EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 28 MAY 2024 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case A-003-2023

(Follow-up to dossier evaluation – Article 42(1) of the REACH Regulation – Addressees – Good administration – Equal treatment – Non-discrimination)

Factual background

The appeal concerned the follow-up to the compliance check of a registration dossier for tributyl O-acetylcitrate (the **'Substance'**).[1] The Appellant is the lead registrant for the Substance.

On 24 July 2017, the Agency adopted a decision (the '**initial compliance check decision**') under Article 41 following the compliance check of the Appellant's registration dossier for 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.

At the time of the adoption of the initial compliance check decision, there were a number of other registrants of the Substance at the Annex IX and Annex X levels. However, following the Agency's policy at that time, the Contested Decision was addressed only to the Appellant as lead registrant of the Substance.

From 1 January 2019, the Agency started initiating compliance check processes towards all affected members of the joint submission.

On 9 December 2022, after an examination of the information submitted by the Appellant in consequence of the initial compliance check decision, the Agency adopted the Contested Decision under Article 42(1).

In the Contested Decision, the Agency rejected an adaptation 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 Contested Decision states that the Appellant is still required to submit the information requested in the initial compliance check decision and that the Agency will inform the competent national authority with a view to taking enforcement action.

At the time of the adoption of the Contested Decision, there were a number of other registrants of the Substance registered at the Annex IX and Annex X levels. The Contested Decision was addressed to the Appellant only.

The Appellant requested the Board of Appeal to annul the Contested Decision and remit the case to the competent body of the Agency to adopt an amended decision addressed to all registrants of the Substance affected by the requirements of the Contested Decision. Alternatively, the Appellant requested the Board of Appeal to amend the Contested Decision to that effect.

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

Main findings

The Board of Appeal rejected the Appellant's argument that the Agency infringed Article 42, in conjunction with the right to good administration, by addressing the Contested Decision only to the Appellant as the lead registrant of the Substance and not to the other registrants of the Substance at the relevant tonnage bands.

The Contested Decision is a follow-up compliance check decision adopted on the basis of Article 42(1). The check carried out by the Agency following the initial compliance check decision requiring the registrant to bring its dossier into compliance is merely the continuation of the same, single procedure. The scope of the follow-up decision – including the information identified as missing from the registrant's dossier and the addressees of the decision – is defined in the initial check decision adopted under Article 41.

A follow-up compliance check decision under Article 42(1) is intended to determine whether the information provided by the addressee of an initial compliance check decision either corresponds to the information requested in that decision or constitutes compliant adaptations under the rules laid down in the relevant annexes to the REACH Regulation.

In the present case, the initial compliance check decision was addressed to the Appellant only. The initial compliance check decision has not been appealed and is therefore final. The Appellant was therefore bound to provide information on PNDT studies in the first and second species, or acceptable adaptations, by the deadline set in the initial compliance check decision.

The other registrants of the Substance were not addressees of the initial compliance check decision. In such circumstances, it was legally impossible for the Agency to involve the other registrants of the Substance in the follow-up process. The addressees of follow-up decisions under Article 42(1) cannot include registrants who were not addressees of the corresponding initial compliance check decision under Article 41 and who have not, therefore, benefited from the procedural guarantees foreseen in Article 41 and Articles 50 and 51.

The Board of Appeal also rejected the Appellant's argument that the Agency breached the principle of equal treatment and non-discrimination by failing to address the Contested Decision to the other registrants of the Substance. The Board of Appeal decided that, at the time of the adoption of the Contested Decision, the Appellant was not in a comparable situation to the other registrants of the Substance. This is because the Appellant is the only addressee of the initial compliance check decision finding that there is a data-gap in its registration dossier with regards to the PNDT studies required under Section 8.7.2. of Annex IX and Section 8.7.2. of Annex X.

The Board of Appeal therefore dismissed the appeal.
