

Meeting

Final Minutes of the 9th July 2024 COT Meeting

This is a paper for discussion.

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Meeting of the Committee at 10:00 on 9th July 2024 on Microsoft Teams.

Present

Chair: Professor Alan Boobis

Dr James Coulson

Professor Gary Hutchison

Professor Thorhallur Halldórsson

Dr Natalie Thatcher

Dr Simon Wilkinson

Professor Philippe Wilson

Dr Gunter Kuhnle

Professor Shirley Price

Dr Cheryl Scudamore

COT Members:

Dr Stella Cochrane

Professor Peter Barlow

Dr Steven Enoch

Dr Mac Provan

Mr Gordon Burton

Dr Meera Cush

Mr Nick Richardson

Dr Chris Morris

Dr Andreas Kolb

Dr Alison Yeates

Ms Cath Mulholland - FSA Scientific Secretary

Ms Chara Tsoulli

Ms Abigail Smith

Dr Alex Cooper

Mr Michael Dickinson

Ms Claire Potter

Dr Barbara Doerr

Dr Olivia Osborne

Ms Sabrina Thomas

Dr Gail Drummond

Ms Cleanncy Hoppie

Ms Jocelyn Frimpong-Manso

Ms Sophy Orphanos

Food Standards

Dr Gaetana Spedalieri

Agency (FSA)

Mr Thomas Hornsby

Secretariat:

Dr Emily Hudson

Dr Aaron Bradshaw

Ms Jessica Cairo

Dr Lorcan Browne

Ms Natasha Adams

Dr Katie Schulz

Ms Katie Wetherall

Mr Barry Maycock

Ms Frederique Uy

Dr Rachel Kerr

Mr James Metcalfe

UK HSA Secretariat: Ms Britta Gadeberg - UK HSA Scientific Secretary
Ms Sanyukta Pallavi

Assessors: Ms Helen McGarry - Health and Safety Executive (HSE)
Ms Rachel Elsom - Office of Health Improvement and Disparities (OHID)
Ms Susannah Brown - (OHID)
Ms Ovnair Sepai - (UKHSA)

Observers: Professor Ian Young - Scientific Advisory Committee on Nutrition (SACN) Chair.
Professor Ken Ong - Member, Plant- based drinks Working Group.
Professor Sue Lanham- New - Member, Plant- based drinks Working Group.

Mr Craig Jones - FSA
Ms Holly-Jones - FSA
Mr David Kovacic - FSA
Ms Emma French - FSA
Ms Pamela Ihezor-Ejiofor - FSA
Dr Joseph Shavila - FSA
Dr Mindy Dulai - FSA
Ms Laura-Jayne Quinn - FSA
Ms Krystle Boss - Food Standards Scotland (FSS)
Ms Lucy Smythe - FSS
Ms Lucy Reid - Food Standards Agency Northern Ireland (FSA NI)
Ms Colleen Mulrine - FSA NI
Mr Edward Latter - Department for Environment, Food and Rural Affairs (DEFRA)
Ms Nat Tonge - Environment Agency (EA)
Ms Julia Lavery - Health & Safety Executive (HSE)

FSA and other
Officials:

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Announcements

1. The Chair welcomed Members and other attendees.

2. COT Members were informed that Professor Shirley Price had kindly agreed to take up the role of COT Deputy Chair. Following the discussions on ways of working at the May COT meeting, Professor Price would be focusing particularly on the regulated products area of the COT's work.

Interests

3. The Chair reminded those attending the meeting to declare any commercial or other interests they might have in any of the agenda items.

Item 1: Apologies for absence

4. Apologies were received from COT Members Professor Maged Younes, Dr Michael Routledge, Dr David Lovell and Dr Silvia Gratz.

Item 2: Minutes of the meeting held on the 21st May 2024 - TOX/MIN/2024/03

5. The Committee reviewed the draft minutes and the reserved minutes of the 21st May 2024 meeting (TOX/MIN/2024/03).

6. It was requested that paragraph 23 be amended to state "Dr Stella Cochrane declared a non-personal specific interest as her employer may use titanium dioxide in their products. This interest did not preclude this Member from contributing to the discussion of this item". Post meeting note: The interests of Dr Natalie Thatcher were noted with the same wording, and it was further noted that Professor Shirley Price was part of the JECFA Working Group on titanium dioxide.

