EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	2 March 2022
Case	A-001-2022
Appellant	Cytec Engineered Materials GmbH, Germany
Appeal received on	25 January 2022
Subject matter	A decision taken by the European Chemicals Agency pursuant to Article 41 of the REACH Regulation[2]
Keywords	*Dossier Evaluation - Compliance Check – Legal certainty – Legitimate expectations – Error of assessment – Duty to state reasons – Column 2 of Section 9.1. of Annex IX*
Contested Decision	CCH-D-2114573706-39-01/F
Language of the case	English

Remedy sought by the Appellant

On 25 October 2021, the Agency adopted the Contested Decision following the compliance check of the registration dossiers for 4,4'-(9H-fluoren-9-ylidene)bis(2-chloroaniline) (EC No 407-560-9; the 'Substance').

The Contested Decision requires the Appellant and other registrants of the Substance to submit, depending on the tonnage at which they registered the Substance, information on:

1. *In vitro* gene mutation study in bacteria (Section 8.4.1. of Annex VII, test method: EU B.13/14 / OECD TG 471);
2. *In vitro* cytogenicity study in mammalian cells (Section 8.4.2. of Annex VIII; OECD TG 473) or *in vitro* micronucleus study (Section 8.4.2. of Annex VIII; OECD TG 487);
3. Long-term toxicity testing on fish (Column 2 of Section 9.1.3. of Annex VIII and Section 9.1.6. of Annex IX; OECD TG 210);
4. Simulation testing on ultimate degradation in surface water (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.2. of Annex IX; test method: EU C.25 / OECD TG 309) at a temperature of 12°C and non extractable residues ('NER') must be quantified;

[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.

[2] All references to Articles and Annexes concern the REACH Regulation unless stated otherwise.

5. Soil simulation testing (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.3. of Annex IX; test method: EU C.23 / OECD TG 307) at a temperature of 12°C and NERs must be quantified;
6. Sediment simulation testing (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.4. of Annex IX; test method: EU C.24 / OECD TG 308) at a temperature of 12°C and NERs must be quantified; and
7. Identification of degradation products (Column 2 of Section 9.2. of Annex VIII and Section 9.2.3. of Annex IX; OECD TG 307 and/or 308 and/or 309).

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

Pleas in law and main arguments

In relation to each of the information requirements requested in the Contested Decision, the Appellant raises all or some of the following pleas in law:
- The Agency failed to take into account all information, committed an error of assessment, and exceeded its competence,
- The Agency breached its duty to state reasons, as well as the principles of legal certainty and legitimate expectations,
- The Agency breached the Appellant's right to be heard, and
- The Agency breached Articles 25 and 41, as well as the Sections of Annexes VIII and IX in which the relevant information requirements are found.

The Appellant supports its pleas in law with the following arguments.

In relation to the first information requirement, the Appellant argues that the Agency incorrectly rejected the results of the OECD TG 471 study submitted in the registration dossier for the Substance on the ground that it was performed according to the version of the test guideline applicable at the time the study was performed rather than the updated version which required the investigation of an additional strain of bacteria.

In relation to the second information requirement, the Appellant argues that the Agency wrongly assessed the OECD TG 473 study submitted in the dossier for the Substance against the current version of the OECD test guideline rather than the version in the force at the time the study was performed. In addition, in the Contested Decision, the Agency relied on QSAR predictions which were not included in the draft decision on which the Appellant commented.

In relation to the third information requirement, the Appellant argues that the conditions for requesting long-term toxicity testing on fish under Annexes VIII and IX are not met. The Appellant argues that the Agency also incorrectly interpreted Column 2 of Section 9.1 of Annex IX.

In relation to the fourth, fifth, sixth and seventh information requirements, the Appellant argues that Annex XIII cannot serve as a justification for requesting information under Article 41 and further testing is not necessary since a conclusion can already be reached on the PBT/vPvB properties of the Substance. In addition, the Appellant argues that the simulation testing in water would not generate data obtained under relevant conditions and the Agency incorrectly rejected the Appellant's waiver regarding the technical feasibility of the simulation study in water.

The Appellant argues that in requesting information on NERs the Agency failed to take into account the Appellant's conclusion that the Substance is a PBT/vPvB substance and the fact that, as the persistence of the Substance has already been established, any further information on NERs would not yield new, meaningful information. In addition, there are technical limitations and a lack of guidance regarding the assessment NERs.

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