EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-012-2018
Appellant	BASF SE, Germany
Appeal received on	10 July 2018
Subject matter	A decision adopted by the European Chemicals Agency (the 'Agency') under Article 46(1) of the REACH Regulation.
Keywords	*Substance evaluation – Proportionality – Legal certainty – Persistence – Bioaccumulation – Toxicity – Step-wise approach*
Contested Decision	Decision of 17 April 2018 on the substance evaluation of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC No 270-128-1)
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision in its entirety and order the Agency to refund the appeal fee.

As an alternative the Appellant requests the Board of Appeal to amend the Contested Decision so that:
- *'the timeframes required for generating and providing the requested information are extended to a reasonable length'*;
- *'an exit option for the Appellant in case of a cease of manufacturing is provided'*; and
- *'a formal procedure for specifying the test item and for the interpretation of the test results is provided'*.

Pleas in law and main arguments

The Appellant is one of the registrants of benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (the 'Substance'). The Contested Decision requires the Appellant to provide further information on ditertbutyldiphenylamine ('DTBDA') which is a constituent of the Substance. The isomer of DTBDA to be tested can be either ppDTBDA or poDTBDA. The information required is needed to assess the persistence, bioaccumulation and toxicity of the Substance following a step-wise testing approach.

The Appellant is required to provide the following information on the chosen isomer of DTBDA:
- Water solubility (OECD TG 105).
- Octanol–water partition coefficient (OECD TG 123 or OECD TG 117).
- Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test (OECD TG 309).

[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.

If the results of OECD TG 309 study indicates that the Substance is persistent or very persistent the Appellant is required to additionally provide the following information on the chosen isomer of DTBDA:
- Bioaccumulation in Fish: Aqueous and Dietary Exposure (OECD TG 305).

If the OCED TG 309 and OECD TG 305 studies indicate that the Subtance is both persistent and bioaccumulative the Appellant is required to additionally provide the following information on the chosen isomer of DTBDA:
- *Daphnia magna* Reproduction Test (OECD TG 211)
- Freshwater Alga and Cyanobacteria, Growth Inhibition Test (OECD TG 201)

If the OECD TG 211 and OECD TG 201 studies do not indicate that the Substance is a toxicant the Appellant is required to provide the following information on the chosen isomer of DTBDA:
- Fish, Early-life Stage Toxicity Test (OECD TG 210).

The Appellant argues that by stipulating sequential or step-wise information requests in only one decision (the Contested Decision) the Agency breaches:
- Article 46 together with Articles 50 and 52 of the REACH Regulation as the conditional requirements should be requested in subsequent substance evaluation decisions;
- Article 50(3) of the REACH Regulation and the principle of proportionality as the Appellant would be obliged to conduct the bioaccumulation and toxicity studies even if it ceases manufacturing the Substance; and
- Article 25(1) of the REACH Regulation as the obligation to conduct the bioaccumulation and toxicity studies would result in unnecessary vertebrate animal testing if the Appellant ceases manufacturing the Substance.

The Appellant claims that the time limits stipulated by the Contested Decision for providing each of the requested studies are too short.

The Appellant claims that the step-wise approach adopted by the Contested Decision is in breach of the principle of legal certainty. According to the Appellant it is '*highly possible*' that the results of the studies do not allow clear conclusions to be reached and it will therefore be unclear to the Appellant whether or not it is obliged to conduct the subsequent bioaccumulation and toxicity studies. The Appellant further argues that the Contested Decision does not adequately specify the substance to be tested or clearly specify the role of the evaluating Member State Competent Authority in analysing the study results and in deciding on any subsequent testing needs.

Other information

As the Appellant withdrew the Appeal, the case was closed by the Chairman of the Board of Appeal on 10 December 2018.

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