7. The minutes and reserved minutes were accepted as an accurate record.

Item 3: Matters arising

Joint Expert Group (JEG) updates AEJEG

8. The Joint Expert Group on Additives, Enzymes and other Regulated Products (AEJEG) met on the 4th June and were presented with an update paper covering all 6 previous Requests for Further Information (RFIs) on the application for authorisation of the substance glycolipids (E 246) (Nagardo, AM-1) for use as a

new food additive (RP1457). The substance has antimicrobial effects and is proposed for use in beverages with a normal use level of 10 mg/L and a maximum proposed level of up to 50 mg/L.

9. It was agreed that RP1457 would return to the AEJEG as a committee advice document, capturing their discussion and conclusions. Once agreed by the AEJEG this document would be presented to COT.

10. The next AEJEG meeting will be on the 19th of July.

11. The Smoke Flavourings Working Group will next meet on the 25th of July to start phase 3 assessment of these flavourings (conclusions on genotoxicity, assessment of general toxicity and Extended One-Generation Reproductive Toxicity (EOGRT)).

FCMJEG

12. The most recent meeting of the Joint Expert Group for Food Contact Materials (FCMJEG) was held on the 3rd of July, at which two applications for recycling processes, RP1862 and RP1741, were discussed. Members were content with the applications and it was agreed that they could progress to the COT. The FCMJEG also reviewed an updated statement on ocean bound plastics.

13. The next FCMJEG meeting will be held on the 28th of August.

Publications

14. The COT position paper on bisphenol A (BPA) has now been published.

15. The executive summary of the COT statement on titanium dioxide is expected to be published soon after the July 2024 General Election.

COT Workshop 2024

16. The 2024 COT workshop will be taking place on Tuesday the 22nd of October at Broadway House in London, with the October COT meeting taking place on Monday 21st of October.

17. As Members had agreed previously, the workshop will be on the subject of the microbiome. It is provisionally titled "Gut reactions: xenobiotics and the microbiome."

18. Members made a number of suggestions on possible topics and speakers, stressing in particular the need to keep the agenda focussed, given the breadth of the topic. Members were invited to send any additional thoughts to the Secretariat.

Subgroups and working groups

19. The next meeting of the ACNFP/COT working group on cannabidiol (CBD) will take place on the 16th of July.

20. The next meeting of the COT Working Group on per and polyfluoroalkylated substance (PFAS) will take place on the 24th of July.

SAC recruitment.

21. The 2025 recruitment round for the FSA Scientific Advisory Committees would be starting shortly, with applications provisionally being open from the end of August to early October. Members would be provided with more information when this was available.

EFSA consultation

22. A draft EFSA opinion on brominated phenols was currently open for consultation, closing on the 1st of August. There were no plans to present it to COT, but Members were welcome to comment in their own capacity if they wished to do so.

Item 4: Hazardous Substances Advisory Committee (HSAC) discussion on the effects of flame retardants on human health: developing a work programme. (TOX/2024/30)

23. No interests were declared for this item.

24. Mr Ed Latter, Chemicals Policy Lead (Defra), Ms Nat Tonge (EA) and Ms Julia Laverty (HSE) were in attendance for this item.

25. Paper TOX/2024/30 presented a discussion paper, which was also considered at the 5th of July 2024 meeting of the Defra Hazardous Substances Advisory Committee (HSAC), which was attended by the COT Chair and by the

Vice-Chair of the Office for Product Safety and Standards (OPSS) Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS). The paper was presented to the COT and to HSAC to scope a workstream to prioritise flame retardants for review and to consider how information on potential risk to human health might contribute to this.

26. The Committee was informed of work by the OPSS on flame retardants, including on the benefits of their use, which Defra will also consider as part of the prioritization process, alongside the output from an Environment Agency scoping study.

