EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 9 FEBRUARY 2021 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case A-015-2019

(Testing proposal – Extended one-generation reproductive toxicity study – Error of assessment – Third-party consultation – Animal welfare – Proportionality)

Factual background

The appeal concerned a decision of the European Chemicals Agency (the 'Agency') on a testing proposal for the substance hexahydro-4-methylphthalic anhydride (EC number 243-072-0, CAS number 19438-60-9; the 'Substance').

The Appellant sought the annulment of the Agency's decision requesting the Appellant to carry out an extended one-generation reproductive toxicity study ('EOGRTS'), including Cohort 3 (developmental immunotoxicity). In the alternative, the Appellant requested the partial annulment of the contested decision insofar as it required the EOGRTS to include Cohort 3.

Main findings of the Board of Appeal

In its Decision of 9 February 2021, the Board of Appeal dismissed the appeal.

The Board of Appeal rejected the Appellant's claim that, under the specific rules for adaptation contained in the first and third indents of Column 2 of Section 8.7. of Annex X to the REACH Regulation, the EOGRTS was not necessary.

In an earlier decision, the Agency had decided that, due to its respiratory sensitising properties, the Substance raises an '*equivalent level of concern*' to substances that are carcinogenic, mutagenic, or toxic for reproduction. The Agency therefore identified the Substance as a substance of very high concern ('SVHC') in accordance with Articles 57(f) and 59 of the REACH Regulation. The Appellant argued that, based on this identification of the Substance as an SVHC, the requirement to perform the EOGRTS can be omitted under the first indent of Column 2 of Section 8.7. of Annex X.

According to the first indent of Column 2 of Section 8.7. of Annex X, an EOGRTS does not need to be conducted if the Substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented.

The Board of Appeal decided that Column 2 of Section 8.7. of Annex X contains a closed list of conditions which, if fulfilled, relieve registrants of the obligation to conduct studies on reproductive toxicity. Column 2 of Section 8.7. of Annex X does not make provision for omitting studies on reproductive toxicity on the basis that a substance has been identified as an SVHC due to its respiratory sensitising properties. Indeed, the fact that the Substance has respiratory sensitising properties gives no indication as to its reproductive toxicity and therefore cannot justify the omission of a requirement to provide standard information on the Substance's potential to cause reproductive toxicity. Consequently, the requirement to perform the EOGRTS in the present case could not be omitted under the first indent of Column 2 of Section 8.7. of Annex X on the basis that the Substance is a respiratory sensitiser.

The Appellant's argument that, under the third indent of Column 2 of Section 8.7. of Annex X, the Appellant was not required to provide information on an EOGRTS was rejected as unsubstantiated by the Board of Appeal.

The Board of Appeal also rejected the Appellant's claim that the Agency made an error of assessment in requiring the inclusion of Cohort 3 in the requested EOGRTS. In particular, the Appellant did not demonstrate that the Agency had made an error of assessment in requiring the inclusion of Cohort 3 in the EOGRTS based on the reduction in thymus weight observed in a sub-chronic toxicity study on the Substance submitted by the Appellant.

The Appellant's plea that the Agency breached Article 40(2) of the REACH Regulation regarding the third-party consultation on the testing proposal was also rejected by the Board of Appeal. The Appellant did not demonstrate that the Agency had failed to take into account the observations on the testing proposal submitted by a third-party.

The Appellant's plea that the Agency breached Article 13 of the Treaty on the Functioning of the European Union, Article 25 of the REACH Regulation, and '*the principle of proportionality/animal welfare/sound administration*' was also rejected. In particular, the Appellant failed to demonstrate that the EOGRTS, including Cohort 3, was not necessary or that a suitable alternative existed.

Following the Board of Appeal's Decision, the Appellant must provide the EOGRTS in the form required in the contested decision by 20 February 2023.
