SUMMARY OF DECISION OF 29 JANUARY 2020 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-008-2018

(Substance evaluation – Legal basis – Potential risk)

Factual background

The appeal concerned a decision of the European Chemicals Agency (the 'Agency') on the substance evaluation of zinc bis dimethyldithiocarbamate (EC No 205-288-3, CAS No 137-30-4; 'Ziram').

The contested decision required the appellants to provide information on a combined developmental neurotoxicity study (OECD TG 426) and neurotoxicity study in rats (OECD TG 424). The request for information was based on concerns for developmental neurotoxicity and parkinsonian disorders.

The appellants requested the Board of Appeal to annul the contested decision.

Main findings of the Board of Appeal

In its Decision of 29 January 2020, the Board of Appeal dismissed the appellants' claim that the Agency had failed to identify the correct legal basis for the contested decision. The Board of Appeal decided that the information requested in the contested decision went beyond the information requirements set out in the Annexes to the REACH Regulation and could therefore only be requested under substance evaluation. Consequently, the Agency was not required to identify a provision of the Annexes to the REACH Regulation as the basis for its request for information.

The Board of Appeal then examined the appellants' claim that the Agency had failed to establish a potential risk of parkinsonian disorders being caused by exposure to Ziram.

To demonstrate the concern that exposure to Ziram may induce parkinsonian disorders the Agency had relied in particular on several epidemiological and mechanistic studies.

The Board of Appeal found however that there were a number of shortcomings in the epidemiological studies relied on by the Agency. In particular, there was a lack of clarity regarding which substances the subjects of the study were exposed to and for how long. As a result, those studies offered only weak evidence of an association between exposure to Ziram and the development of parkinsonian disorders.

The Board of Appeal also found that the mechanistic studies relied on by the Agency did not demonstrate a link between exposure to Ziram and parkinsonian disorders. In particular, the Board of Appeal observed that those studies did not demonstrate that Ziram reaches the relevant parts of the human brain to cause the effects observed in those studies. This is primarily because the mechanistic studies used test subjects which, unlike humans, have no blood-brain barriers.

The Board of Appeal therefore annulled the OECD TG 424 part of the combined study.

In its Decision, the Board of Appeal did not examine whether the Agency had established a concern for developmental neurotoxicity for the purposes of requesting the OECD TG 426 part of the combined study.

The Board of Appeal noted that, if it were to uphold the request for a developmental neurotoxicity study (OECD TG 426) alone, it might need to adopt its own decision by amending the contested decision and ordering the appellants to perform the developmental neurotoxity study (OECD TG 426).

The Board of Appeal is competent under Article 93(3) of the REACH Regulation to replace an Agency decision with its own decision where the Agency decision in question is vitiated by errors. However, before doing so, the Board of Appeal must examine whether it has enough evidence at its disposal and must bear in mind the procedure for adopting Agency decisions under the substance evaluation process, and in particular the role of the various actors in that procedure.

In the present case, the Board of Appeal found that it did not possess sufficient information to decide whether the performance of the OECD TG 426 study requested in the contested decision, when performed without the OECD TG 424 study, would provide additional information to that already available. It was unclear whether a request to provide information from a new OECD TG 426 study on its own would help to clarify whether Ziram is a developmental toxicant. It was also unclear whether conducting a new OECD TG 426 study would result in the unnecessary repetition of testing on vertebrate animals. Furthermore, considering the important role of the various actors in the procedure for adopting a substance evaluation decision, the Board of Appeal considered that it was not appropriate to examine itself those open questions.

The Board of Appeal therefore remitted the case to the Agency for further action.