27. Members queried whether there would be sufficient evidence available to balance the effectiveness of a flame retardant alongside the available toxicology evidence, and to allow comparison across flame retardants. Likewise, whether there was sufficient exposure data available on use and levels in the environment, e.g. in household dust, to inform the consideration.

28. It was suggested that grouping and read-across might be a useful means of aiding prioritization. Hazard and NAMs data were available in the EPA CompTox Chemicals dashboard (<https://comptox.epa.gov/dashboard/>), which could provide some granularity with respect to toxicological hazard, and which might allow predictions based on chemical properties. Further information was also available from a 2019 report from the US National Academies of Sciences, Engineering and Medicine (<https://nap.nationalacademies.org/catalog/25412/a-class-approach-to-hazard-assessment-of-organohalogen-flame-retardants>).

29. With respect to exposure, the Committee noted there were a number of aspects to consider such as sources and routes of exposure, exposure at different life-stages and differences between sexes, exposures occurring at the end of product life in which the flame retardant is used, and occupational exposures. It was noted that there were limitations in the data available from REACH. EA had conducted an analysis of the available EU-REACH data and considered it possible to classify different flame retardants into broad groups based on use (e.g. in plastics or textiles). EFSA had also adopted a grouping approach, based on structure, in their assessments of these compounds. Some information had also been made available from consultation with industry.

30. It was noted that given the overlap across a number of UK Expert Committees and Government Departments and Agencies on the topic of flame retardants, it might be useful to put together an organogram to help direct the aspects for consideration appropriately and to delineate areas of responsibility.

31. The Committee was thanked for its input, and Defra would work with the Secretariat as well as other partners in taking the work forward.

Item 5: First draft Statement on the potential health effects of raspberry leaf tea in the maternal diet (TOX/2024/23)

32. No interests were declared.

33. This item was part of the COT's current programme of work assessing risks from the maternal diet, to feed into the Scientific Advisory Committee on Nutrition's (SACN) review of nutrition and maternal health, focusing on maternal outcomes during pregnancy, childbirth and up to 24 months after delivery.

34. With respect to exposure, the Committee noted there were a number of aspects to consider such as sources and routes of exposure, exposure at different life-stages and differences between sexes, exposures occurring at the end of product life in which the flame retardant is used, and occupational exposures. It was noted that there were limitations in the data available from REACH. EA had conducted an analysis of the available EU-REACH data and considered it possible to classify different flame retardants into broad groups based on use (e.g. in plastics or textiles). EFSA had also adopted a grouping approach, based on structure, in their assessments of these compounds. Some information had also been made available from consultation with industry.

35. A draft statement had now been prepared, reflecting the COT's discussion and conclusions at the September 2022 meeting. Members were asked to consider the structure and content of the draft statement.

36. The draft statement was considered well-structured and to reflect the discussion that took place at the September 2022 meeting. It was noted that there was no evidence of adverse effects from the available data, but a number of data gaps were highlighted, in particular, which constituents are biologically active and of potential concern and the limited information available on reproductive toxicity and genotoxicity.

37. The Committee noted the high prevalence of use of raspberry leaf in pregnancy, without any apparent safety signal, which was considered to provide some reassurance, and this should be noted in the conclusions section.

