EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	4 January 2022
Case	A-012-2021
Appellant	Covestro S.L., Spain
Appeal received on	25 November 2021
Subject matter	A decision taken by the European Chemicals Agency pursuant to Article 41 of the REACH Regulation
Keywords	*Dossier evaluation – Compliance check – Section 9.2. of Annex VIII – Margin of discretion – Duty to state reasons*
Contested Decision	Decision No CCH-D-2114566726-36-01/F of 26 August 2021 on the compliance check of the substance reaction mass of 2,6-Bis[(dimethylamino)methyl]-4-(1-{3-[(dimethylamino)methyl]-4-hydroxyphenyl}-1- methylethyl)phenol and 4-(1-{3,5-Bis[(dimethylamino)methyl]-4-hydroxyphenyl}-1-methylethyl)-2,6-bis[(dimethylamino)methyl]phenol (EC No 947-794-3; the 'Substance')
Language of the case	English

Remedy sought by the Appellant

On 26 August 2021, the Agency adopted the Contested Decision following the compliance check of the Appellant's registration dossier for the Substance.

The Contested Decision requests the Appellant to provide information on several studies required under Annex VIII to the REACH Regulation. The Appellant requests the Board of Appeal to annul the Contested Decision insofar as it requires the following information:

1. Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided;

[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. Soil simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.23./OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided;
3. Sediment simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided;

4. Identification of degradation products (triggered by Annex VIII, Section 9.2.; test method: using an appropriate test method); and

5. Bioaccumulation in aquatic species (triggered by Annex I, Section 0.6.1. and 4.; Annex XIII, Section 2.1.; test method: OECD TG 305, aqueous exposure).

The Appellant also requests the Board of Appeal to order the Agency to refund the appeal fee.

Pleas in law and main arguments

The Appellant argues that its registration dossier complies with the standard information requirements on degradation set out in Annexes VII and VIII to the REACH Regulation that are applicable to the Substance manufactured in quantities of less than 100 tonnes per year.

The Appellant argues that the Agency:

- breached Articles 10, 12(1) as well as Annexes VIII and XIII of the REACH Regulation and exercised incorrectly its margin of discretion under Article 41 of the REACH Regulation by requesting the contested information;

- erred in finding that the conditions triggering further degradation testing under Column 2 of Section 9.2. of Annex VIII to the REACH Regulation were fulfilled whilst the chemical safety assessment performed by the Appellant had indicated that there is no need for further degradation testing;

- erred in requesting the Appellant to provide information on identification of degradation products and bioaccumulation whilst those information requirements are applicable only to the substances that are manufactured or imported in quantities of 100 tonnes or more per year; and

- breached its duty to state reasons by failing to provide any reasoning for contradicting with the Appellant's conclusion and its finding that the degradation of the Substance should be investigated further.

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