ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	24 August 2020
Case	A-005-2020
Appellant	S. Goldmann GmbH & Co. KG, Germany
Appeal received on	12 June 2020
Subject matter	A decision adopted by the European Chemicals Agency pursuant to Article 46(1) of the REACH Regulation
Keywords	*Substance evaluation – Substance evaluation – Dossier evaluation in parallel to substance evaluation – Error of assessment – Duty to state reasons – Read-across – Proportionality – Animal welfare*
Contested Decision	Decision of 12 March 2020 on the substance evaluation of 2,5,7,10,11,14-hexaoxa-1,6-distibabicyclo[4.4.4]tetradecane (EC No 249-820-2; CAS No 29736-75-2; the 'Substance')
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision requesting information on a 90-day (subchronic) toxicity study in rats, oral route (test method: OECD test guideline 408) with the Substance, including cardiovascular effect evaluations and toxicokinetic assessment.

The Appellant also requests the Board of Appeal to order the Agency to pay the costs of the appeal proceedings.

Pleas in law and main arguments

The Appellant argues that the Agency committed an error by failing to fulfil the conditions for requesting information under Article 46 of the REACH Regulation. According to the Appellant, the Agency failed to demonstrate that there is an actual, and not only theoretical, risk related to the Substance. The Appellant argues that the Agency also failed to demonstrate that there are real information needs to address that risk, and that the information required in the Contested Decision will lead to an improvement in the risk management measures in place. The Appellant argues that the Agency also failed to provide an adequate statement of reasons in this regard.

[1] Announcement published in accordance with Article 6(6) of Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency, as amended by Commission Implementing Regulation (EU) 2016/823.

The Appellant argues that the Agency infringed an essential procedural requirement of the REACH Regulation as it did not perform a compliance check on the Substance prior to the substance evaluation.

The Appellant argues that the Contested Decision breached the Appellant's legitimate expectations by dismissing the grouping of antimony compounds and the read-across approach used by the Appellant for the human health endpoints.

The Appellant argues that the Agency committed an error of assessment by failing to examine, carefully and impartially, all the relevant information on the Substance submitted by the Appellant including the proposed read-across and weight-of-evidence adaptation, and the comments submitted during the substance evaluation process.

The Appellant argues that the Contested Decision is inappropriate insofar as it requires a subchronic oral toxicity study in rats when the alleged toxicity is still unclear. The Appellant also argues that the parameters for the toxicokinetic assessment and cardiovascular effects requested in the Contested Decision are inappropriate. In particular, the toxicokinetic studies requested will be unable to establish the mechanisms of action and the investigation of cardiovascular effects will provide no benefit for the protection of the exposed populations.

The Appellant argues that the Agency failed to state reasons for the Contested Decision. In particular, the Contested Decisions does not explain why the dossier evaluation was performed in parallel to, rather than before, the substance evaluation. According to the Appellant, the Agency also failed to state reasons as to why it considered the Appellant's read-across proposal and its proposed step-wise study programme was inadequate.

The Appellant argues that the Agency infringed the principles of proportionality and animal welfare by:

- requesting information that is in some respects inappropriate and will not yield more precise results than the alternatives proposed by the Appellant;
- requesting the OECD test guideline 408 study prematurely, before the results of the OECD test guideline 422 (screening study) are finalised; and
- requesting a study that is not the least burdensome for the Appellant or the most proportionate from the point of view of animal welfare.

Further information

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

http://echa.europa.eu/web/guest/regulations/appeals