MUT/MIN/2025/02

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

Minutes of the meeting held at 10:00 am on 19th June 2025 at 10 South Colonnade London E14 4PH and via MS Teams.

Present:

Chairman:	Professor G Jenkins
Members:	Dr A Doherty Dr P Fowler Dr N Goldsmith (Associate member) Dr G Johnson Ms J Kenny Dr A Povey Mrs M Wang Mr P Rawlinson Dr Robert Searle Foster
Secretariat:	Dr O Sepai (UKHSA Scientific Secretary) Mr S Robjohns (UKHSA Secretariat) Ms N Stratford Devalba (UKHSA Secretariat) Mr T Fraser (UKHSA) Dr C Mulholland (FSA Secretariat) Dr C Potter (FSA Secretariat) Ms C Tsoulli (FSA Secretariat) Ms E Hudson (FSA Secretariat) Dr T Khan (FSA Secretariat) Dr A Cooper (FSA Secretariat)
Secretariat Support:	Mr R Young (Bibra) Ms B O'Connell (Bibra)
Assessors:	Ms Kerry Webster (HSE) Dr Poornima Paramasivan (HSE)

Observers:

Professor David Harrison (COC)
Professor L Stanley (COT)
Dr D Lovell (COT)
Dr M Walker (COT)
Dr G Clare (COT)
Dr A Collins (COT)
Dr Q Choudry (COT)
Dr G Spedalieri (FSA)
Mr T Hornsby (FSA)
Mr A Hardgrave (FSA)
Dr N Burden (NC3Rs)

ITEM 1: WELCOME AND APOLOGIES FOR ABSENCE

1. The Chair welcomed the COM members, assessors, secretariat and observers. The Chair also welcomed members of the Food Standards Agency Joint Expert Group on Additives, Enzymes and other regulated products (FSA AEJEG) attending for item 6 on smoke flavourings and Natalie Burden from the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). Apologies for absence were received from the COM member Dr Robert Smith, and the assessors Liz Lawton (DEFRA) and Ms Krystle Boss (FSS). Apologies for absence were also received from Pete Watts of Bibra.

ITEM 2: ANNOUNCEMENTS

2. Members were requested to declare any interests before the discussion of any items.

3. The Chair announced that the consultancy Bibra toxicology advice and consulting had recently been awarded the contract for providing support to the COM (e.g., in terms of writing papers). Two representatives from Bibra, namely Richard Young and Beth O'Connell, gave an introductory presentation to the committee. The presentation outlined the history of Bibra, its structure, Bibra's consultancy sectors, and their TRACE database. The Chair welcomed Bibra to COM.

ITEM 3: MINUTES OF THE MEETING HELD ON 13TH MARCH 2025 (MUT/MIN/2025/01)

4. The minutes of the COM meeting held on the 13th of March 2025 were agreed with minor amendments.

ITEM 4: MATTERS ARISING

5. There were no matters arising.

ITEM 5: PRESENTATION FROM NC3RS – 'FACILITATING THE DEVELOPMENT AND UPTAKE OF NEW APPROACH METHODOLOGIES IN SAFETY ASSESSMENT'

6. Dr Natalie Burden from the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) presented to the committee on New Approach Methodologies (NAMs) and the work the NC3Rs has been doing to gauge opinions on NAMs and barriers to their uptake. The aim is to use this information to advance the wider adoption of NAMs via science and innovation; supporting people and organisations; and policy and regulatory change. In an introduction of the work of the NC3Rs it was noted that there has previously been a lot of expectation of NAMs but little translation into regulatory test methods. In looking to find solutions to this, the NC3Rs is investing in the development and progression of test methods, with an aim to accelerate commercialisation and uptake by industry. The NC3Rs CRACK IT scheme helps connect industry, academia and SMEs to support the development of new marketable products. It

also hosts events such as in collaboration with the regulatory MHRA and helps build relevant networks and communities to support work on NAMS. NC3RS also supports the training and upskilling as part of the BTS skills gap initiative.

7. Preliminary results of a survey sent to various stakeholders suggested that there is a regulatory and scientific need for the development of NAMS, as well as ethical considerations. However, there are a number of key challenges to address including validation; reproducibility; lack of standards and protocols; lack of regulatory acceptance and harmonisation; scientific and technical challenges; funding and infrastructure; and education, training and awareness. A need for data sharing and transparency was also identified. Another challenge was a need for the development of a UK Roadmap aligned with EU and global efforts. There was a need for the promotion of case studies comparing NAMS with traditional methods, perhaps with a focus on high-impact areas (e.g., DART, carcinogenicity and endocrine disruption).

