

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

Minutes of the meeting held at 10.00 am on Thursday 18 July 2024 by Teams.

Present

Chair: Professor D Harrison

Members: Dr E Barnes
Mr A Bhagwat
Dr R Dempsey
Prof S Doak
Dr J Doe
Dr C Harris
Prof N Pearce
Ms J Rix
Dr S Stalford
Dr L Stanley

Secretariat:	Ms B Gadeberg	UKHSA Scientific Secretary
	Ms S Pallavi	UKHSA
	Ms C Potter	FSA
	Mr T Fraser	UKHSA

Sponsor:	Ms C Boccia	DHSC (Items 1-4)
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Assessors:	Ms K Boss	FSS
	Mr N O'Brien	VMD
	Ms A Slack	HSE (on behalf of Dr V Swaine)

Officials:	Prof John O'Brien	FSA Science Council
	Mr A Loh	HSE

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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 Prof G Jenkins and Dr R Haworth (COC members), Ms C Mulholland (FSA Secretariat), Dr R Bevan and Prof J Weeks (IEH consulting, providing Secretariat support) and Dr V Swaine (HSE assessor) who was represented by Ms A Slack.
2. Dr Emma Barnes, Dr Susanne Stalford, Dr Caroline Harris, Professor Shareen Doak and Dr John Doe had been appointed to the COC and were welcomed.
3. Members were reminded to declare any interests they may have in an item before its discussion.

ITEM 2: Minutes of meeting held on 21st March 2024 (CC/MIN/2024/01)

4. The first draft of the minutes of March 2024 meeting were agreed.

ITEM 3: Matters arising.

Interim position on hydroxyanthracene derivatives

5. The COC interim position on hydroxyanthracene derivatives (HADs) had been published.

Horizon Scanning planning for a virtual workshop in September

6. A further COC session was planned for September 2024 to progress the horizon scanning work previously discussed.

Appraisals

7. Members were thanked for returning their appraisals to the Secretariat, these would be considered by the Chair.

ITEM 4: “A case for change: Developing a better approach to assessing risk of cancer from chemicals” - Guidance statement G11 — draft 0.c (CC/2024/05)

8. COC had agreed at the March meeting to proceed with the proposed new guidance statement to make a call for proposals and evidence to reevaluate the process for assessing the risk of carcinogenicity.
9. Members were reminded that the COC guidance documents were valuable for government departments and agencies, for example drawing on COC’s recommendations for risk assessment when supporting chemical incidents and evaluating exposures, as well as when undertaking regulatory evaluations.
10. A number of amendments were suggested for the document and a further draft would be shared with the Committee.

ITEM 5: Developing new guidance documents

11. The COC had regularly updated its concise, standalone documents encapsulating key guidance points and underpinning evidence in the COC guidance statement series. These had been based on a Committee review of recent research papers and had at times led to a critique of the evidence base rather than producing clear, actionable guidance.

12. A new approach was proposed which would utilize Members' expertise to produce updated and re-cast standalone short guidance documents, supported by the underpinning evidence. It was noted that the guidance was not necessarily outdated, however it was important for the Committee to show awareness of recent evidence.

13. The Committee considered this as a sensible approach and would enable consideration of new approach methods (NAMs) in a timely manner in the future.

14. It was noted that the FSA Science Council was considering a project on the wider impacts of risk assessment in the following risk management and other considerations, e.g. of benefits, technical feasibility and costs, which is beyond the remit of COC and other similar advisory committees. The value of the COC's guidance was flagged to support the subsequent stages. The Committee did note that informing the COC of these risk management and other stages would benefit the Committee in providing its risk assessment guidance.

15. It was agreed that further consideration of such a new approach would be made, including ensuring input from the Lay Members to ensure guidance would be clear and understandable.

ITEM 6: Annual Report (CC/2024/04)

16. This paper presented the draft COC annual report for 2023. Members were invited to review the contents and update the Secretariat by correspondence on any updates to their affiliations and declarations of interest for 2023.

ITEM 7: EFSA Consultation on draft Scoping paper on the revision of the opinion on the Margin of Exposure for chemicals which are both genotoxic and carcinogenic (CC/2024/06)

17. This paper presented the recently published draft EFSA scoping paper for the revision of its opinion on the margin of exposure approach for chemicals which are genotoxic and carcinogenic. The COC was invited to consider whether it would respond to the consultation and discuss any specific comments to be provided in the response.

18. The Committee welcomed EFSA's proposed review of this opinion. It was considered timely to anticipate that there would be a decrease in carcinogenicity studies conducted in the future, and that it would be important to develop an approach that utilised data from other studies. The COC recognised the intention in

this scoping document to make useful steps in the move away from using animal test data for risk assessment and communication.

19. The COC did not agree with the continued assumption that chemicals can be categorised as carcinogenic or not carcinogenic, suggesting instead that the outcome should be an expression of risk if increasing the possibility of cancer occurring. This was discussed further in the paper by Harrison DJ and Doe JE (2021) (Toxicol Res, 10(4):800-809. doi: 10.1093/toxres/tfab064).

20. The use of BMDLs and T25 were recommended as the reference points for use in the MOE approach in the 2005 EFSA opinion. The COC noted that there was often insufficient information available to derive a BMDL so a NOAEL might have to be used. Therefore, the Committee welcomed development of advice on a range of options for reference points that can be used with an MOE approach.

21. EFSA's ambition to develop an approach which does not necessarily require animal carcinogenicity studies was welcomed. The COC noted that EFSA may wish to consider how much data would be adequate for an assessment and using an MOE approach, e.g. for some compounds only a single dose 90 day study may be available to form the basis of a risk assessment.

22. The COC agreed that it would be helpful for EFSA to consider any further guidance or clearer definitions on MOEs which were less than 10,000 as could be the case for natural contaminants. Similarly, it would be helpful to strengthen the scientific rationale and explanation for use of an MOE of 10,000 with a BMDL₁₀ from an animal carcinogenicity study to support risk managers.

23. The COC noted that it would be helpful to supplement the planned considerations on the toxicology evidence, with further consideration of the uncertainties in occurrence data to support the exposure assessment aspect of an MOE approach. This could also include guidance for less than lifetime exposures.

ITEM 8: Any other business

Accessing MS Teams/ Sharepoint for collaborative working.

24. The Secretariat was in the process of creating a Teams/SharePoint site and adding members. This would allow easier collaboration on documents between meetings to progress drafts. The Secretariat would keep Members informed on progress with this.

COM October meeting – COC member attendance of presentations

25. It was anticipated that Professor Charles Swanton would be attending the October 2024 COM meeting to present on his work on air pollution and lung cancer. COC had previously discussed this work and recommended COM also consider it. COC members would be invited to join the COM meeting to hear the presentation and discussions.

26. In addition, COM might also have a presentation from HSE on UK REACH at its October 2024 meeting, which COC members might also find useful.

ITEM 9: Date of next meeting

27. The next main COC would be on Thursday 21st November, likely as a virtual meeting, and the horizon scanning workshop would be virtual and was planned for September and Members would be informed of the date in due course.