Minutes

Final Minutes of the 9th December 2025 COT Meeting

Minutes from the Meeting of the Committee at 11:00am, Tuesday 21st October 2025 at Broadway House and via Microsoft Teams.

Present

Chair:	Reverend Professor Lesley Stanley
Deputy Chair:	Professor Shirley Price

COT Members:	Professor Gary Hutchison
	Dr David Lovell
	Dr Cheryl Scudamore
	Professor Mireille Toledano
	Dr Simon Wilkinson
	Professor Philippe Wilson
	Professor Peter Barlow
	Dr Meera Cush
	Mr Gordon Burton
	Dr Andreas Kolb
	Mr Nick Richardson
	Dr Michelle Bellingham
	Professor Martin Clift
	Dr Aravindan Veiraiah
	Professor Mohammad Qasim Chaudhry
	Dr Tarek Abdelghany
	Ms Christel Wake
	Dr Antonio Peña Fernández
SACN Liaison:	Dr Susan Fairweather-Tait
Science Council Liaison	Ms Jacqueline Healing

Secretariat: Food Standards Agency (FSA)	Ms Cath Mulholland – FSA Scientific Secretary
	Ms Claire Potter
	Dr Alex Cooper
	Dr Barbara Doerr
	Dr Olivia Osborne
	Ms Sabrina Thomas
	Dr Gail Drummond
	Ms Chara Tsoulli
	Ms Frederique Uy
	Ms Jocelyn Frimpong-Manso
	Ms Sophy Orphanos
	Mr Thomas Hornsby
	Dr Emily Hudson
	Dr Katie Schulz
	Ms Katie Wetherall
	Mr James Metcalfe
	Ms Yoana Petrova
	Ms Polly Bevan
	Ms Abigail Smith
	Ms Alba Ureña Rusillo
	Ms Chloe Thomas
Secretariat: UKHSA - UK Health Security Agency	Ms Britta Gadeberg
	Ms Sanyukta Pallavi

UKHSA Contractor – Bibra	Ms Beth O’Connell
Assessors: Health Improvement Global and Public Health Group	Ms Neeve Pearce (Items 4 and 5).
Assessor: Health and Safety Executive (HSE)	Ms Minako Allen
Assessors: Environment Agency (EA)	Mr Ian Martin
Assessors: Business, Energy and Industrial Strategy (BEIS)	Ms Frances Hill
FSA officials:	Mr Izaak Fryer-Kanssen Ms Esse Hughes Ms Aisling Jao
UKHSA officials	Ms Gopika Chettuvatty (Item 6) Mr Stephen Robjohns (Item 6) Dr Alison Gowers, COMEAP Secretariat (Item 9
External Observers:	Dr Stephen Ruckman, Principal Consultant - Sagentia Regulatory (Item 4 onwards).

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Announcements

1. The classification of the COT, along with that of the other FSA Scientific Advisory Committees (SACs), is being changed from Arm’s Length Body to Departmental Expert Committee. However, this should have no effect on the way the COT works. Members will be kept informed about the progress of this change and can contact the Secretariat if they have any questions.

Interests

2. 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

3. Apologies were received from COT Members Dr Steven Enoch, Dr Alison Yeates, Professor Chris Morris and Dr Bryony Ross. Comments on the agenda items were received from some absent Members and addressed in the meeting as appropriate.

Item 2: Draft minutes and reserved minutes of the Tuesday 21st October 2025 meeting (TOX/MIN/2025/06)

4. The Committee reviewed the draft and reserved minutes of the meeting held on the 21st of October 2025. The minutes were accepted as an accurate record.

Item 3: Matters arising

Ashwagandha

5. Following the discussions on *Ashwagandha* at the October meeting, the Secretariat explained that work was underway to develop a suitable structure for the review, drawing on the FSA Advisory Committee on Novel Foods and Processes (ACNFP) template but adapting it to accommodate a literature review rather than a regulated product application. The Secretariat was also sifting the available studies to identify Organisation for Economic Co-operation and Development (OECD) Test Guideline compliant ones, with the aim of focussing on these, due to the volume of data available.

Joint Expert Group (JEG) updates

Additives, Enzymes and other Regulated Products Joint Expert Group (AEJEG)

6. An AEJEG hybrid meeting had been held on the 2nd of December. At this meeting an update had been provided on an application for authorisation of soy leghaemoglobin as a flavouring precursor for plant-based meat alternatives. Following discussions, the AEJEG had requested that a further Request for Further Information be sent setting out a number of questions regarding the new data that had been provided.

