

SUMMARY OF DECISION OF 19 JANUARY 2021 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-010-2019

(Dossier evaluation – Compliance check – Section 9.1. of Annex IX – Requirements for aquatic toxicity testing on fish)

Factual background

The appeal concerned the compliance check of the Appellant's registration dossier for the substance propane-1,2,3-triyl 3,5,5-trimethylhexanoate (EC No. 260-257-1, CAS No. 56554-53-1; the 'Substance').

The Appellant is the lead register of the Substance and registered it at the 100 to 1000 tonnes per year tonnage band.

The contested decision required the Appellant to submit information on several studies, but after having being rectified by the Executive Director of the Agency, only information on a fish early-life stage (FELS) toxicity test (Section 9.1.6.1. of Annex IX to the REACH Regulation) was still required.

The appeal lodged on 22 July 2019 was therefore limited to the information requirement concerning the FELS test.

Main findings of the Board of Appeal

The Appellant argued that the Agency had incorrectly rejected an adaptation according to which long-term toxicity testing on fish was not needed as the chemical safety assessment of the Substance did not indicate a need to investigate further its effects on aquatic organisms.

In its Decision of 19 January 2021, the Board of Appeal dismissed the appeal.

The Board of Appeal confirmed its previous interpretation that Column 2 of Section 9.1. of Annex IX to the REACH Regulation is neither a '*trigger*' nor a '*waiver*' for the requirement to submit information on one of the three long-term toxicity tests on fish under Column 1 of Section 9.1.6. of Annex IX.

Instead, Column 2 of Section 9.1. of Annex IX is a specific adaptation rule that requires registrants to submit information on a further study than one of the three studies listed in Column 1 of Section 9.1.6. of Annex IX if the chemical safety assessment indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond the information that any of those three studies would provide.

Column 2 of Section 9.1. of Annex IX allows a registrant to forgo submitting information on one of the three studies listed in Column 1 of Section 9.1.6. of Annex IX, only if it provides, instead, a longer-term and/or more extensive toxicity test on fish.

The Board of Appeal found that the Agency was therefore correct in finding that the Appellant's registration dossier has a data-gap as regards long-term toxicity testing on fish. As a result, the Agency made no error in rejecting the Appellant's adaptation and requiring it to submit information on the FELS test.

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.

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>*