38. It was noted that the exposure window in the reproductive toxicity studies, in which animals were dosed during pregnancy, did not necessarily match with the window of exposure in human pregnancies, in which raspberry leaf is typically taken in the last trimester.
39. The draft statement referred to raspberry leaf having low oral bioavailability. Members considered that the text should be modified to make it clear that there were no pharmacokinetic data available, but the low bioavailability was inferred by the much lower toxicity observed in old animal studies, when raspberry leaf extracts were administered orally compared to intraperitoneally.
40. Medicines were out of scope of the statement, but it was asked whether any medicinal products containing raspberry leaf were available in the UK. Several raspberry leaf products were registered as traditional herbal medicines in the UK, based on history of safe use but not on efficacy; these were intended for non-pregnant women for the symptomatic relief of menstrual cramps.
41. Members considered an *in vitro* study (Teo et al., 2021) which compared the cytotoxicity of an aqueous extract of raspberry leaf to that of a mixture of herbal extracts to be difficult to interpret, and the *in vivo* relevance to be over-interpreted by its authors, though the study findings were included in the statement for completeness. For another study (Majaki et al., 2011), Members considered an interpretation of the potential implication of a finding by the authors to be an unsupported extrapolation, for which they considered there to be no evidence.
42. Members requested that the statement should note that products were available which contained raspberry leaf together with other herbal constituents. Members also requested that the statement note that some clinics provided raspberry leaf tea enemas, though it was noted that these are not foods.
43. In the absence of data from the National Diet and Nutrition Survey (NDNS) on the consumption of raspberry leaf tea by pregnant women (as NDNS does not include pregnant women), one method of exposure assessment had used data on consumption of herbal and fruit teas by women of child-bearing age. However, it was observed that this may underestimate exposure since raspberry leaf is targeted at pregnant women as a supplement.
44. Members considered that the draft statement should specifically cross-reference some of the more detailed information on the variability of findings in

animal studies and in the composition of extracts studied, which was described in the previous COT scoping paper, so it was clear why the statement was describing the uncertainty as high.

45. Members requested a number of additional editorial changes to the draft statement. The Committee agreed that following the requested changes being made, the Statement could be cleared by Chair's action.

Item 6: Risk assessment of T-2 and HT-2 in food (TOX/2024/24)

46. No interests were declared.

47. In 2020, the European Commission proposed establishing maximum levels for the mycotoxins T2 and HT2 in foods, which are lower than the current indicative levels set out in the European Commission Recommendation 2013/165/EU. The COT was asked by the FSA to assess the risk to UK consumers from T2/HT2 in foods, to aid in their review of T2/HT2 in light of the new maximum levels proposed.

48. Paper TOX/2024/24 was a scoping paper reviewing potential consumer exposure and included occurrence data supplied by industry, some from a study by the British Oat & Barley Millers' Association (BOBMA), which had been obtained through a call for data conducted by the FSA. Consumption data from the NDNS population was used, rather than from specific food group consumers, and the majority of occurrence data was from unprocessed foods rather than from foods as would be consumed; this complicated the accuracy of the exposure assessment. The 97.5th percentile consumption rate was used for each food group; this approach led to a significant overestimation of exposure, as it was unrealistic for someone to be a 97.5th percentile consumer of all food groups simultaneously. The occurrence data used for the exposure assessments spanned from 2008 to 2023, with significant variability in the occurrence levels over this period. However, it was likely that the analytical methods had improved during this time, which could explain some of the variability in the data.

49. Members had a number of questions about the analytical methods used to measure mycotoxins in food since this could affect the reliability of exposure assessments. The FSA Policy team agreed to contact BOBMA for further information regarding validation of their analytical methods.

50. The FSA Policy team also agreed to provide a link to the maximum legislative levels which came into force in the European Union on the 1st of July 2024, which had now been published online. Post meeting note [Maximum legal levels](#) .

51. Due to the significant uncertainties in the exposure assessment, the Committee was unable to conclude on the possible risk of any exceedances of the health-based guidance values. The Committee discussed the challenges of communicating this information, especially when presenting high exposure estimates that might be unrealistic.

52. The Committee suggested a number of ways in which the approach to the exposure assessment could be refined. This included the effect of processing on the mycotoxin levels in food, some consideration of the analytical methodology used, and information on actual consumer behaviour to better estimate risks. More targeted surveys to gather accurate data on processed foods would help to better understand actual levels of exposure. The Committee agreed that further analysis to visualise any year-on-year trends in the occurrence data would be helpful.

53. One Committee Member circulated a paper, which analysed mycotoxins in the urine of UK children, suggesting this might also provide an insight into actual exposure levels.

Item 7: Advice on the risk to human health from consumption of bivalve molluscs (shellfish) harvested from UK waters associated with marine biotoxins. TOX/2024/25

54. No interests were declared.

55. The FSA is considering the current advice and monitoring programme for marine biotoxins and whether there is a need to update or change existing legislative standards.

