ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 29 JUNE 2021
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-001-2020

(Dossier evaluation – Compliance check of a registration for a monomer – Unreacted monomer in a polymer – Monomer as a degradation product of a polymer – Exposure-based adaptation – Error of assessment – Powers of the Agency – Data-sharing – Organic or inorganic nature of a substance – Duty to state reasons)

Factual background

The appeal concerned the compliance check of the Appellant's registration dossier for the substance cyanoguanidine (EC number 207-312-8, CAS number 461-58-5; the 'Substance'). The Appellant imports into the European Union polymers which contain the Substance as a monomeric unit.

The Appellant submitted all information separately from the other registrants of the Substance under Article 11(3) of the REACH Regulation.

By the contested decision the Agency rejected the adaptations by which the Appellant had sought to fulfil the standard information requirements for a sub-chronic toxicity study (Section 8.6.2. of Annex IX to the REACH Regulation), a pre-natal developmental toxicity ('PNDT') study on one species (Section 8.7.2. of Annex IX to the REACH Regulation), and a simulation of ultimate degradation in surface water (Section 9.2.1.2. of Annex IX to the REACH Regulation).

The Appellant requested the Board of Appeal to annul all the three information requirements of the contested decision.

Main findings of the Board of Appeal

In its Decision of 29 June 2021, the Board of Appeal dismissed the appeal as regards the sub-chronic toxicity study and the PNDT study but annulled the contested decision insofar as it required the Appellant to submit information on the simulation of ultimate degradation.

1. Sub-chronic toxicity study

In its registration dossier the Appellant did not submit an OECD TG 408 sub-chronic toxicity study but sought to fulfil the standard information requirement of Section 8.6.2. of Annex IX of the REACH Regulation by providing other data. The Board of Appeal held that the Agency did not err in finding that there was a data-gap in the Appellant's registration dossier as regards the sub-chronic toxicity study. The data provided by the Appellant did not cover all the key parameters investigated in an OECD TG 408.

2. Pre-natal developmental toxicity study on one species

In its registration dossier the Appellant omitted the PNDT study claiming that the exposure

to the Substance was equivalent to zero as the life-cycle of the Substance had ended upon polymerisation. The Appellant argued that it could not be required to consider in its registration the exposure occurring during the life-cycle of another substance, the polymer.

The Board of Appeal held that as an importer of polymers the Appellant's obligation to register the Substance was based solely on Article 6(3) of the REACH Regulation. In order to comply with its registration obligation, the Appellant was required to fulfil all the relevant standard information requirements set out in the REACH Regulation, but was not required to document the chemical safety assessment of the Substance after the polymerisation. However, the need to provide information on exposure to the Substance after polymerisation was a direct consequence of the fact that the Appellant sought to rely on an exposure-based adaptation under Section 3 of Annex XI of the REACH Regulation in order to omit the PNDT study.

The Board of Appeal found that the Appellant had failed to establish its adaptation with adequate justification and documentation as required under Section 3.2. of Annex XI of the REACH Regulation. Therefore, the Agency was correct in finding that the Appellant's registration dossier did not comply with the standard information requirement set out in Section 8.7.2. of Annex IX of the REACH Regulation.

3. Choice of the data for filling the data-gaps

The Appellant's plea that the Agency exceeded its powers by limiting the manner by which the Appellant could comply with the information requirements for the sub-chronic toxicity study and the PNDT study was also rejected by the Board of Appeal. Contrary to the Appellant's arguments the contested decision did not oblige the Appellant, as the only option, to seek permission to refer to the OECD TG 408 study and the PNDT study available in the lead registrant's dossier.

4. Simulation of ultimate degradation in surface water

The Board of Appeal held that the Agency breached its duty to state reasons when it rejected the Appellant's adaptation for the simulation of ultimate degradation. In its registration dossier the Appellant defined the substance as inorganic and considered that the biodegradability testing was therefore not feasible. In the contested decision the Agency found that the substance can be tested for biodegradability as it is organic but failed to state any reasons for this finding.

The Board of Appeal therefore annulled the contested decision insofar as it required the simulation of ultimate degradation and remitted to case to the Agency for further action.

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