EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

# Announcement of appeal[1]

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| **Published on** | 4 May 2023 |
| **Case** | A-004-2023 |
| **Appellant** | Evonik Operations GmbH, Germany |
| **Appeal received on** | 7 March 2023 |
| **Subject matter** | A decision taken by the European Chemicals Agency pursuant to Article 42(1) of the REACH Regulation[2] |
| **Keywords** | *Dossier evaluation – Follow-up procedure – Failure to comply with a previous compliance check decision – EOGRTS – Section 8.7.3. of Annex X* |
| **Contested Decision** | CCH-D-2114621395-51-01/F |
| **Language of the case** | English |

## Background and remedy sought by the Appellants

On 29 October 2018, the Agency adopted a compliance check decision under Article 41 on the registration for the substance 2,4,6-tris(dimethylaminomethyl)phenol (the **Substance**).[3]

By that decision, the Agency required the Appellant to provide information on an extended one-generation reproductive toxicity study (**EOGRTS**) under Section 8.7.3. of Annex X, including cohorts 1A (reproductive toxicity) and 1B (reproductive toxicity) with extension to mate the cohort 1B animals to produce the F2 generation.

In consequence of that decision, the Appellant carried out an EOGRTS study and provided a summary of that study to the Agency.

On 9 December 2022, the Agency adopted a follow-up decision under Article 42(1) (the **Contested Decision**).

By the Contested decision, the Agency held that the EOGRTS study carried out by the Appellant was not sufficient to satisfy the information requirement under Section 8.7.3. of Annex X because systemic toxicity was not fully investigated in the conduct of that study. In particular, the Appellant failed to investigate the organs of cohort 1B (all dose-levels), target organs in cohort 1B (only liver and spleen were preserved), and organs of P0 and cohort 1A animals at low and mid-dose.

The Contested Decision therefore declared that the Appellant's registration still does not comply with Section 8.7.3. of Annex X, that the Appellant remains required to provide the information required in the compliance check decision of 22 November 2016, and that the relevant national authorities will be informed accordingly.

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[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 202-013-9; CAS No 90-72-2.

The Appellant requests the Board of Appeal to:

- annul the Contested Decision insofar as it obliges the Appellant to generate investigations of organs of cohort 1B, target organs in cohort 1B, and organs of P0 and cohort 1A animals at low and mid-dose;
- 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 Appellant raises two pleas in law in support of its appeal.

By its first plea, the Appellant argues that the Agency committed an error of assessment and breached Articles 10 and 12 of the REACH Regulation, Annex X to that Regulation, and OECD test guideline 443 by requesting the Appellant to generate histopathological investigations of organs of cohort 1B at all dose-levels as part of an EOGRTS.

By its second plea, the Appellant argues that the Agency committed an error of assessment and failed to take relevant information into account by requesting the Appellant to generate the EOGRTS in accordance with OECD test guideline 443 without accounting for the transferable information generated by performing a study according to OECD test guideline 408 insofar as it requires the histopathological investigation of organs of P0 animals at low and mid-dose levels.

**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