SUMMARY OF THE DECISION OF 23 APRIL 2024 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case A-010-2022

(Substance evaluation – DPHP – Amphibian metamorphosis assay with non-standard specifications – Proportionality – Necessity – Appropriateness to achieve the objective pursued – Burden of proof)

Background

The appeal concerned a decision requiring further information pursuant to the evaluation of the substance bis(2-propylheptyl) phthalate (**DPHP**).[1]

The Contested Decision was adopted by the Agency under Article 46(1) of the REACH Regulation.[2] It required the Appellant to perform and submit the results of an amphibian metamorphosis assay (**AMA**) with DPHP pursuant to OECD test guideline 231.

Due to the properties of DPHP – specifically, its low solubility in water – the Contested Decision prescribed a specific and novel method for ensuring that the AMA study would produce meaningful results. The Contested Decision required the study to be carried out by dissolving DPHP in acetone, drenching the animals' feed with the solution, and evaporating the acetone so as to produce feed coated in DPHP. The treated feed should then be suspended in water and fed to the test animals.

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

Main findings of the Board of Appeal

1. *Whether further information on DPHP is necessary*

The Appellant argued that it is not necessary to generate further information on DPHP to determine whether that substance has environmental endocrine properties. Specifically, according to the Appellant, there is no potential risk to the environment which needs to be clarified, and no realistic possibility of improved risk management measures.

As regards the existence of a potential risk to the environment, the Board of Appeal recalled that a potential risk is a combination of potential hazard and potential exposure.

With regard to the existence of a potential hazard, the Board of Appeal confirmed that two studies available on DPHP show that the substance may disrupt the thyroidal endocrine system. This is sufficient to consider that DPHP poses a potential hazard potential hazard concerning endocrine disruption.

With regard to the existence of potential environmental exposure, the Board of Appeal noted that DPHP is manufactured or imported in high quantities and used widely in such a way that

[1] EC No 258-469-4; CAS No 53306-54-0.

[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).

the environment may be exposed to DPHP. Moreover, the Agency is not required to establish real or realistic exposure levels to demonstrate potential exposure, and the Appellant had not provided any evidence to show that potential exposure would be so low that DPHP cannot exert its potential endocrine disrupting properties.

The Board of Appeal consequently concluded that the Agency did not err in concluding that DPHP poses a potential risk to the environment, that this risk needs to be clarified, and that doing so has a realistic possibility of leading to improved risk management measures.

The appeal was consequently rejected insofar as it alleged that it is not necessary to generate further information on DPHP.

2. Whether the AMA study was appropriate to clarify the potential risk

The Appellant further argued that the required AMA study was not appropriate to clarify the potential risk posed by DPHP.

First, the Board of Appeal found that it is not incumbent upon the Agency, pursuant to the principle of proportionality, to establish *ex ante* that a study will certainly produce a definitive conclusion as to whether a substance has a certain property. It is sufficient that the study is capable of contributing to the objective of clarifying the property at issue.

Second, the Board of Appeal noted that the Agency had properly explained, in the Contested Decision, why it considered that the AMA study would deliver meaningful results in this case despite specific challenges in the study design due to the poor solubility of DPHP.

However, the Board of Appeal also noted that the Appellant had carried out a new feasibility study, which supported its argument that the AMA study, as it is designed in the Contested Decision, would not deliver meaningful results. According to this new feasibility study, treating the feed with acetone alters the feed in such a way that the animals in the study are negatively affected, so that the study will not produce meaningful results. The Agency and the intervening Member State Competent Authority were not able to rebut the results of this new feasibility study in the appeal proceedings.

The Board of Appeal therefore concluded that the AMA study, as it is designed in the Contested Decision, was not appropriate to achieve its objective in this specific case. This conclusion was not a general finding on the feasibility of AMA studies. It was based on the distribution and discharge of the parties' respective burden of proof in the appeal proceedings.

3. Result

The Board of Appeal annulled the Contested Decision and remitted the case to the competent body of the Agency for further action. The appeal fee was refunded.

NOTE: The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 91(1) of the REACH Regulation. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.
