

Announcement of appeal¹

Published on	12 February 2024
Case	A-001-2024
Appellant	LANXESS Deutschland GmbH, Germany
Appeal received on	8 January 2024
Subject matter	A decision taken by the European Chemicals Agency under Article 41 of the REACH Regulation ²
Keywords	<i>Dossier evaluation – Compliance check – Tonnage downgrade – Cut-off point for considering dossier updates – Substantial new information – Right to good administration – Proportionality – Article 25</i>
Contested Decision	CCH-D-2114655178-41-01/F
Language of the case	English

Background and remedy sought by the Appellant

As part of the compliance check of the Appellant's registration dossier for 1,2-dichlorobenzene (the **Substance**)³, initiated on 7 July 2022, the Agency notified a draft decision to the Appellant on 21 June 2023.

On 25 July 2023, the Appellant submitted its comments on the draft decision underlining the continuous decrease of the volume of production of the Substance. The Appellant indicated its intention to submit a tonnage downgrade for the Substance for the year 2023. In this respect, on 27 July 2023, the Appellant updated its registration dossier to downgrade the Substance volume of production from above 1000 to 100-1000 tonnes per year.

On 11 October 2023, the Agency adopted the Contested Decision requesting the Appellant to provide information on an extended one-generation reproductive toxicity study (EOGRTS; Section 8.7.3. of Annex X; test method: OECD TG 443).

¹ Announcement published in accordance with Article 6(6) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5).

² Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1). All references to Articles and Annexes concern the REACH Regulation unless stated otherwise.

³ EC No 202-425-9; CAS No 95-50-1.

In the Contested Decision, the Agency indicated that the Appellant's tonnage downgrade was not considered for the purposes of the decision-making process as the available information showed that within the year preceding the adoption of the Contested Decision the Appellant was still operating at the higher tonnage band (above 1000 tonnes per year).

On 8 December 2023, the Appellant performed a second dossier update to downgrade the tonnage from 1000 tonnes per year to 100-1000 tonnes per year for 2022.

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

Pleas in law and main arguments

In support of its appeal, the Appellant raises two pleas in law.

First, the Appellant argues that the Agency committed a manifest error of assessment of the scientific facts of the case and infringed its duty of good administration. According to the Appellant, the Agency erred by taking into account the tonnage information registered for the year preceding the adoption of the Contested Decision, thereby disregarding new and substantial information, i.e. the Appellant's tonnage downgrade for 2023.

The Appellant claims that the Agency's approach to tonnage downgrades is contrary to previous decisions taken by the Board of Appeal⁴ and would render the relevant provisions on the obligation to keep registration dossiers up to date⁵ devoid of purpose.

Second, the Appellant argues that, by requesting it to provide information under Annex X, the Agency infringed the principle of proportionality as enshrined in Article 5(4) of the Treaty on European Union. In addition, the Appellant claims that the Contested Decision violates Article 25(1) of the REACH Regulation according to which testing on vertebrate animals should be undertaken only as a last resort.

Further information

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

<https://echa.europa.eu/web/guest/regulations/appeals>

⁴ Decision of the Board of Appeal of 9 November 2021, *BASF Colors & Effects GmbH BASF SE*, Joined Cases A-006-2020 and A-007-2020.

⁵ Article 3(30) and Article 22(1)(c) of the REACH Regulation read in conjunction with Recital (3) of Commission Implementing Regulation 2019/1692 on the application of certain registration and data-sharing provisions of the REACH Regulation after the expiry of the final registration deadline for phase-in substances (OJ L 259, 10.10.2019, p. 12) and Commission Implementing Regulation 2020/1435 on the duties placed on registrants to update their registrations under the REACH Regulation (OJ L 331, 12.10.2020, p. 24).