

## **SUMMARY OF DECISION OF 25 APRIL 2023 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

### **Case numbers: Joined Cases A-002-2022 and A-003-2022**

*(Dossier evaluation – Compliance check – Section 8.7.3. of Annex IX – EOGRTS – Additional investigations on learning and memory function)*

#### *Factual background*

The Appellants are registrants of the substance O,O,O-triphenyl phosphorothioate (the **Substance**).<sup>1</sup>

On 14 January 2022, the Agency adopted a compliance check decision under Article 41 of the REACH Regulation<sup>2</sup> (the **Contested Decision**). The Contested Decision required the Appellants to submit information on an extended one-generation reproductive toxicity study (**EOGRTS**) (EU test method B.56) under Section 8.7.3. of Annex IX, including cohorts 2A and 2B (developmental neurotoxicity) and additional investigations on learning and memory function as described in paragraph 37 of EU test method B.53.

The Appellants requested the Board of Appeal to annul the Contested Decision insofar as it required additional investigations on learning and memory function. They did not challenge the rest of the Contested Decision.

#### *Main findings of the Board of Appeal*

The Board of Appeal determined, at the outset, that the legal basis used in the present cases by the Agency to require the contested investigations on learning and memory function was Article 41(3) in conjunction with the second paragraph of Column 2 of Section 8.7.3. of Annex IX, Article 13(3) and paragraph 50 of EU test method B.56.

The Board of Appeal held that investigations on learning and memory function are not an information requirement for the Appellants' registration under those provisions. None of those provisions require investigations on learning and memory function as an information requirement. They merely ensure that the integrity of the evaluations conducted under cohorts 2A and 2B of an EOGRTS is not compromised by any potential other functional testing that may be carried out, but without providing for an obligation to carry out such testing.

The Board of Appeal therefore concluded that investigations on learning and memory function are not an information requirement for the Appellants' registration of the Substance under the legal basis used by the Agency. By requiring those investigations in the Contested Decision, the Agency exceeded its powers.

The Contested Decision was therefore annulled insofar as it required the Appellants to conduct the contested investigations on learning and memory function on the said legal basis. The Contested Decision was upheld for the remainder.

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<sup>1</sup> EC No 209-909-9; CAS No 597-82-0.

<sup>2</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1). All references to Articles and Annexes hereafter concern the REACH Regulation unless stated otherwise.

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**NOTE:** The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 91(1) of the REACH Regulation. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.

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*Unofficial document, not binding on the Board of Appeal*

*The full text of the decision is available on the Board of Appeal's section of ECHA's website:*  
<http://echa.europa.eu/about-us/who-we-are/board-of-appeal>