7. Members also received a presentation on the FSA work to support negotiations and planning for implementation of an EU-UK SPS Agreement.

8. The next AEJEG meeting is scheduled for February 2026.

Food Contact Materials Joint Expert Group (FCMJEG)

9. An FCMJEG meeting took place on the 3rd of December, where an application for polymer film agar palmitate was reviewed: points were raised requiring clarification before the Committee Advice Document (CAD) could be finalised. The FCMJEG discussed new guidance on polyolefin decontamination and a challenge test report developed with recycling industry input. The recycled plastics auditing is continuing, and future meetings will be addressing novel technology dossiers.

10. COT Members noted that it would be helpful for COT Members to have access to the table detailing the current work of the FCMJEG and timelines of CAD submission to COT. Members also noted that it would be helpful for COT Members to have access to the guidance developed by the environmental Non-Governmental Organisation (NGO) Waste and Resources Action Programme (WRAP).

11. Members also received a presentation on the FSA work to support negotiations and planning for implementation of an EU-UK SPS Agreement.

12. The next meeting of the FCMJEG is scheduled for February 2026.

EU-UK SPS

13. COT Members were updated on recent developments following the presentation on the FSA work to support negotiations and planning for implementation of an EU-UK SPS Agreement discussed at the October COT meeting.

Subgroups and working groups

14. The PFAS working group would be holding a short update meeting following today’s COT meeting.

15. There were no further working group updates,

Publications

16. The 2024 annual report and the statements on mercury, citrinin in the maternal diet, and emerging marine biotoxins would be published shortly.

Item 4: Scope of the nutrition and maternal health project (TOX/2025/44)

17. No interests were declared.

18. A draft annex outlining the scope of the Scientific Advisory Committee on Nutrition (SACN) project on nutrition and maternal health was presented to the COT. This was an ongoing project assessing maternal health outcomes during pregnancy, childbirth and up to 24 months *post partum*. The aim was that the annex would be attached to all maternal diet papers to aid consistency and would be included in the eventual over-arching statement.

19. COT Members were reminded that the SACN nutrition and maternal health project focussed on adverse effects on the mother up to 24 months *post partum*, effects on the unborn child that are mediated via the mother, and effects on the offspring through breast feeding (up to the age of 24 months). The project does not address direct adverse health effects on infants and young children.

20. It was suggested that the schematic presented in figure 1 should be in a linear form rather than a cyclical one to avoid the interpretation that reproduction was a cyclical process. It was noted that the stages in the schematic transitioned from ‘Gamete Production & Release’ to pregnancy, and then back to ‘Gamete production & Release’ in the offspring. Therefore, COT Members agreed a linear model would better aid the reader’s understanding and would represent a 3-to-4-year period. Several COT Members volunteered to assist with the redesign, and it was agreed that the proposed change be confirmed with SACN.

21. COT Members suggested that the preconception phase should be defined more precisely rather than by timespan alone and that placental health could be added to the proposed list of endpoints.

22. COT Members were reminded that a scoping exercise had been conducted in the early stages of the project to identify the chemicals and components in the maternal diet that should be considered. It was suggested that the list of proposed chemicals in the diet be revisited and updated, as the scope of the project had not been significantly updated in 3 years, although since the initial list was agreed, liquorice and tea (non-caffeine components) had been added at the request of SACN Members.

23. The potential effects of nicotine patches and vapes on maternal health was discussed; however, COT Members were reminded that the nutrition and maternal health project was on chemicals and components in the diet and did not cover exposure from non-dietary sources. The effects of nicotine had also been considered as part of the COT review of Electronic Nicotine Delivery Systems.

24. COT Members raised concerns about potential exposures from herbal supplements, particularly among certain ethnic groups, that may not currently be listed under chemicals for consideration. It was confirmed that the any revision to the list of chemicals to consider would encompass this, and that vulnerable groups were always considered in the COT's risk assessments.

25. COT Members noted that data on implantation and embryo loss had been included amongst the toxicity data presented in maternal diet papers. Members were reminded that this was to cover pre-agreed endpoints of 'time to conception' and 'miscarriage'.

26. COT Members questioned whether cannabidiol (CBD) should be included in the proposed list of chemicals. However, CBD had undergone extensive review by the ACNFP and the COT, and the recommendation was that it should not be consumed by pregnant women; therefore, it did not need to be included.

27. The Secretariat agreed to provide COT Members with an updated and more detailed table setting out the status of the individual chemicals and components currently listed.

