

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

Minutes of the meeting held at 10.30 am on Thursday 15<sup>th</sup> July 2021 by Teams.

Present

Chair: Professor D Harrison

Members: Mr D Bodey  
Dr G Clare  
Dr M Cush  
Dr R Dempsey  
Dr J Doe  
Dr R Haworth (am only)  
Prof G Jenkins  
Prof N Pearce  
Dr L Rushton  
Dr L Stanley  
Prof H Wallace

Secretariat: Miss B Gadeberg PHE Scientific Secretary  
Dr D Gott FSA

Assessors: Dr H McGarry HSE  
Mr N O'Brien VMD  
Mr S Robjohns PHE  
Mr L Johnstone BEIS-OPSS

Officials: Dr K Broom PHE  
Dr B Doerr FSA  
Prof T Gant PHE  
Dr M Jacobs PHE  
Dr O Osbourne FSA (Item 6)

Invited Experts Dr R Bevan IEH Consulting  
and Contractors: Prof J O'Brien FSA Science Council  
Dr P Rumsby IEH Consulting

Observers: Professor L Levy IEH Consulting

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**ITEM 1: Announcements and apologies for absence**

1. The Chair welcomed Members, and other attendees to the meeting. Apologies were received from Dr Ray Kemp, Ms C Mulholland (FSA Secretariat), and Dr O Sepai (PHE Assessor) who was represented by Mr S Robjohns.

2. Professor Gareth Jenkins was congratulated on his appointment as COM Chair and welcomed to his *ex officio* role on COC.

3. Members were reminded to declare any interests they may have in an item before its discussion.

**ITEM 2: Minutes of meeting held on 11<sup>th</sup> March 2021 (CC/MIN/2021/01)**

4. The second draft minutes were agreed with no further changes.

**ITEM 3: Matters arising**

***COT principles for assessing risks from less than lifetime exposure or variable exposure over a lifetime***

5. Following the COC work on less than lifetime exposure, the COT had developed principles for assessing risks from less than lifetime exposure or variable exposure over a lifetime. Its statement had been published:  
<https://cot.food.gov.uk/sites/default/files/2021-07/Statement%20on%20less%20than%20lifetime%20and%20variable%20exposure.pdf>.

***Item 3 Matters Arising – Draft position paper: The Tumour Microenvironment***

6. This document had been approved by Chair's action and would be published on the Committee website soon.

***Item 3 Matters Arising – Cancer Risk Characterisation Methods G06 Update***

7. This document had been approved by Chair's action and would be published on the Committee website soon.

***Item 4 Presentation on the Human Biomonitoring for EU (HBM4EU) Project and Item 5 Development of Human Biomonitoring Guidance Values in the HBM4EU Project (CC/2021/15)***

8. Following the last COC meeting, this presentation and paper had been presented to the COT meeting on 23rd March, and the minutes of the COT discussion were provided in paper CC/2021/15.

9. The COC and COT deliberations on this topic would be summarised in the 2021 Joint COT, COM, COC Annual Report.

***Item 7 Updated Scoping Document for New Guidance Statement on Weight of Evidence Approach to Assessing Modification of Cancer Risk***

10. A small group had met to discuss development of this scoping document to a position paper.

11. There had been a delay in getting the paper developed after that meeting for further comment by the smaller group before coming to the full Committee, so it was anticipated this topic would be further discussed in the autumn.

**Item 10 Lay Summary on How Committees Evaluate the Relevance and Reliability of Evidence**

12. Following the last COC meeting, this paper was presented to the COT meeting on 23rd March.

13. The COT were in agreement for development of two separate documents (i) an overall general description of how the expert Committee's review process is conducted, aimed at a lay reader; and (ii) a discussion of the interplay between biological relevance and statistical analysis in the evaluation of evidence, which would be non-technical but aimed at a more informed audience.

14. These would be progressed for discussion by COM.

**Item 11 FSA Science Council Draft Principles and Guidelines on Third Party Evidence**

15. The FSA Science Council agreed its final report on this piece of work on the 10th June. This follows revisions made based on earlier feedback, including that from COC and a public consultation. The full report is available at the following link <https://science-council.food.gov.uk/SCRapidReview1>.

