ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 11 DECEMBER 2018
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-006-2017

(Compliance check - Pre-natal developmental toxicity study (OECD TG 414) – Column I of Section 8.7.2. of Annex IX)

Background

The appeal concerns a compliance check decision on the Appellant's registration dossier for the substance disodium molybdate (EC No 231-551-7, CAS No 7631-95-0; the 'Substance').

The contested decision found that the dose levels used in a submitted pre-natal developmental toxicity study were too low to comply with OECD test guideline 414 and therefore did not satisfy the information requirement set out in Column 1 of Section 8.7.2. of Annex IX to the REACH Regulation.

The Appellant requested the Board of Appeal to annul the contested decision.

Main findings of the Board of Appeal

First, the Appellant argued that the Agency committed an error of assessment when it found that the dose levels used in the study in question were too low.

The Board of Appeal found that the Agency has the power to conduct its own assessment in order to verify whether an information requirement has been met by means of a submitted study. The Board of Appeal then verified whether the dose levels used in the study submitted by the Appellant had been set correctly based on adequate and relevant data. It concluded that they had been set too low, and that the submitted study therefore did not comply with OECD test guideline 414. Consequently, the submitted study did not fulfil the information requirement set out in Column 1 of Section 8.7.2. of Annex IX to the REACH Regulation.

Second, the Appellant argued that the study in question had been relied on under the OECD Cooperative Chemicals Assessment Programme. According to the Appellant, the Agency was therefore obliged to accept the study as compliant with OECD test guideline 414 under OECD Council Decision OECD/LEGAL/0194 of 12 May 1981 concerning the mutual acceptance of data in the assessment of chemicals (the 'MAD Decision').

The Board of Appeal found that the MAD Decision does not bind ECHA. This is because, first, the European Union has not acceded to the Convention on the Organisation for Economic Co-operation and Development, nor adhered to the MAD Decision. Second, not all the Member States of the European Union have acceded to the MAD Decision.

Moreover, according to the MAD Decision, studies must be accepted for purposes of assessment and other uses relating to the protection of human health and the

environment if they have been carried out in accordance with OECD test guidelines. This does not mean that the Agency cannot carry out its own assessment of whether a study was performed in accordance with a test guideline. Therefore, even assuming that the Agency would be bound by the MAD Decision, the Agency would in any event have been entitled to conclude that the study in question did not comply with Column 1 of Section 8.7.2. of Annex IX.

Third, the Appellant argued that the dose levels used in study in question were sufficiently high to show that the Substance poses no risk to human health. Rejecting that study was therefore disproportionate.

The Board of Appeal found that once the Agency had correctly found that the study in question did not comply with the information requirement set out in Column 1 of Section 8.7.2. of Annex IX, it had no margin of discretion as to whether or not to find the existence of a data gap in the Appellant's registration dossier.

In addition, the consequence of the Agency's finding of a data-gap is that the Appellant must either perform an OECD TG 414 study pursuant to Column 1 of Section 8.7.2. of Annex IX or, alternatively, adapt this information requirement pursuant to Annex XI of the REACH Regulation.

These requirements are not discretionary requests for further information, such as those which the Agency adopts in the context of the substance evaluation procedure. They are the direct and automatic consequence of the Agency's finding of a data-gap, flowing from the REACH Regulation itself. The relevant provisions of the REACH Regulation already ensure proportionality and the protection of animal welfare by allowing the submission of an adaptation or waiver whenever possible.

The Board of Appeal therefore found that the contested decision did not breach the principle of proportionality.

The appeal was dismissed.