8. The committee were informed there was still time to contribute to the survey. It would be distributed to COM members as well as to COT & COC members. A public facing document with the findings from the survey was due to be published in 2026 however the evaluation of the results was expected to be completed in July 2025, and it was noted that it would be useful for the COM, COT and COC to see the final analysis.

9. There was a discussion regarding the initial survey finding that there may be a publication bias against NAMs, as the opposite may be expected. There was need to delve deeper into the responses and see the context to this finding to distinguish between perceived challenges and actual challenges to NAMs uptake. It was noted that a new NAMs journal had recently been launched which may give a natural home to NAMs papers.

10. The NC3Rs works with the Organisation for Economic Co-operation and Development (OECD) from multiple angles whilst working within OECD processes. For example, the NC3Rs have led the development of formal OECD projects that have been accepted onto the workplan via the UK National Coordinators. The NC3Rs are also looking to expand on the use of the OECD Integrated Approaches to Testing and Assessment (IATA) to develop case studies that can be published and endorsed by the OECD.

11. There was discussion around the perception of NAMs within genotoxicity, as a member noted that there is not a lot of interest within the wider toxicology community regarding NAMs in genotoxicity. It was suggested that there may be the perception that a lot of genotoxicity testing is already done by *in vitro* methods, however it is not that straight forward as in vivo testing is still used. The presenter noted that the use of NAMs in genotoxicity will be included in the European Chemicals Agency (ECHA) framework due to be published in 2026.

ITEM 6: CLOSED SESSION – SMOKE FLAVOURINGS (MUT/2025/04)

12. Dr Paul Fowler declared a Specific personal conflict of interest and withdrew from the meeting for this item. Mr Paul Rawlinson declared that when at a previous employer, he had worked on a product from one of the smoke flavourings applicants. However, this related to cosmetic products and not smoke flavourings and Mr Paul Rawlinson was able to take part in the discussion for this item. Dr Nathan Goldsmith, an associate member of the COM, declared that he had received funding for a European research project on smoke flavourings during his PhD. This was not considered to be a conflict of interest. Dr George Johnson declared that he had worked with Firmenich and the International Organisation of the Flavourings Industry, specifically on smoke flavourings, but not mixtures. This was noted but Dr George Johnson was not excluded from the discussion. Dr Robert Searle Foster (Lhasa) declared an interest because the DEREK software developed by Lhasa that had been used in the evaluation of smoke flavourings. This was not considered to be a conflict of interest. Dr Qasim Choudhry a COT AEJEG member declared that he took part in a discussion with an EFSA panel on smoke flavourings. This was not considered to be a conflict of interest.

13. This item was considered as reserved business due to the consideration of commercially sensitive data.

ITEM 7: OECD UPDATES

14. The COM was informed that the development of an OECD Test Guideline (TG) for the ToxTracker in vitro assay for genotoxicity testing was progressing and there had been a presentation on this at a recent European Environmental Mutagenesis and Genomic Society meeting.

15. Development of an OECD test guideline for the gamma H2AX assay was also making progress with relevant data being gathered required for this test guideline.

16. It was noted the *in vitro* comet assay was in its early stages with ongoing work towards a validation report for the enzyme-linked comet assay along with the standard *in vitro* comet assay. There was only one representative from the UK in the working group for the comet assay and it would be beneficial to have additional representatives. COM and United Kingdom Environmental Mutagen Society (UKEMS) members will be asked to share this request.

ITEM 8: AOB

17. Professor David Harrison was coming to the end of his term as Chair of COC. Therefore, a process of recruiting a new Chair of the COC would be undertaken. Applications for the new Chair of COC were encouraged. There would also be other vacancies within the COC including epidemiology expertise, so members were encouraged to consider applying themselves or encourage others to apply. There are also two vacancies on the COM – one expert member and one lay member. Adverts for these positions were not yet out as they are awaiting ministerial approval. There will also be upcoming vacancies on the COT.

18. There was a paper published earlier this year by Huang et al. (2025) in PLOS Biology which came to the attention of the Chair via the COT titled “the end of the genetic paradigm of cancer”. The Chair noted it would be useful for this paper to be sent round to committee members and possibly be included as an agenda for discussion in a future meeting. It was noted that the paper overlaps with the idea of non-genotoxic carcinogens that were discussed in the previous meeting held on the 13th of March 2025.

19. The COT workshop this year will be on artificial intelligence (AI) in toxicology and will be held on the 22nd of October 2025 in person.

ITEM 9: DATE OF NEXT MEETING

20. Date of next meeting – 16th October 2025.