**ITEM 4: Draft report on the synthesis and integration of epidemiological and toxicological evidence in risk assessments (CC/2021/09)**

16. No interests were declared for this item.

17. This paper presented a revised draft report from the Synthesis and Integration of Epidemiological and Toxicological Evidence (SETE) subgroup following comments from COC and COT at their March 2021 meetings. A few minor text changes had been added following comments on this revised draft at the July COT meeting

18. Some suggestions were made to further modify the added text if they were considered necessary to add. This version also had worked examples provided as an Annex, and it was suggested to add short problem formulations to each example.

19. With respect to the recommendations section, the COC agreed with the approach of using upcoming examples to test the document before making further recommendations.

20. Overall the COC was content with the amendments made to the draft report, and supported development of a published paper to further promote the work of the subgroup.

21. The Secretariat and Subgroup were thanked for their work on the report.

110 **ITEM 5: Second draft revised Guidance Statement (G04): The Use of**  
111 **Biomarkers in Carcinogenic Risk Assessment (CC/2021/10)**

112 22. No interests were declared for this item.

113 23. This paper presented a second draft revised guidance statement G04,  
114 addressing the use of biomarkers in carcinogenic risk assessment, amended in line  
115 with discussions at the meeting in March 2021. It was noted that the DNA adduct  
116 section remained unbalanced with regards to length and would be shortened for the  
117 third draft revision.

118 24. There was a consensus that the DNA adduct section of the guidance  
119 statement should be shortened, with the COM being asked to evaluate G04, once it  
120 was further revised. In addition, it was considered that the summary section would  
121 need to be updated to reflect any changes suggested by the COM. The opinions  
122 expressed in G04 were highlighted as a conservative approach, based on the  
123 current science. However, it was agreed that G04 should be further updated once  
124 the COC position paper on new approaches to the risk assessment of chemicals for  
125 carcinogenicity had been published.

126 25. Following the discussion, it was agreed that any additional changes would be  
127 agreed by correspondence and the final revised version of G04 signed off by Chair's  
128 action.

129 **ITEM 6: Follow up to horizon scan topics – July 2021 (CC/2021/11)**

130 26. No interests were declared for this item.

131 27. The paper presented the standing item on horizon scanning topics, as well as  
132 providing an outline of the FSA-COT led UK Roadmap on New Approach  
133 Methodologies (NAMs) which had previously been a topic of interest for the  
134 Committee.

135 28. Dr Olivia Osborne (FSA) was present for the discussion of the FSA-COT led  
136 UK Roadmap on NAMs. It was noted that some of the techniques being used are  
137 not necessarily new, but it was a coined term for the approach and would be used  
138 going forward. Members were invited to provide comments in advance of a next draft  
139 expected in the early autumn.

140 29. Professor Tim Gant gave a presentation on the NIHR Health Protection  
141 Research Units (HPRUs), how they came about and the current iteration and the  
142 topics being considered under these. Dr Kerry Broom, who is responsible for  
143 Knowledge Mobilisation for the HPRU's, was also in attendance explaining the role  
144 and the intended interaction with groups such as COC.

145 30. One Member noted a recent ECHA tender for work on Mixture Assessment  
146 Factor work including an element for non-threshold genotoxicity, and also one on  
147 derivation of Derived Minimal Effect Levels (DMELs). It was agreed that it was useful  
148 for Members to raise such calls, or relevant papers for the Committees awareness,  
149 where these were not picked up by the Secretariat. Another Member flagged an

150 EFSA conference on Combined Exposures which could be of interest to Committee  
151 Members.

152 31. It was suggested that in 2022 it would be helpful to have an update on  
153 activities following EU Exit, possibly as an information session at a joint meeting.

154 **ITEM 7: First draft updated Guidance Statement (G03): Hazard**  
155 **Identification and Characterisation: Conduct and Interpretation of**  
156 **Animal Carcinogenicity Studies (CC/2021/12)**

157 32. No interests were declared for this item.

