the information on a sub-chronic toxicity study that had been requested in the initial compliance check decision. The Board of Appeal therefore rejected the Appellant's claim that the Agency breached Articles 42(1) and 50 of the REACH Regulation by adopting

the contested decision.

The Board of Appeal held that the guidance provided by the Agency on the consequences of a cessation of manufacture after the adoption of a compliance check decision was clear and precise and enabled the Appellant to know without ambiguity what its rights and obligations are and to take steps accordingly. Therefore, there was no breach of the principle of legal certainty and the principle of protection of legitimate expectations.

Likewise, the Agency was correct in addressing the contested decision to the Appellant, and not to another registrant of the Substance that had not ceased to manufacture it. The fact that the Substance was still manufactured by another registrant did not have any bearing on the finding that the Appellant continued to be bound to provide the information requested in the initial compliance check decision.

The Appellant also argued that the Agency breached Articles 5 and 6 of the REACH Regulation by requesting the Appellant to generate and submit data on the Substance that could no longer be manufactured either by the Appellant or by anyone else in the European Union due to the unavailability of suitable raw material. The Board of Appeal rejected those claims. The Appellant continued to be bound to provide the information requested in the initial compliance check decision irrespective of the reasons due to which it had ceased the manufacture of the Substance. Moreover, the Appellant had not established that it would be impossible to obtain a sample of the Substance for performing the requested sub-chronic toxicity study.

The Board of Appeal also held that the Agency did not make an error of assessment in rejecting the Appellant's read-across adaptation. The Appellant sought to comply with Section 8.6.2. of Annex IX to the REACH Regulation by providing sub-chronic toxicity data on three structurally similar substances. The Agency was correct in finding that the predictions from computational methods provided by the Appellant were not sufficient to support the hypothesis that the toxicological properties of the Substance and the three source substances are likely to be similar or follow a regular pattern.
