

Ongoing work

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Guidance on the use of QSARs - draft paper for discussion

2.10 A sub-group of COM members are developing a guidance document for the use of QSARs both in the preliminary evaluation of a chemical (stage 0) and in the evaluation of impurities. In June 2024, paper MUT/2024/3 was presented by this subgroup, outlining best practices for using (Q)SAR in genotoxicity evaluation, including the prioritization of compounds, selection of the (Q)SAR model, reporting of (Q)SAR predictions, considerations of expert knowledge, read-across approaches, and integration of findings into a weight-of-evidence evaluation.

2.11 The approach taken so far to produce this discussion paper had been to evaluate existing guidance on (Q)SARs (e.g., OECD, ECHA, ICH and SCCS). It was determined that current guidance is limited in its specificity for genotoxicity, especially clastogenicity. Therefore, to address this information gap, the primary literature was also reviewed.

2.12 During discussions, COM members considered that the current paper outlines the 'state of the science' and a more specific set of COM recommendations on how to use QSARs for evaluating genotoxicity should be established, based on the synthesis of information in the paper. The inclusion of case studies from Government departments and agencies in the final COM guidance was thought to be useful, but these may be hard to define. Members noted that the COM recommendations should have improved narration of data quality and a clear identification of the strengths and weaknesses of the different (Q)SAR models. In addition, incorporation of a summary of recommendations at the start of the document, possibly in the form of a flow-chart as per the overarching COM Guidance, was considered important for the accessibility of information to users.

2.13 A follow-up meeting with the subgroup was agreed upon to review feedback and finalize next steps. The target completion for the guidance document was set for the March 2025.

UN GHS germ cell mutagenicity - for information

2.14 In June 2024, members of the COM were informed (MUT/2024/04) that UK REACH Independent Scientific Expert Pool (RISEP) had comments regarding the classification of mutagens. In response to these comments, the Health and Safety Executive (HSE) drafted a document on the classification of germ cell mutagenicity and had requested this to be considered by the COM. The COM recommended preparing a background document on CLP and UK REACH to provide context before detailed discussions. This document was circulated to members, and a more detailed discussion paper from HSE is scheduled for a future meetings.