**SUMMARY OF THE DECISION OF 22 MARCH 2022 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

**Case A-004-2020**

*(Substance evaluation – Error of assessment – Potential risk – Improved risk management measures)*

*Factual background*

The appeal concerned a decision of the European Chemicals Agency (the 'Agency') on the substance evaluation of antimony sulphide ('ATS') requesting the Appellant and other registrants of ATS to provide information on a 90-day (sub-chronic) inhalation toxicity study in rats (test method: OECD test guideline 413), including bronchoalveolar lavage, measurements of lung burden, and additional cardiovascular and toxicokinetic parameters.

The Contested Decision stated that the requested information was necessary to clarify concerns that ATS may cause respiratory tract and systemic toxicity, and potentially cancer after prolonged inhalation exposure, as well as cardiotoxicity.

The Appellant requested the Board of Appeal to annul the Contested Decision in its entirety or, alternatively, annul the additional parameters required in the Contested Decision.

*Main findings of the Board of Appeal*

In its decision of 22 March 2022, the Board of Appeal dismissed the appeal.

The Board of Appeal confirmed that, to request information under substance evaluation, the Agency must establish that:

- there are grounds for considering that, based on a combination of exposure and hazard information, a substance constitutes a potential risk to human health or the environment,
- the potential risk needs to be clarified, and
- the requested information has a realistic possibility of leading to improved risk management measures.

The Board of Appeal rejected the Appellant's argument that the Agency had failed to demonstrate a potential risk. The Appellant did not demonstrate that the Agency made an error in finding that there was a potential hazard related to cardiotoxicity – the potential hazard in relation to the other concerns was not disputed – and that there was potential exposure to ATS for workers, professionals, and consumers.

The Board of Appeal rejected the Appellant's argument that the Agency had not demonstrated that the requested information has a realistic possibility of leading to improved risk management measures. In this respect, the Contested Decision stated that the requested study can be used for deciding on the classification of ATS for specific target organ toxicity repeat exposure ('STOT RE') 1 or 2 under the CLP Regulation[1].

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1; the 'CLP Regulation').

The Board of Appeal decided that the requested study has a realistic possibility of leading to a harmonised STOT RE classification. Furthermore, such a classification triggers certain obligations that constitute improved risk management measures. For example:

- labelling obligations, such as 'warning' for STOT RE 2 classification and 'danger' for STOT RE 1 classification, improve information for users of the substance concerned as to the risks incurred;
- establishment of concentration limits under Article 10(1) of the CLP Regulation; and
- inclusion of the STOT RE classification in the safety data sheet which the supplier of the substance concerned must provide to the recipients of the substance.

The Board of Appeal also rejected the Appellant's argument that, since ATS is already self-classified as STOT RE 2 by some of the registrants of ATS, the requested study would not lead to an improvement of the risk management measures in place. The Board of Appeal highlighted that a harmonised classification must be uniformly and consistently applied by all registrants of a substance and in the supply chain. However, self-classification can be changed at any time and does not bind either the other registrants of the same substance or other actors in the supply chain. In this respect, it was noted that not all registrants of ATS currently apply the STOT RE 2 self-classification.

The Appellant's argument that the Agency infringed an essential procedural requirement of the REACH Regulation as it did not perform a compliance check on ATS prior to the substance evaluation was rejected. The Board of Appeal confirmed that the Agency should not, in principle, use the substance evaluation process to request the standard information listed in Annexes VII to X to the REACH Regulation. However, in the present case, the requested study could not have been requested under the compliance check procedure as it is not standard information. Furthermore, the Agency is not required to complete a compliance check, concerning all information contained in a registration dossier, before performing a substance evaluation.

The Appellant's argument that the Agency should have allowed the Appellant to complete its own testing strategy and develop a grouping approach and read-across proposals before requesting additional information under substance evaluation was also rejected. The Board of Appeal noted that the Appellant's testing strategy has not been completed and the Agency is not required to wait for a registrant to generate information to support or improve potential adaptations. The Board of Appeal also highlighted that the information needed to establish structural similarity for the purposes of identifying a potential risk under the substance evaluation process is different from that needed to justify a read-across adaptation for registration purposes under Section 1.5. of Annex XI to the REACH Regulation.

Following the Board of Appeal's decision, the Appellant is required to provide the information requested in the Contested Decision by 30 December 2023.

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**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.

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