ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	4 June 2020
Case	A-001-2020
Appellant	SNF SA, France
Appeal received on	5 May 2020
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 41 of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	*Dossier evaluation – Compliance check of a monomer – Opt-out from the joint submission – Error of assessment – Powers of the Agency – Duty to state reasons*
Contested Decision	CCH-D-2114497433-41-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision which requires the Appellant to submit:

- a sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2. of the REACH Regulation; test method OECD TG 408) in rats,
- a pre-natal developmental toxicity ('PNDT') study (Annex IX, Section 8.7.2. of the REACH Regulation; test method OECD TG 414) in a first species (rat or rabbit), oral route, and
- a simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2. of the REACH Regulation; test method EU C.25./OECD TG 309).

The Appellant also requests the Board of Appeal to order the refund of the appeal fee and take such other or further measures as justice may require.

Pleas in law and main arguments

The Agency adopted the Contested Decision on 6 February 2020 following a compliance check of the Appellant's dossier for the substance cyanoguanidine (EC No 207-312-8; CAS No 461-58-5; the 'Substance'). In its registration the Appellant had submitted information separately from the joint submission under Article 11(3) of the REACH Regulation.

The Appellant argues that, by rejecting the information it provided on the 90-day sub-chronic toxicity study and by requesting that a study is performed following a specific OECD test

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guideline, the Agency committed an error of assessment. The Appellant argues that the information it provided complies with Section 8.6.2. of Annex IX to the REACH Regulation and is most relevant information for the sub-chronic toxicity endpoint.

The Appellant argues that the Agency exceeded its powers and breached Articles 2(9), 6(3) and 41 of the REACH Regulation as it based the request for the PNDT study on the potential human exposure to the Substance released from a polymer as a degradation product or as an unreacted monomer. The Appellant contends that the degradation products and the unreacted monomers are not part of the life-cycle of the polymer and therefore the Agency did not have powers to request information on them in the Contested Decision.

The Appellant also argues that the Agency exceeded its powers as it required the Appellant to submit the information on the 90-day sub-chronic study and the PNDT study contained in the dossier of the lead registrant of the Substance. The Appellant argues that in a compliance check under Article 41 the Agency's powers are limited to requesting a registrant to bring its registration dossier into compliance by submitting the relevant standard information. However, the registrant can choose the data that it uses to meet that information requirement.

The Appellant argues that the Agency breached its duty to state reasons, failed to take into account all relevant factors, failed to conduct its own assessment and committed an error of assessment when it concluded that the substance is organic and requested the Appellant to perform the OECD TG 309 study. The Appellant argues that as the Substance is inorganic it cannot be tested for biodegradability.

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