CC/MIN/2021/02

Committee on carcinogenicity of chemicals in food, consumer products and the environment (COC)

Minutes of the meeting held at 10.30 am on Thursday 15th 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, Public Health England Scientific Secretary
	Dr D Gott, Food Standards Agency
Assessors:	Dr H McGarry, Health and Safety Executive
	Mr N O'Brien, Veterinary Medicines Directorate
	Mr S Robjohns, Public Health England
	Mr L Johnstone, Office for Product Safety and Standards
Officials:	Dr K Broom, Public Health England
	Dr B Doerr, Food Standards Agency
	Prof T Gant, Public Health England
	Dr M Jacobs, Public Health England
	Dr O Osbourne, Food Standards Agency (Item 6)

Invited Experts	Dr R Bevan	IEH Consulting
and Contractors:	Prof J O'Brien	Food Standards Agency Science Council
	Dr P Rumsby	IEH Consulting
Observers:	Professor L Levy	IEH Consulting

Contents

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 (Food Standards Agency Secretariat), and Dr O Sepai (Public Health England Assessor) who was represented by Mr S Robjohns.

2. Professor Gareth Jenkins was congratulated on his appointment as Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (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 11th March 2021 (CC/MIN/2021/01)

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

ITEM 3: Matters arising

Committee on Toxicity (COT) principles for assessing risks from less than lifetime exposure or variable exposure over a lifetime

5. Following COC's work on less than lifetime exposure, 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 European Union (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. 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. COT was in agreement on the 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 Food Standards Agency (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, COC agreed with the approach of using upcoming examples to test the document before making further recommendations.

20. Overall, 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.

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

22. No interests were declared for this item.

23. This paper presented a second draft revised guidance statement G04, addressing the use of biomarkers in carcinogenic risk assessment, amended in line with discussions at the meeting in March 2021. It was noted that the DNA

adduct section remained unbalanced with regards to length and would be shortened for the third draft revision.

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

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

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

26. No interests were declared for this item.

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

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

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

30. One Member noted a recent European Chemicals Agency (ECHA) tender for work on Mixture Assessment Factor work including an element for non-threshold genotoxicity, and also one on derivation of Derived Minimal Effect Levels (DMELs). It was agreed that it was useful for Members to raise such calls, or relevant papers for the Committees awareness, where these were not picked up by the Secretariat. Another Member flagged an EFSA conference on Combined Exposures which could be of interest to Committee Members.

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

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

32. No interests were declared for this item.

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

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

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

35. No interests were declared for this item.

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

37. Members made a number of suggestions for amendment to the document, including a change of the title to accurately portray the content. It was agreed that as G07 had been developed and added to over a number of years, it had become too long and could be improved considerably by reducing the length through removal of historic data into Appendices.

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

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

39. No interests were declared for this item.

Post-meeting note: Dr Gill Clare declared an interest on this item after the meeting, as a Member of the SAG-CS.

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

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

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

ITEM 10: Any other business

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

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

ITEM 11: Date of next meeting

45. The next meeting would be held on 18th November 2021 by Teams.