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# Committee on \_\_\_\_\_ **MUTAGENICITY**

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MUT/MIN/2020/3

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

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

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### **Present:**

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### **Chairman:**

Dr D Lovell

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### **Members:**

Mr A Bhagwat

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Dr C Beevers

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Dr G Johnson

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Professor D Harrison (Ex officio)

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Professor S Doak

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Dr S Dean

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Professor P Fowler

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Dr J Kenny

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Dr R Morse

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Dr A Povey

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Mrs M Wang

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### **Secretariat:**

Dr O Sepai (PHE Scientific Secretary)

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Mr S Robjohns (PHE Secretariat)

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Dr C Mulholland (FSA Secretariat)

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### **Secretariat Support:**

Dr R Bevan (IEH Consulting)

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### **Assessors:**

Dr L Koshy (HSE)

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Dr H Stempleski (MHRA)

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Ms F Fernandez (VMD)

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Mr L Johnstone (BEIS)

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42 **Observers**

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Ms Gilly Stoddart -PETA International  
Science Consortium Ltd.

Ms Sam Saunders - PETA International  
Science Consortium Ltd.

Gail Drummond (PHE)

Dr Chang Guo (PHE)

DRAFT

	Paragraph
1. Announcements/Apologies for absence	1
2. Minutes of the meeting held on 9 <sup>th</sup> June 2020 (MUT/MIN/2020/2) and QSAR Item 5 from 20 <sup>th</sup> February 2020 (MUT/MIN/2020/1.5)	4
3. Matters Arising	5
4. COM Overarching Guidance document (MUT/2020/16)	6
5. COM Guidance statements on:	9
a. Germ cell mutagens (MUT/2020/17)	
b. 3D models (MUT/2020/18)	
c. Nanomaterial testing (MUT/2020/19)	
d. QSAR models (MUT/2020/20)	
6. Guidance statement on testing for impurities (MUT/2020/21)	20
7. Statement on Quantitative assessment of genotoxicity data – A discussion paper (MUT/2020/22)	22
8. Any other business	24
9. Date and venue of next meeting – 11 <sup>th</sup> February 2021	25

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51 **ITEM 1: ANNOUNCEMENTS/APOLOGIES FOR ABSENCE**  
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53 1. The Chair welcomed the COM members, assessors and secretariat. The  
54 Chair also welcomed new members Dr G Johnson (Swansea University), Dr J  
55 Kenny (GlaxoSmithKline) and Mrs M Wang (lay member) to their first COM  
56 meeting. Apologies were received from the member Dr M O'Donovan and the  
57 assessors John O'Brien, Jacqui McElhiney and Sam Fletcher.  
58

59 2. The COM was informed that there was a vacancy for the position of chair  
60 of the COM for the next year for meetings occurring after February 2021 and  
61 requested members to inform suitable candidates. It was announced that IEH  
62 Consulting had successfully obtained a renewal of its contract to provide  
63 secretariat support to the COM and COC.  
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65 3. Members were requested to declare any interests before the discussion  
66 of any items.  
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68 **ITEM 2: MINUTES OF MEETING ON 9<sup>th</sup> JUNE 2020 (MUT/MIN/2020/2) AND**  
69 **THE OUTSTANDING MINUTES for ITEM 5 FOR THE COM MEETING ON THE**  
70 **20<sup>th</sup> February 2020**  
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72 4. Members agreed the minutes of the COM meeting held on the 9<sup>th</sup> June  
73 2020 (MUT/MIN/2020/2) the 20<sup>th</sup> February 2020 (MUT/MIN/1.5).  
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75 **ITEM 3: MATTERS ARISING**  
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77 5. There were no matters arising not on the agenda.  
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80 **ITEM 4: COM OVERARCHING GUIDANCE DOCUMENT (MUT/2020/16)**  
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82 6. Amendments to the overarching COM Guidance document as a whole  
83 have been ongoing and previously considered at Committee meetings in June  
84 2018 (paper MUT/2018/09), October 2018 (paper MUT/2018/13), February  
85 2019 (MUT/2019/01), October 2019 (MUT/2019/12), February 2020  
86 (MUT/2020/03) and June 2020 (MUT/2020/09).  
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88 7. At the last consideration, the Committee suggested a few further  
89 amendments to the main text to the overarching Guidance document. In  
90 addition, two ex COM members were asked to review the whole  
91 document to highlight any remaining amendments. The presented paper  
92 (MUT/2020/16), contained amendments made following the June  
93 meeting and comments received from the two ex COM members for  
94 review and discussion.  
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96 8. Members addressed each query that was outstanding. However, due to  
97 a reduced meeting length only half of the document was covered. To  
98 facilitate finalisation of the document, members were asked to review  
99 the remaining sections and send any comments to the Secretariat by  
100 the 31<sup>st</sup> 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<sup>[SR1]</sup>.

## **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 will 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)**

16. 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).

17. 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 will be addressed, in a revised draft for finalisation at the meeting in February 2021.

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

18. The COM Guidance on the use of 3D models for genotoxicity testing is 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).

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

20. 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.

21. 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)**

22. 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.

23. 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**

24. 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**

31. 11 February 2021