EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 19 SEPTEMBER 2023 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-009-2022

(Dossier evaluation – Compliance check – Requirements of Columns 1 and 2 of Section 8.7.3. of Annex IX – EOGRTS – Basic study design – Cohorts 2A and 2B – Additional investigations on learning and memory function)

Factual background

The Appellants are registrants of the substance 1,1,4,4-tetramethyltetra-methylene diperoxide (the **Substance**).[1]

On 8 June 2022, the Agency adopted a compliance check decision under Article 41 of the REACH Regulation[2] (the **Contested Decision**). The Contested Decision required the Appellants to submit inter alia information on an extended one-generation reproductive toxicity study (**EOGRTS**) 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 that information.

Main findings of the Board of Appeal

The Appellants argued that the Contested Decision was vitiated by legal and factual errors as regards the requirement for information on an EOGRTS, the inclusion of cohorts 2A and 2B in that EOGRTS, and the additional investigations on learning and memory function.

1. *The requirement for information on an EOGRTS*

In the Contested Decision, the Agency found that available information on the Substance meets the conditions of Column 1 of Section 8.7.3. of Annex IX, so that information on an EOGRTS is required as standard information in this case. The Appellants argued that the Agency failed to assess whether it is proportionate to require that information.

The Board of Appeal held that where the Agency has a power of discretion as to the measure to be taken, it must ensure that the measure it chooses is proportionate. Where it has no such power of discretion because the measure to be taken has been determined by the legislature, the Agency is neither required nor empowered to examine the proportionality of the measure, that assessment being reserved to the EU Courts.

Under Column 1 of Section 8.7.3. of Annex IX, an EOGRTS with the basic study design is a standard information requirement for registration if the available information shows at least one of the following: adverse effects on reproductive organs, adverse effects on reproductive tissues, or other concerns in relation to reproductive toxicity.

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1 EC No 201-128-1; CAS No 78-63-7.

2 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.

If at least one of those conditions is fulfilled, the Agency is obliged to require information on an EOGRTS with the basic study design as standard information. The Agency has no power of discretion as regards the measure to be taken. In addition, the Agency does not have the obligation to wait for a registrant to generate further information before adopting its decision. The Agency therefore was not required to examine whether requesting information on an EOGRTS as standard information is consistent with the principle of proportionality.

Furthermore, the Board of Appeal examined in detail the Agency's scientific assessment in this case and concluded that the Agency had not committed any error in that regard.

2. The inclusion of cohorts 2A and 2B

In the Contested Decision, the Agency found that available information on the Substance meets the conditions of the second paragraph of Column 2 of Section 8.7.3. of Annex IX, so that the EOGRTS must include cohorts 2A and 2B (developmental neurotoxicity). The Appellants argued that the Agency failed to assess whether this requirement is proportionate, and failed to examine whether the effects triggering these investigations were serious or severe.

The Board of Appeal held that the second paragraph of Column 2 of Section 8.7.3. of Annex IX must be interpreted as meaning that registrants who are required to submit information on an EOGRTS as standard information are also required to include cohorts 2A and 2B in the EOGRTS if the available information gives reasonable grounds for considering that a substance may cause effects related to (developmental) neurotoxicity, and cohort 3 if the available information gives reasonable grounds for considering that a substance may cause effects related to (developmental) immunotoxicity.

If one or more of those conditions are fulfilled, the Agency is obliged to require the registrants of the substance to include cohorts 2A and 2A, and/or cohort 3, in their EOGRTS. The Agency has no power of discretion as regards the measure to be taken. The Agency therefore was not required to examine whether requesting information on an EOGRTS as standard information is consistent with the principle of proportionality.

Furthermore, the Board of Appeal held that the effects referred to in the second paragraph of Column 2 of Section 8.7.3. of Annex IX must be 'particular' or 'specific' in the sense that they must relate to (developmental) neurotoxicity or (developmental) immunotoxicity, and not merely to reproductive or systemic toxicity in general. However, that provision does not state that the effects observed in the available studies must be especially serious or severe.

Finally, the Board of Appeal examined in detail the Agency's scientific assessment in this case and concluded that the Agency had not committed any error in that regard.

3. The additional investigations on learning and memory function

The Contested Decision required that the EOGRTS should include additional investigations on learning and memory function as described in paragraph 37 of EU test method B.53. The Appellants argued that the Agency exceeded its powers by requiring those investigations on that legal basis.

The Board of Appeal held that investigations on learning and memory function are not an information requirement for the Appellants' registration of the Substance under the second paragraph of Column 2 of Section 8.7.3. of Annex IX in conjunction with Article 13(3) and paragraph 50 of EU test method B.56.[3]

[3] See also decision of the Board of Appeal of 25 April 2023, *BASF Lampertheim and Metall-Chemie*, joined cases A-002-2022 and A-003-2022.

4. Result

The appeal was upheld as regards the additional investigations on learning and memory function, and the Contested Decision was annulled to that extent. The appeal was dismissed as regards the requirement for information on an EOGRTS including cohorts 2A and 2B.
