EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 22 MARCH 2022 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case A-005-2020

(Substance evaluation – Error of assessment – Potential risk – Improved risk management measures)

Factual background

The appeal concerned a decision of the European Chemicals Agency (the 'Agency') on the substance evaluation of 2,5,7,10,11,14-hexaoxa-1,6-distibabicyclo[4.4.4]tetradecane ('ATEG') requesting the Appellant to provide information on a 90-day (sub-chronic) toxicity study in rats, oral route (test method: OECD test guideline 408), including additional cardiovascular and toxicokinetic parameters.

The Contested Decision stated that the requested information was necessary to clarify concerns that ATEG may cause systemic toxicity and potentially cancer after prolonged exposure, as well as cardiotoxicity.

The Appellant requested the Board of Appeal to annul the Contested Decision in its entirety or, alternatively, annul the additional parameters required in the Contested Decision.

Main findings of the Board of Appeal

In its decision of 22 March 2022, the Board of Appeal dismissed the appeal.

The Board of Appeal confirmed that, to request information under substance evaluation, the Agency must establish that:

- there are grounds for considering that, based on a combination of exposure and hazard information, a substance constitutes a potential risk to human health or the environment,
- the potential risk needs to be clarified, and
- the requested information has a realistic possibility of leading to improved risk management measures.

The Board of Appeal rejected the Appellant's argument that the Agency had failed to demonstrate a potential risk. The Appellant did not demonstrate that the Agency made an error in finding that there was a potential hazard related to cardiotoxicity – the potential hazard in relation to the other concerns was not disputed – and that there was potential exposure to ATEG for workers and consumers.

The Board of Appeal rejected the Appellant's argument that the Agency had not demonstrated that the requested information has a realistic possibility of leading to improved risk management measures. In this respect, the Contested Decision stated that the requested study can be used for deciding on the classification of ATEG for specific target organ toxicity repeat exposure ('STOT RE') 1 or 2 under the CLP Regulation[1].

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1; the 'CLP Regulation').

The Board of Appeal decided that the requested study has a realistic possibility of leading to a harmonised STOT RE classification. Furthermore, a STOT RE classification triggers certain obligations that constitute improved risk management measures, notably as regards the labelling and packaging of the substance concerned. 'Warning' for STOT RE 2 classification and 'danger' for STOT RE 1 classification are examples of labelling requirements. Such labelling enhances the protection of human health as it improves information for users of the substance concerned as to the risks incurred. In addition, a STOT RE classification must be included in the safety data sheet which the supplier of the substance concerned must provide to the recipients of the substance. Since ATEG is not classified as STOT RE, the introduction of such a classification for that substance would constitute an improved risk management measure.

The Appellant's argument that the Agency infringed an essential procedural requirement of the REACH Regulation as it did not perform a compliance check on ATEG prior to the substance evaluation was rejected. The Board of Appeal confirmed that the Agency should not, in principle, use the substance evaluation process to request the standard information listed in Annexes VII to X to the REACH Regulation. However, in the present case, the requested study could not have been requested under the compliance check procedure as it is not standard information. Furthermore, the Agency is not required to complete a compliance check, concerning all information contained in a registration dossier, before performing a substance evaluation.

The Appellant's argument that the Agency should have allowed the Appellant to complete its own testing strategy and develop a grouping approach and read-across proposals before requesting additional information under substance evaluation was also rejected. The Board of Appeal noted that the Appellant's testing strategy has not been completed and the Agency is not required to wait for a registrant to generate information to support or improve potential adaptations. The Board of Appeal also highlighted that the information needed to establish structural similarity for the purposes of identifying a potential risk under the substance evaluation process is different from that needed to justify a read-across adaptation for registration purposes under Section 1.5. of Annex XI to the REACH Regulation.

Following the Board of Appeal's decision, the Appellant is required to provide the information requested in the Contested Decision by 30 December 2023.
