

Committee on _____ **MUTAGENICITY**

MUT/MIN/2020/3

COMMITTEE ON MUTAGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Minutes of the meeting held at 2 to 4pm on 25th November 2020 via teleconference.

Present:

Chairman: Dr D Lovell

Members: Mr A Bhagwat
Dr C Beevers
Dr G Johnson
Professor D Harrison (Ex officio)
Professor S Doak
Dr S Dean
Professor P Fowler
Dr J Kenny
Dr R Morse
Dr A Povey
Mrs M Wang

Secretariat: Dr O Sepai (PHE Scientific Secretary)
Mr S Robjohns (PHE Secretariat)
Dr C Mulholland (FSA Secretariat)

Secretariat Support: Dr R Bevan (IEH Consulting)

Assessors: Dr L Koshy (HSE)
Dr H Stemplewski (MHRA)
Ms F Fernandez (VMD)
Mr L Johnstone (BEIS)

Observers

Ms Gilly Stoddart -PETA International
Science Consortium Ltd.
Ms Sam Saunders - PETA International
Science Consortium Ltd.
Gail Drummond (PHE)
Dr Chang Guo (PHE)

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ITEM 1: ANNOUNCEMENTS/APOLOGIES FOR ABSENCE

1. The Chair welcomed the COM members, assessors and secretariat. The Chair also welcomed new members Dr G Johnson (Swansea University), Dr J Kenny (GlaxoSmithKline) and Mrs M Wang (lay member) to their first COM meeting. Apologies were received from the member Dr M O'Donovan and the assessors John O'Brien (FSA Scientific Council), Jacqui McElhiney (FSS) and Sam Fletcher (VMD).
2. The COM was informed that there was a vacancy for the position of chair of the COM for the next year for meetings occurring after February 2021 and requested members to inform suitable candidates. It was announced that IEH Consulting had successfully obtained a renewal of its contract to provide secretariat support to the COM and COC.
3. Members were requested to declare any interests before the discussion of any items.

ITEM 2: MINUTES OF MEETING ON 9th JUNE 2020 (MUT/MIN/2020/2) AND THE OUTSTANDING MINUTES for ITEM 5 FOR THE COM MEETING ON THE 20th February 2020

4. Members agreed the minutes of the COM meeting held on the 9th June 2020 (MUT/MIN/2020/2) the 20th February 2020 (MUT/MIN/1.5).

ITEM 3: MATTERS ARISING

5. There were no matters arising not on the agenda.

ITEM 4: COM OVERARCHING GUIDANCE DOCUMENT (MUT/2020/16)

6. Amendments to the overarching COM Guidance document as a whole have been ongoing and previously considered at Committee meetings in June 2018 (paper MUT/2018/09), October 2018 (paper MUT/2018/13), February 2019 (MUT/2019/01), October 2019 (MUT/2019/12), February 2020 (MUT/2020/03) and June 2020 (MUT/2020/09).
7. At the last consideration, the Committee suggested a few further amendments to the main text to the overarching Guidance document. In addition, two ex COM members were asked to review the whole document to highlight any remaining amendments. The presented paper (MUT/2020/16), contained amendments made following the June meeting and comments received from the two ex COM members for review and discussion.
8. Members addressed each query that was outstanding. However, due to a reduced meeting length only half of the document was covered. To facilitate finalisation of the document, members were asked to review the remaining sections and send any comments to the Secretariat by the 31st December 2020. All changes suggested by members would be incorporated into a new version of the overarching Guidance Document to be agreed at the next

meeting in February 2021. It was intended that once finalised; the overarching document would be updated as part of a rolling revision. The topic of genomics would not be included in the overarching document because it was a rapidly developing field and likely to become out of date very quickly. A separate guidance document on genomics may be developed in the future.

ITEM 5. COM GUIDANCE UPDATES

ITEM 5a. GERM CELL MUTAGENS (MUT/2020/17)

9. Drafts of a stand-alone guidance statement on genotoxicity testing strategies for germ cell mutagens were considered at the Committee meeting in February 2019 (MUT/2019/05), in October 2019 (MUT/2019/12) and in June 2020 (MUT/2020/11).