158 33. Guidance statement G03 was last updated in 2018 as part of the COC rolling  
159 update process. The suggested amendments to the document presented in this  
160 paper were those that were previously highlighted for members to consider at the  
161 COC meeting in July 2020. In the interim period (July 2020 – July 2021)  
162 considerations were made of a new COC position paper exploring some of the  
163 elements from G03 as part of a weight of evidence approach to assessing  
164 modification of cancer risk. COC had concluded in March 2021 that there was  
165 insufficient information available at the time on all aspects of cancer development  
166 and the potential modification of these events by chemicals on the cancer process to  
167 facilitate its utility for risk assessors. Therefore, Members had agreed that the update  
168 of COC guidance statement G03 should be continued.

169 34. Specific comments were provided along with suggestions for further additions  
170 to the text for clarification. Following the discussion, it was agreed that the additional  
171 changes would be agreed by correspondence and the final revised version signed off  
172 by Chair's action.

173 **ITEM 8: First draft updated Guidance Statement (G07): Alternatives to the**  
174 **2-year bioassay (CC/2021/13)**

175 35. No interests were declared for this item.

176 36. Guidance Statement G07 is an overview of approaches developed as  
177 potential replacements to the 2-year bioassay and was last updated in 2017 as part  
178 of the COC rolling revision process. The suggested amendments to the document  
179 presented in this paper were those that were previously highlighted for members to  
180 consider at the COC meeting in July 2020. In the interim period considerations were  
181 made of a new COC position paper exploring some of the elements from G07 as part  
182 of a weight of evidence approach to assessing modification of cancer risk. COC had  
183 concluded in March 2021 that there was insufficient information available at the time  
184 on all aspects of cancer development and the potential modification of these events  
185 by chemicals on the cancer process to facilitate its utility for risk assessors.  
186 Therefore, Members had agreed that the update of COC guidance statement G07  
187 should be continued.

188 37. Members made a number of suggestions for amendment to the document,  
189 including a change of the title to accurately portray the content. It was agreed that as  
190 G07 had been developed and added to over a number of years, it had become too

191 long and could be improved considerably by reducing the length through removal of  
192 historic data into Appendices.

193 38. It was agreed that an updated draft would be prepared for consideration at the  
194 November 2021 COC meeting.

195 **ITEM 9: For Information: Terms of Reference for the Office for Product**  
196 **Safety and Standards (OPSS) Scientific Advisory Group on**  
197 **Chemical Safety of Non-Food and Non-Medicinal Consumer**  
198 **Products (SAG-CS) (CC/2021/14)**

199 39. No interests were declared for this item.

200 40. This paper presented the Terms of Reference for the recently formed  
201 Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal  
202 Consumer Products (SAG-CS), supporting the Office for Product Safety and  
203 Standards (OPSS) on their assessment of consumer products. It was noted that  
204 OPSS were aware of the overlap with the remit of COC, COM and COT.

205 41. It was suggested that the SAG-CS would benefit from having lay  
206 representation on the group.

207 42. Members flagged that as was the case with other Committees and Groups,  
208 Members of the SAG-CS would be entitled to claim fees for their role on the Group.  
209 The COC, and COM, as DHSC Expert Committees are out of step with other  
210 Committees and Groups within the toxicology field, as they are not paid fees, and the  
211 Chair agreed to raise this with DHSC.

212 **ITEM 10: Any other business**

213 43. The Committee was informed that the Advisory Committee for Novel Food  
214 and Processes (ACNFP) were considering a number of applications for use of  
215 cannabidiol in food, with support from COT and COM.

216 44. The Committee discussed its preferences for future meetings as Covid  
217 restrictions were coming to an end. It was agreed that the November 2021 meeting  
218 would be held virtually, but in 2022, a mixture of two face to face and one virtual  
219 meeting would be preferred, but with the option to videoconference in to the face to  
220 face meetings for those who had difficulties attending in person.

221 **ITEM 11: Date of next meeting**

222 45. The next meeting would be held on 18<sup>th</sup> November 2021 by Teams.