

**SUMMARY OF DECISION OF 8 SEPTEMBER 2017
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

Case number: A-026-2015

*(Substance evaluation – PBT assessment – Persistence – Proportionality –
Relevant conditions – Equal treatment)*

Background

The substance BENPAT (1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives; CAS No 68953-84-4, EC No 273-227-8) is used predominantly in the production of tyres as an antioxidant in rubber mixtures.

Following an evaluation by the Member State Competent Authority of Germany (the 'eMSCA'), the Agency required the following information on BENPAT:

- Simulation testing in surface water (OECD TG 309),
- Identification of the metabolites of BENPAT formed in the OECD TG 309 study, and
- If the OECD TG 309 study does not show that BENPAT is persistent, additional simulation testing in an aquatic sediment system (OECD TG 308).

The Appellants requested the Board of Appeal to annul these three information requirements.

Main findings of the Board of Appeal

- *Simulation testing in surface water (OECD TG 309)*

The Appellants argued, amongst other things, that conducting a test according to OECD TG 309, which is performed in pelagic water, is not environmentally relevant for BENPAT because it quickly adsorbs into soil and sediment.

The Board of Appeal held that the persistence criteria set out in Annex XIII to the REACH Regulation concern the intrinsic hazardous properties of a substance and not the risk that a particular use or uses may pose in practice. Under substance evaluation, once the Agency has established that a substance poses a potential risk to the environment because of its persistence it may require testing in any environmental compartment to clarify the persistence concern. It is not obliged to choose, from several compartments, the one that mirrors most closely the distribution patterns of a substance in the environment from one particular use or user.

The Board of Appeal consequently rejected the appeal with regard to the requirement for an OECD TG 309 study (see paragraphs 104 to 117 of the Board of Appeal decision).

- *Obligation to identify the metabolites of BENPAT in the OECD TG 309 study*

In addition to performing an OECD TG 309 study, the Contested Decision obliged the Appellants to identify all the metabolites of BENPAT formed in the study. The Appellants argued that this could not be done because BENPAT is very poorly soluble in water and the quantities of metabolites formed would be too small to be identified.

The Board of Appeal held that the Agency failed to establish that all the metabolites formed in a test according to OECD TG 309 could be identified at the low concentrations in which they would be present. It therefore annulled the obligation to identify all the metabolites of BENPAT. However, the Board of Appeal highlighted that, according to the details of OECD TG 309, major transformation products should still be identified when performing the test unless justified otherwise (see paragraphs 118 to 125 of the Board of Appeal decision).

- *Simulation testing in aquatic sediment system (OECD TG 308)*

The Appellants argued that an OECD TG 308 study would not be appropriate to determine the half-life of BENPAT because of its properties. In particular, BENPAT tends to partition from the water phase and to form non-extractable residues in the solid phase. The complex test system of an OECD TG 308 study, which includes both water and sediment, would therefore not lead to results that can be clearly interpreted.

The Board of Appeal held that the Agency had not established that an OECD TG 308 study was appropriate to achieve its objective (see paragraphs 133 to 142 of the Board of Appeal decision). It found, first, that it is not certain whether an OECD TG 308 study would measure the adsorption or degradation of BENPAT because of its properties. Second, the Agency had not explained how the study would clarify the identity and properties of non-extractable residues. Third, as the obligation to identify the metabolites formed in the OECD TG 309 test was annulled, one of the justifications for a subsequent OECD TG 308 test was removed.

The Board of Appeal therefore annulled the requirement to conduct an OECD TG 308 study. It highlighted, however, that the Agency may yet require further persistence testing in the future, especially once the results of the test according to OECD TG 309 are available.

- *Outcome*

The Board of Appeal upheld the obligation to perform a test according to OECD TG 309, and annulled the obligation to identify the metabolites formed in this test as well as the obligation to perform a test according to OECD TG 308.

The Federal Republic of Germany has challenged the decision of the Board of Appeal before the General Court (Case T-755/17, *Germany v ECHA*).

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>