10. The paper presented (MUT/2020/17) included the changes discussed at the meeting in June 2020. Due to the reduced meeting length it was not possible to discuss the questions posed and members were asked to send their responses to these by email before the 14th December 2020. These would be addressed, along with comments received from HSE, in a revised draft for finalisation at the meeting in February 2021.

ITEM 5b. 3D MODELS (MUT/2020/18)

11. Drafts of a stand-alone guidance statement on the use of 3D models for genotoxicity testing were considered at the Committee meetings in February 2019 (MUT/2019/04), October 2019 (MUT/2019/12) and June 2020 (MUT/2020/11).

12. The paper presented (MUT/2020/18) included the changes discussed at the meeting in June 2020. Due to the reduced meeting length it was not possible to discuss the questions posed and members were asked to send their responses to these by email before the 14th December 2020. These would be addressed, in a revised draft for finalisation at the meeting in February 2021.

ITEM 5c. NANOMATERIAL TESTING (MUT/2020/19)

13. The draft COM Guidance on the genotoxicity testing of nanomaterials was a new document, as this area has not been included previously within the overarching COM Guidance. A draft paper was considered at the Committee meeting in February 2019 (MUT/2019/04) and in October 2019 (MUT/2019/12).

14. The paper presented (MUT/2020/19) a proposed outline for a re-structured version of the former document. It was agreed that this structure was suitable, and a draft document would be prepared for discussion at the COM meeting in February 2021.

ITEM 5d. QSAR MODELS (MUT/2020/21)

15. The draft statement had been updated following discussion at the February 2020 meeting. Due to the reduced meeting length it was not possible to discuss the questions posed and members were asked to send their responses to these by

email. These would be addressed, and a revised document would be prepared for discussion at the meeting in February 2021.

ITEM 6. GUIDANCE STATEMENT ON TESTING FOR IMPURITIES - UPDATE (MUT/2020/21)

16. COM published a guidance statement in 2012 on a strategy for genotoxicity testing and mutagenic hazard assessment of impurities in chemical substances. There have been a number of initiatives since 2012 in this area and as part of the ongoing update of the COM Guidance Statement series, members agreed that the document should be updated.

17. The paper presented (MUT/2020/21) a revised interim draft of this statement for discussion by members. There was general agreement for the changes suggested and some additions and clarifications to the text were discussed. It was agreed that these would be incorporated in a second revised interim draft to be presented at the COM meeting in February 2021. In addition, comments had also been received from HSE which would be addressed in the second revised interim draft.

ITEM 7. STATEMENT ON QUANTITATIVE ASSESSMENT OF GENOTOXICITY DATA – A DISCUSSION (MUT/2020/22)

18. The COM first considered quantitative approaches for assessing genotoxicity data, and how they may be used in chemical risk assessment, at its Horizon Scanning exercise in June 2013 and a guidance statement was published in 2015. The European Food Safety Authority (EFSA) has recently released a draft guidance on aneugenicity assessment for public comment, which focuses on the *in vivo* assessment of chemicals identified *in vitro* as aneugens. The draft EFSA document was reviewed by COM members and a Committee response to the public consultation was submitted.

19. It was suggested that the COM guidance statement on quantitative assessment of genotoxicity data should be reviewed in light of the changes proposed in the EFSA 2020 document, and the paper presented (MUT/2020/22) highlighted where updates could be made. The suggested updates were discussed by COM members and it was agreed that due to a number of concerns regarding the EFSA document, the COM guidance should not be updated at this time to reflect these. An alternative approach was agreed whereby the COM would prepare a directed statement in response to the EFSA document, once it had been adopted and published.

ITEM 8: ANY OTHER BUSINESS

20. A draft glossary of scientific terms used by the COM, COC and COT was circulated. It was noted that it would be useful if the set of terms used by the different sister committees were consistent. Members were asked to send

any comments (e.g. for any inconsistencies or definitions that needed to be updated) to the secretariat via email.

ITEM 13: DATE OF NEXT MEETING

21. 11 February 2021.