56. In December 2023 a scoping paper was presented to the Committee on whether a number of emerging marine biotoxins would pose a risk to human health. This paper provided an overview of the available toxicological information, occurrence data, and any additional relevant information, such as proposed or

current limits, monitoring data and considerations in other countries. To aid the Committee in ranking the risk of each emerging toxin, Members requested that the Secretariat produce a table providing the main toxicological information of the marine biotoxins (as discussed in the scoping paper) for easier comparison to one another. The Committee also requested a table of the main toxicological information of currently regulated marine biotoxins for comparison.

57. Paper TOX/2024/25 provided a limited estimate of potential adult exposures to the unregulated marine biotoxins, based on the European Food Safety Authority's (EFSA) shellfish portion size of 400 g, and a fish portion size of 140 g, as suggested by the Ministry of Agriculture, Fisheries and Food portion size book and assuming a body weight of 78.6 kg. The aim of the estimated exposures was to help Members establish whether occurrence at the levels reported in the literature would be of potential risk. However, this was not a detailed exposure assessment, and consumption data was not based on UK consumers, and hence may have overestimated actual exposures in the UK.

58. The shellfish portion size (400 g) applied by EFSA represents high level consumption across Europe and Members agreed that it was likely too high and not necessarily representative of shellfish consumption in the UK. The National Health Service (NHS) website recommended consumption of 2 portions of fish of 140 g per week, with one of those portions consisting of oily fish. Other sources, such as the recent EAT-Lancet report (which also considered sustainability) suggested 1 to 2 portions of fish/shellfish per week (approximately 28 g), and a study in Southern Ireland funded by the Department of Agriculture Marine Institute estimated daily shellfish consumption at 43 g. Members stated that it would be preferable to use data from the National Diet and Nutrition Survey (NDNS) to enable a more accurate and refined exposure assessment, although data for consumption of shellfish from this survey may still be limited.

59. It was noted that the respective portion sizes used to estimate exposure were intended for different purposes, as the 400 g for shellfish was intended for risk assessment while the 140 g for fish was intended for nutritional advice.

60. Members queried whether emerging biotoxins were present in freshwater and if this could lead to multiple exposure sources, for example, from other animals, or imported rice.

61. The Committee acknowledged the limited data available showing the impact of biotoxins on other animals living in (e.g. fish and shellfish) or frequenting (e.g. wild birds) freshwater. It is generally assumed that animals

would avoid areas of high blooms, if they can. The overlap between algal blooms and exposure to toxins was not exact since the fish and shellfish could have benthic stages or behaviours.

62. The Committee noted that data on adverse effects of marine biotoxins were commonly from animal studies, and not from human data. It was specifically noted that cyclic imines (CIs) were monitored in some countries even though no human intoxications had been reported. Members also highlighted how the route of administration in animal studies differed widely and how intraperitoneal injection appears to increase toxicity in a number of studies compared to oral administration.

63. Members noted that it would be useful for the UK to have a more formal strategy for the reporting of potential marine biotoxin intoxications, however the Committee acknowledged that this may prove difficult for some marine toxins as standard testing may not be available.

64. The Committee asked whether information was available on current algae monitoring programmes and whether there were links between the presence of toxin producing algae, and the levels of marine biotoxins detected in shellfish. Members noted that if environmental monitoring data could predict algae blooms and identify which kind of algae to expect in a given area, there may be the potential to predict which toxins may be present. The Committee queried whether there was any literature available in this regard or if this work was being done anywhere globally. The Committee also highlighted the benefits from enhanced UK surveillance programmes and suggested to look at monitoring programmes in other countries, specifically e.g. in Scotland and Northern Ireland, and whether they could be adapted for England or rolled out UK wide. The Committee acknowledged the potential cost of such monitoring programmes but noted that this was outside the Committee's remit and would sit with the FSA.

65. Given the potential impact of climate change on the presence of marine biotoxins in UK waters, Members suggested that it could prove useful to feed into the climate change impact strategy when considering the effects/impact of global warming on the ecosystem.

