EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	12 April 2023
Case	A-003-2023
Appellant	Jungbunzlauer Ladenburg GmbH, Germany
Appeal received on	3 March 2023
Subject matter	A decision taken by the European Chemicals Agency under Article 42(1) of the REACH Regulation[2]
Keywords	*Dossier evaluation – Follow-up to a compliance check – Article 42 – Right to good administration – Equal treatment – Non-discrimination – Article 25*
Contested Decision	CCH-D-2114620385-53-01/F
Language of the case	English

Background and remedy sought by the Appellant

On 24 July 2017, the Agency adopted a decision (the 'Initial Decision') under Article 41 following the compliance check of the registration dossier for the substance tributyl O-acetylcitrate[3] (the 'Substance'). In that decision, the Agency required the Appellant to submit information on, amongst other things, a pre-natal developmental toxicity ('PNDT') study in both a first and a second species under Section 8.7.2. of Annex IX and Section 8.7.2. of Annex X.

On 9 December 2022, after an examination of the information submitted in consequence of the Initial Decision, the Agency adopted the Contested Decision under Article 42(1). The Agency rejected a weight-of-evidence adaptation under Section 1.2. of Annex XI submitted by the Appellant and concluded that the Appellant's registration dossier remains non-compliant with Section 8.7.2. of Annex IX and Section 8.7.2. of Annex X.

The Appellant requests that the Board of Appeal:

- annuls the Contested Decision,

[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 201-067-0, CAS No 77-90-7.

- remits the case to the competent body of the Agency to adopt an amended decision addressed to all registrants of the Substance that are affected by the requirements of the Contested Decision, and
- orders the refund of the appeal fee.

In the alternative, the Appellant requests that the Board of Appeal:

- amends the Contested Decision so that it is addressed to all registrants of the Substance that are affected by the requirements of the Contested Decision, and
- orders the Agency to refund the appeal fee.

Pleas in law and main arguments

The Appellant argues that, in addressing the Contested Decision only to the Appellant as the lead registrant of the Substance and not to the other registrants at the respective tonnage band, the Agency violates Article 42, the right to good administration, and the principles of equal treatment and non-discrimination.

The Appellant argues that the Agency also breached Article 25(1) by failing to ensure that testing on vertebrate animals is undertaken only as a last resort. According to the Appellant, this is because the Agency failed to examine whether the other registration dossiers for the Substance – including the dossiers of registrants that opted-out of the joint submission under Article 11(3) – already contained the information requested in the Contested Decision.

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