Item 5: *Echinacea* in the maternal diet (TOX/2025/45)

28. No interests were declared.

29. A discussion paper (TOX/2024/43) was presented to COT Members in December 2024.This reviewed the available *in vitro*, animal, and human data on

Echinacea, including mechanisms of action, drug-herb interactions, contaminants, toxicity (including genotoxicity), reproductive and developmental endpoints, and adverse effects in humans. COT Members had concluded that deriving a point of departure (POD) for *Echinacea* would be challenging due to the variability in preparations, extracts and doses and the limited amount of high-quality data available. It had been acknowledged that individuals with atopic disease or autoimmune disorders might be at higher risk to the adverse effects than the general population and that this should be reflected in the risk assessment.

30. The first draft statement on the potential effects of *Echinacea* in the maternal diet was presented to the Committee in paper TOX/2025/46. The statement set out the views of the COT Members and included tables summarising immunomodulatory effects and reproductive/developmental endpoints which had been requested. A section on pharmacokinetics had also been added.

31. COT Members welcomed the inclusion of the tables and suggested some refinements to the table on reproductive and developmental effects, including the addition of a legend clarifying that the studies summarised in the table were discussed in subsequent paragraphs, removing the colour coding and replacing the term ‘covered’ by ‘insufficient’, ‘limited’ or ‘adequate’ to reflect data sufficiency and the quality of the studies examined.

32. COT Members recommended restructuring of the reproductive and developmental data, with maternal outcomes presented first, followed by foetal and offspring outcomes. It was also suggested that the human adverse effects section should be presented before the reproductive and developmental effects section. In addition, it should be clarified that the adverse effects section referred to studies in the general population, not specifically in pregnant women.

33. It was agreed that the language throughout the statement should remain neutral, particularly regarding immunomodulatory and anti-inflammatory effects, since the focus was on potential toxicity rather than efficacy. However, it was noted that some information on efficacy was needed to provide context on why consumers used *Echinacea* supplements; for previous supplements the phrase “purported benefits” had been used.

34. It was agreed that the risk characterisation section should note the complexity of *Echinacea* preparations, which should be treated as complex mixtures for risk assessment purposes. The information considered should include batch-to-batch variability, the uncertainty associated with the extraction

efficiency of *Echinacea* tea preparations when assessing exposure and the bioavailability of active components.

35. COT Members noted that EFSA advises against requiring or including acute toxicity data for the authorisation of novel foods. However, for a product such as *Echinacea,* where safety was being reviewed rather than an application being authorised, there were often few data available and acute toxicity information could contribute to a weight of evidence assessment. It was agreed that the acute toxicity section would be shortened to acknowledge the toxic dose in rats and to note that there was no evidence of acute toxicity in humans at the doses reportedly consumed.

36. COT Members requested clarification as to whether the genotoxicity studies were OECD test guideline compliant and whether internal exposure was assessed (e.g., whether the test substance had reached the bone marrow). If available this information should be included.

37. COT Members recommended a change to the wording of the conclusion in the last paragraph to state that, having reviewed the evidence, the COT did not have a reason to expect adverse effects in humans.

38. A number of additional editorial and structural changes were proposed. Members were asked to send any additional comments to the Secretariat. A second draft statement would be prepared reflecting COT Members' comments for discussion at a future meeting.

Item 6: Statement on the derivation of a health-based guidance value for boron – First Draft (TOX/2025/46)

39. Dr Meera Cush had previously declared a personal specific interest and withdrew from the discussion of this item. No other interests were declared.

40. Following the UK exit from the European Union, the Drinking Water Inspectorate (DWI) was reviewing the regulatory standards for some chemicals in drinking water, including boron. The UKHSA, which advises the DWI on the health risks of chemicals in drinking water, had requested advice from the COT on an appropriate health-based guidance value (HBGV) for boron. This topic was initially discussed at the COT meeting in September 2025 (paper TOX/2025/31). At that meeting, COT Members had requested an updated search for human

epidemiological evidence at exposure levels relevant to drinking water, along with a revised table summarising the evaluations by authoritative bodies. Paper TOX/2025/46 presented these additional materials along with a draft statement.

41. COT Members agreed that the additional human epidemiological data provided useful supporting information alongside the consideration made at the September meeting.

42. The Committee were broadly content with the draft statement and suggested some minor changes including ensuring the description of the 90-day dog study (Weir and Fisher (1972) in Toxicology and Applied Pharmacology, 23(3), pp.351-364). reflected aspects such as age of the animals that raises uncertainty in use of the study. In addition, clarifications were requested with respect to funding statements for the Heindel et al. (1992) (Fundamental and Applied Toxicology, 18(2), pp.266-277) and Price et al. (1996) (Fundamental and Applied Toxicology, 32(2), pp.179-193) studies.

