

Ongoing work - COM 2022

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COM guidance series update

Guidance statement the use of biomarkers in genotoxicity in risk assessment

2.1 At the request of the COC, the COM considered a revised version of the COC Guidance Statement G04 ‘The use of biomarkers in carcinogenic risk assessment’ at the COM March 2022 meeting (MUT/2022/03). Particular focus was given to the ‘DNA’ and ‘genotoxicity biomarkers’ sections, both of which had had been shortened in the current version of G04 as part of a document revision process.

2.2 It was agreed that COM would produce a guidance statement that provided a more comprehensive overview of these areas, which could then be referred to by the other Committees. A draft scoping document outlining the proposed content of guidance statement was presented to the COM at its meeting in June 2022 (MUT/2022/06).

2.3 Several modifications to the scoping document were suggested by members and these were incorporated into a first draft document presented at the COM October 2022 meeting (MUT/2022/11). Members considered that the focus of the COM document should be *in vivo* biomarkers of DNA damage, with greater distinction from the COC Guidance Statement G04. Work is ongoing to progress a second draft document.

Guidance on how the committees evaluate the relevance and reliability of data when assessing a chemical of concern

2.4 At the COM March 2022 meeting, the COM considered a draft document outlining the Committee evaluation process focussing on the relevance and reliability of data written specifically to inform the lay person (MUT/2022/03). This document evolved from a scoping paper on the topic of ‘biological relevance and statistical significance’, presented to the Joint COC/COM meeting in November 2020 (CC/MUT/2020/03) also attended by some COT members, which outlined some of the more relevant and significant work that has been published on this issue in recent years. It was agreed that two documents should be progressed.

The first document should be aimed at the lay audience about the process used by the Committees to evaluate evidence and reach conclusions and a second document aimed at a more informed audience on statistical significance testing and consideration of biological relevance.

2.5 Paper MUT/2022/04 presented an updated version of the draft document, amended following comments from COM members at the March 2022 meeting. The draft document would also be discussed by COT and COC at their July 2022 meetings.

2.6 COM members asked for a small number of additional changes to be made prior to the document being evaluated by COC and COT. This included emphasising the public-facing role of the document.

Non-expert summaries for COM website

2.7 At the COM meeting in June 2022, it was agreed that the general public could benefit from the addition of non-expert summaries to the start of each COM guideline document.

2.8 A draft non-expert summary for the overarching COM guideline, 'Guidance on a strategy for genotoxicity testing of chemicals (MUT/2022/13) was presented at the COM October 2022 meeting. Members considered that some text could be removed, as this was available on the COM website, and a link provided to that website. In addition, it was recommended that links to the glossary should be utilised fully as this provided an immediate and understandable definition for readers. Specific comments on the paper were requested to be sent directly to the Secretariat so that the paper could be updated.