EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 17 DECEMBER 2019 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Joined Cases A-003-2018, A-004-2018 and A-005-2018

(Substance evaluation – Potential risk – Read-across – Risk management measures)

Factual background

Cases A-003-2018, A-004-2018 and A-005-2018 concerned separate Agency decisions on the substance evaluation of aluminium chloride, aluminium sulphate and aluminium chloride basic (the 'three Substances'), respectively. The three cases were joined for the purposes of the appeal proceedings.

The addressees of each contested decision were requested to provide information on a combined *in vivo* mammalian erythrocyte micronucleus test, and an *in vivo* mammalian comet assay with additional specific investigation on oxidative DNA damage on the following tissues: liver, kidney, glandular stomach and duodenum (test methods EU B.12/OECD TG 474 and OECD TG 489 in rats, oral route) (the 'contested information requirement'). The addressees of each decision were required to provide information on the contested information requirement using aluminium sulphate.

The Agency identified genotoxicity as the concern to be clarified by the contested information requirement.

In each appeal, the appellant requested the annulment of the contested information requirement.

Main findings of the Board of Appeal

In its Decision of 17 December 2019, the Board of Appeal annulled the contested information requirement. The case was remitted to the Agency for further action.

The Board of Appeal found that there was a lack of clarity, and in some respects consistency, as to whether the genotoxicity concern was for the three Substances only, all soluble aluminium salts or the aluminium ion. The lack of clarity on the substance or substances of concern created uncertainty as to how the requested information would be used by the Agency.

The Board of Appeal also confirmed that the Agency has to demonstrate the necessity for further information under substance evaluation. The Agency must establish that there are grounds for considering that a substance constitutes a potential risk to human health or the environment. The Agency must also demonstrate that the potential risk needs to be clarified, and that the requested measure, to clarify the concern, has a realistic possibility of leading to improved risk management measures.

In the present case, the Board of Appeal found that the Agency had failed to demonstrate clearly that, based on the evidence as a whole, there is a potential risk which requires further investigation under substance evaluation.

In particular, the Agency did not demonstrate that it gave the appropriate importance to both reliable and unreliable *in vitro* and *in vivo* studies. The Agency also failed to demonstrate that its rejection of the proposed read-across from aluminium hydroxide to the three Substances was based on all the available evidence.

The Board of Appeal also found that the Agency did not adequately examine, or explain, in the contested decisions how the contested information requirement could lead to improved risk management measures. In particular, the contested decisions do not explain why exposure to the three Substances is not already adequately controlled even if the three Substances are eventually shown to be genotoxic.

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.

Unofficial document, not binding on the Board of Appeal

The full text of the decision is available on the Board of Appeal's section of ECHA's website:
http://echa.europa.eu/about-us/who-we-are/board-of-appeal