43. COT Members agreed that subject to these minor changes and a few editorial amendments, the statement could be cleared by Chair’s action.

Item 7: Supplementary statement on BPA (TOX/2025/47)

44. No interests were declared.

45. In 2023, EFSA published its final opinion on the re-evaluation of bisphenol A (BPA). This established a tolerable daily intake (TDI) of 0.2 ng BPA/kg bw per day. Exposure assessment indicated that both mean and high-level consumers of all age groups would exceed the TDI by 2-3 orders of magnitude.

46. COT Members had a number of significant reservations about the approach taken by EFSA. They considered it possible that the existing TDI would need to be revised to account for new evidence and to ensure that it was sufficiently protective, but on balance the weight of evidence did not support the conclusions drawn by EFSA or a TDI as low as that established by EFSA.

47. The German Federal Institute for Risk Assessment (BfR) published its own evaluation of BPA in 2023, identifying a TDI that differed from that proposed by EFSA. COT members agreed that, subject to concluding that the approach taken and the scientific assessment of the database were satisfactory, the COT could consider adopting assessments and HBGVs established by other authorities

rather than undertaking a full review of substances such as BPA. In 2024, the COT evaluated the available assessments of BPA.

48. The COT reviewed the EFSA opinion, diverging opinions by the BfR and the European Medical Agency (EMA) and the full assessment by the BfR. Members continued to have significant reservations regarding the approach taken and the HBGV derived by EFSA; in contrast, they considered the BfR approach scientifically robust and more reasonable, though still adequately precautionary. The COT therefore agreed to adopt the BfR TDI in 2024.

49. In order to allow timely risk management, in 2024 COT Members were content to publish a short position statement reflecting their decision to adopt the BfR TDI. They stressed, however, that a detailed supplementary statement providing the scientific basis for this decision and demonstrating that this decision was protective of UK consumers was necessary. The supplementary statement would highlight COT Members' concerns with respect to the EFSA TDI and their review of the relevant studies and approach taken by the BfR, including the modelling and the key studies selected to establish the HBGV. The supplementary statement should also discuss any relevant information published since the BfR assessment; a short literature search on the relevant endpoints should therefore be included.

50. Following the publication of the COT position paper a working group met in October 2024 and December 2024 to discuss the studies/information retrieved from the literature search and determine the outline and (level of) information to be included in the supplementary statement. The supplementary statement presented in paper TOX/2025/47 was the output of the working group and provided the weight of evidence supporting adoption of the TDI set by the BfR.

51. The Chair thanked the working group members for their hard work and expressed her thanks to the Secretariat for the additional literature search and for supporting the working group.

52. COT Members agreed that the supplementary statement accurately reflected the work of the COT on BPA and agreed that no new data changing the conclusions set out in the 2024 position paper had been identified.

53. It was agreed that the statement would be cleared by Chair's action.

Item 8: EFSA Dioxin Consultation (TOX/2025/48)

54. Professor Thorhallur I. Halldorsson was a member of the previous EFSA dioxin working group and an author of the 2018 EFSA opinion; he had not, however, been involved in the preparation of the 2025 EFSA opinion and was therefore free to participate in the discussions. No other interests were declared.

55. Following the publication of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)-derived Toxic Equivalency Factors (TEFs), EFSA had published a draft update to their risk assessment on dioxins and dioxin-like polychlorinated biphenyls (PCBs) for public consultation in December 2025.

56. Previously, when discussing the 2018 opinion, COT Members had agreed with EFSA that fertility was the critical endpoint but had raised concerns over EFSA's use of the Russian Children's Study by Mínguez-Alarcón et al., 2017 (Environmental Health Perspectives, 125, 460-466) to derive a point of departure (POD) for the derivation of a HBGV

57. In their draft update EFSA proposed a tolerable weekly intake (TWI) of 0.6 pg toxic equivalents (TEQ)/kg bw/week, a reduction from 2 pg TEQ/kg bw/week. The new TWI was based on decreased sperm count in rats and not, as previously, on findings of the Russian Children's Study.

58. The terms of reference of the 2025 EFSA assessment, however, stipulated that the assessment should apply to all 29 congeners. As a consequence, EFSA determined that human data could no longer be used as the basis for establishing the TWI. The Russian Children's Study analysed 17 polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/Fs) and 12 dioxin-like polychlorinated biphenyls (DL-PCBs), with a statistically significant inverse association between serum levels of TCDD, PCDD-TEQ, PCDD/F-TEQ and sperm concentrations, but not for PCDF-TEQ, DL-PCB-TEQ or Total-TEQ, expressed using the WHO2022-TEFs. The two Seveso studies (Mocarelli et al., 2008; 2011) lacked information on exposure to congeners other than tetrachlorodibenzo-p-dioxin (TCDD).

