SUMMARY OF DECISION OF 17 JANUARY 2023 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-009-2021

(Substance evaluation – Article 47(1) – Legal certainty – Misuse of powers – Proportionality – Error of assessment)

Factual background

The appeal concerned the substance evaluation of resorcinol[1] as regards its potential endocrine disrupting properties for the environment.

On 29 February 2012, the Agency included resorcinol in the Community rolling action plan (CoRAP) for substance evaluation. The Competent Authority of Finland (TUKES) was appointed as the evaluating Member State Competent Authority for the substance evaluation.

On 24 October 2017, TUKES issued a substance evaluation conclusion under Article 48 of the REACH Regulation[2]. TUKES held that it is likely that has endocrine disrupting properties for the environment. However, TUKES considered that those properties could not be confirmed by using the available study methods available, including the Larval Amphibian Growth and Development Assay (LAGDA). As a result, TUKES did not suggest requesting further information from the registrants of resorcinol and did not prepare a draft decision under Article 46(1).

On 19 March 2019, the Agency reinserted resorcinol in the CoRAP and appointed the Competent Authority of France (ANSES) as the evaluating Member State Competent Authority. The reinsertion of resorcinol in the CoRAP was based on a justification document issued by ANSES which held that further testing, for example LAGDA, could provide sufficient information on whether resorcinol has endocrine disrupting properties for the environment.

On 12 March 2021, following a draft decision submitted by ANSES, the Agency adopted the Contested Decision requesting the LAGDA.

The Appellant, who is the lead registrant for resorcinol, requested the Board of Appeal to annul the Contested Decision.

Main findings of the Board of Appeal

In its Decision of 17 January 2023, the Board of Appeal dismissed the appeal.

By the first plea, the Appellant argued that the Agency breached Article 47(1), breached the principle of legitimate expectations as a corollary of the principle of legal certainty, and misused its powers.

The Board of Appeal held that since the first substance evaluation process did not lead to a decision under Article 52, the conditions set out in the third sentence of Article 47(1) did not

[1] EC No 203-585-2, CAS No 108-46-3.

[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 hereinafter concern the REACH Regulation unless stated otherwise.

apply in the present case and therefore there was no need to assess whether there had been '*a change of circumstances or acquired knowledge'* after the first substance evaluation of resorcinol.

The Board of Appeal also found that the issuance of the conclusion document by TUKES after the first substance evaluation did not give rise to any legitimate expectations that resorcinol could not in the future be subject to another substance evaluation concerning its potential endocrine disrupting properties for the environment. The Board of Appeal also rejected the Appellant's argument that the Agency misused its powers. The reason for adopting the Contested Decision was the identification of the potential risk that resorcinol poses and not the adoption by France of a national priority plan as the Appellant argued.

By the second plea, the Appellant argued that the Agency breached the principle of proportionality, erred in its assessment, and failed to take all relevant information into account in requesting the LAGDA.

The Board of Appeal held that the Agency was correct in finding that resorcinol may pose a potential risk to the environment and that this potential risk needs to be clarified. When considered together, the available *in vitro* and *in vivo* studies were adequate to conclude that resorcinol may have potential endocrine disrupting properties for the environment. Furthermore, the Agency did not err in finding that resorcinol may be released into the environment as wastewater emissions and that these emissions may eventually lead to the exposure of the aquatic wildlife to resorcinol.

The Board of Appeal rejected the Appellant's arguments contesting the appropriateness of LAGDA for examining the potential endocrine disrupting properties of resorcinol. Whilst the Appellant argued that it would be difficult to maintain the concentration of resorcinol during the conduct of LAGDA, it did not demonstrate that the study could not be successfully performed.

The Board of Appeal held that the Agency was also correct in finding that the LAGDA has a realistic possibility of leading to improved risk management measures. The fact that operational conditions and risk management measures are currently applied in industrial plants to minimise the releases of resorcinol to the aquatic environment does not mean that other or further measures could not be necessary to address the risk posed by the potential endocrine disrupting properties of resorcinol. New or additional risk management measures may be realistically introduced irrespective of whether resorcinol is also identified as an endocrine disruptor for human health. Therefore, the conclusion that the LAGDA has a realistic possibility of leading to improved risk management measures was not called into question by the fact that the process for identifying resorcinol as a substance of very high concern due to its endocrine disrupting properties for human health was on-going in parallel.
