EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

**SUMMARY OF DECISION OF 30 JANUARY 2018 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

**Case number: A-005-2016**

*(Testing proposal – Read-across – Duty to state reasons – Article 25 – Legitimate expectations)*

*Factual background*

The Appellant requested the Board of Appeal to annul an ECHA testing proposal decision concerning sodium O,O-diethyl dithiophosphate (EC No 222-079-2; CAS No 3338-24-7) (the 'Substance'). The Contested Decision requires the Appellant to provide the following information on the Substance:

- Sub-chronic toxicity study (90-day), oral route (Section 8.6.2. of Annex IX; test method: EU B.26/OECD TG 408) in rats, and
- Pre-natal developmental toxicity study (Section 8.7.2. of Annex IX; test method: EU B.31/OECD TG 414) in rats or rabbits, oral route.

ECHA rejected the Appellant's read-across proposal according to which the Appellant would have performed the tests on sodium O,O-diisobutyl dithiophosphate (EC No 258-508-5; CAS No 53378-51-1) (the 'source substance'). The tests on the source substance were subject to a separate testing proposal procedure and decision. The results of the tests on the source substance would therefore be available at a later date.

*Main findings of the Board of Appeal*

The Board of Appeal found that the Contested Decision was adopted on the wrong legal basis (see paragraphs 36 to 59 of the Board of Appeal's decision). As it was the Appellant's clear intention to submit a read-across adaptation rather than a testing proposal, the Contested Decision should have been adopted under the compliance check procedure (Article 41 of the REACH Regulation) rather than the testing proposal procedure (Article 40 of the REACH Regulation).

The Board of Appeal found however that the Agency's choice of the wrong legal basis was not sufficient to lead to the annulment of the Contested Decision. In the present case, the Agency's reliance on Article 40 rather than Article 41 as the legal basis for the Contested Decision did not lead to a different assessment of the Appellant's registration dossier for the endpoints in question and would not therefore have led to a different decision. Furthermore, the Agency's error in the choice of legal basis did not deprive the Appellant of the procedural guarantees set out in the relevant provisions of the REACH Regulation, in particular Articles 50 and 51.

The Board of Appeal also found that ECHA did not breach Section 1.5 of Annex XI to the REACH Regulation by rejecting the Appellant's read-across proposal (see paragraphs 84 to 108 of the Board of Appeal's decision). Although the Appellant had established that the two substances are structurally similar it had failed to demonstrate that they had similar toxicological properties as required by Section 1.5 of Annex XI.

The Appellant's argument that the Contested Decision breached the principle of legal certainty was also rejected (see paragraphs 111 to 121 of the Board of Appeal's decision). The Appellant argued in particular that if it submits an updated read-across adaptation with the results of the studies on the source substance it does not know whether this will comply with the Contested Decision and, as a result, it may face enforcement action.

The Board of Appeal found that if the Appellant updates its read-across adaptation with the results of the two studies on the source substance the Agency will be required to examine this in accordance with Article 42 of the REACH Regulation. This additional information would, in the present case, be substantial new information. Consequently, if the Agency decides that the updated read-across adaptation does not comply with the Contested Decision the Agency will be required to draft a new decision following the procedure set out in Articles 50 and 51 of the REACH Regulation.

The Appellant's arguments that the Agency breached Article 25 and the principle of proportionality were also rejected by the Board of Appeal (see paragraphs 158 to 170 of the Board of Appeal's decision). Since the Agency did not commit an error in rejecting the Appellant's proposed read-across adaptation, it had no discretion as to whether to request the Appellant to perform the sub-chronic toxicity study, which is a registration requirement under Section 8.6.2 of Annex IX, and the pre-natal developmental toxicity study, which is a registration requirement under Section 8.7.2. of Annex IX.

The Board of Appeal also rejected the Appellant's claims that the Agency failed to take into consideration all available information (paragraphs 128 to 132 of the Board of Appeal's decision), breached the duty to state reasons (paragraphs 136 to 141) and the duty of good administration (paragraphs 145 to 147), as well as the principle of legitimate expectations (paragraphs 179 to 186).

The appeal was therefore rejected in its entirety. Having regard to the suspensive effect of appeals, the Appellant must comply with the Contested Decision by 7 February 2020.

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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*