66. The Committee discussed the potential applicability of risk ranking based on a scoring system that had previously been applied to score the relative risk of mycotoxins. This consisted of assigning a numerical score to each emerging toxin for the following categories: toxicity, occurrence in UK waters, human health impact, and monitoring and/or regulation. Toxins exhibiting severe

health effects and demonstratable occurrence in UK waters would score high and therefore should be prioritised for monitoring in UK fish and shellfish. However, Members did not think it was feasible to agree on a definitive ranking of the toxins within the time constraints of the meeting, as some considerations would need to be given to the factors driving the final score, e.g. if the occurrence in UK waters is low but the severity of the effect is high, which factor would be given more weight and why. Members also noted that as part of the considerations on risk ranking, further details on long term effects, especially in children may be useful.

67. The Committee asked the Secretariat to produce a discussion paper providing a risk ranking for each toxin, considering the different weighting of factors that would influence the final score. The Secretariat were also asked to add the chemical structures of each toxin to the paper.

68. Overall, the Committee agreed that there were significant data gaps in the occurrence data for the UK therefore making it difficult to conclude on potential risk based on the currently available information on occurrence and estimated exposures. Members highlighted a number of data gaps, including a lack of information on the presence and concentrations of emerging toxins in UK waters, the potential impact of global warming on the occurrence of these toxins in UK waters, detailed studies on human exposure and health outcomes, and potential combinatory effects from co-occurrence of toxins.

69. Given the data gaps in this area, the Committee enquired whether the FSA's areas of research interest and research questions could be made easier to access. Whilst the minutes of the meetings are published, which contain current research questions, Members agreed that their visibility could be improved, enabling better integration with other government departments and academia, and potentially better collaboration with UK Research and Innovation (UKRI).

Item 8: Draft Committee Advice Document on the safety of calcium tert- phosphonate (RP1702) as an additive for use in the manufacture of plastic materials and articles intended to come into contact with food. (Reserved) TOX/2024/26

70. No interests were declared.

71. Dr Gill Clare and Professor Michael Walker from the Food Contact Materials Joint Expert Group (FCMJEG) were in attendance for this item.

72. The FCMJEG had been requested to provide a risk assessment on the safety of calcium *tert*-butylphosphonate as an additive for use as a nucleating agent in the manufacture of polyolefin food contact materials (FCMs) and articles for single and repeated-use applications.

73. This item is currently being treated as reserved, as the data are commercially confidential as the data are treated as commercially confidential during the UK regulated product application process.

74. Members reviewed and commented on the draft document.

Item 9: Draft Committee Advice Document on a recycled poly(ethylene terephthalate) decontamination process for use in the manufacture of materials and articles in contact with food (Reserved) TOX/2024/28

75. No interests were declared.

76. Dr Gill Clare and Professor Michael Walker from the Food Contact Materials Joint Expert Group (FCMJEG) were in attendance for this item.

77. The FCMJEG were requested to provide an assessment on the safety of post-consumer recycled poly(ethylene terephthalate) (PCR-PET) pellets produced from a recycling process (i.e. decontamination process) that utilises PCR-PET flakes as the raw input material.

78. This item is currently being treated as reserved, as the data are treated as commercially confidential during the UK regulated product application process.

79. Members also discussed information on the general requirements for recycling processes as part of this agenda item.

Item 10: Second draft report of the Plant based drinks Working Group (Reserved) TOX/2024/28

80. No interests were declared.

81. SACN Chair Professor Ian Young and WG Members Professor Ken Ong and Professor Sue Lanham-New were in attendance for this item.

82. The COT was asked to review this SACN/COT draft report. This draft report was attached as Annex A to Paper TOX/2024/28.

83. The item is currently being treated as reserved as the WG is operating under SACN rules so discussions are reserved but the draft report will be published for consultation or peer review, prior to finalisation.

84. Members reviewed and commented on the updated draft report.

Item 11: Update on the work of other FSA Scientific Advisory Committees - for information (TOX/2024/29)

85. This paper was circulated for information, but Members should contact the Secretariat if they have any questions.

Item 12: Any other business

86. There was no other business.

Date of next meeting

87. The next meeting of the Committee will be at 10:00 on the 3rd September 2024 by Microsoft Teams.