59. EFSA, in its 2025 draft Opinion, took its POD from a study in rats (Faqi et al., 1998) (Toxicology and Applied Pharmacology, 150, 383–392), while the human studies were used as supportive evidence and to inform decisions on which uncertainty factors (UF) to apply.

60. Given that the experimental animals (rats) in the Faqi et al. (1998) study were exposed to TCDD only and not to a mixture of congeners, additional clarification of the reasons for changing from human to animal data to derive the

POD and the method used to extrapolate from TCDD to total TEQ would have facilitated interpretation of EFSA's reasoning.

61. In addition, COT members noted that EFSA did not consider other – including more recently published – animal data relevant to its assessment; they advised that, instead of selecting one critical study, derivation of a consensus POD from a number of well-conducted studies would be preferable. A detailed justification of EFSA's decision not to adopt this approach, together with an explanation of the way in which the total evidence was weighed, would have facilitated the COT's evaluation of EFSA's conclusions, especially given the lack of robust scientific evidence to derive a reference point for the derivation of a HBGV for dioxins and dioxin-like PCBs.

62. COT Members noted that it would be useful to understand the basis of the JECFA TEFs and whether they were based on animal data and supported by epidemiological data or vice versa. This would permit a clearer understanding of the 2025 EFSA assessment.

63. Actual exposures to dioxins and dioxin-like PCBS have not changed markedly since the 2018 EFSA opinion; however, the approach to the exposure assessment and the basis on which it is calculated have changed. A more in-depth explanation by EFSA would therefore have been useful to assist in understanding the extrapolation from a POD based on TCDD only to an assessment based on the 2022 JECFA TEFs for all 29 congeners. This was especially pertinent given the different adverse effects of TCDD in humans vs rats.

64. COT Members noted the benchmark dose (BMD) modelling undertaken by EFSA. A preliminary analysis was able to reproduce the Bayesian model-averaging approach. There appeared, however, to be appreciable variability in the results between the current EFSA Bayesian approach, the previous EFSA PROAST version, another version of PROST and the online US Environmental Protection Agency (EPA) BMD software (BMDS) version in the size of PODs/benchmark doses. Changing the benchmark dose response/critical effect size (BMR/CES) from 10% to 15% also resulted in appreciable changes in the PODs/benchmark doses.

65. COT Members therefore decided to check the modelling approaches again. Should the variability in the model results remain, this might raise questions regarding the use of the modelling, given the importance of the POD. COT Members also commented on the need for a more detailed breakdown of the

UFs and how EFSA decided to apply the ones they chose.

66. COT Members would have also liked to have seen more detail on EFSA's recommendation on the inclusion of adverse outcome pathways (AOPs) and, in particular, what work would need to be done.

67. The public consultation closes on 26th January 2026. Members were asked to send any additional comments to the Secretariat by Thursday 22nd January 2026 citing line and section numbers where possible.

Item 9: For Information: COMEAP Statement on airborne nano- and microplastic particles and fibres, and associated Synthesis and Integration of Epidemiological and Toxicological Evidence (SETE) assessment (TOX/2025/49)

68. The following declarations of interest were received: Dr Martin Clift was a Committee on the Medical Effects of Air Pollutants (COMEAP) Member so had contributed to the COMEAP statement and had received research funding to investigate micro- and nano-plastics and their impact on environment and human health; Dr Meera Cush had undertaken consultancy work for clients on micro- and nano-plastics; Professor Shirley Price was a co-author on a review of microplastics for JECFA; and Professor Qasim Chaudry chaired the EFSA working group on particle risk assessment in food and feed, including inhalation exposure via nanoform pesticides, and was a member of the Scientific Committee on Consumer Safety (SCCS) nanomaterials in cosmetic products working group. It was agreed that, because this item was presented for information rather than discussion, these members were welcome to participate in the discussion. No other interests were declared.

69. Dr Alison Gowers and Mr James Isaacs of the COMEAP Secretariat were in attendance for this item.

70. Paper TOX/2025/49 presented work by COMEAP on nano- and microplastic particles and fibres and highlighted links to COT's published work on microplastics for Members' awareness. The paper included COMEAP's assessment using the COT-COC Synthesis and Integration of Epidemiological and Toxicological Evidence (SETE) approach.

71. The COMEAP Secretariat noted that COMEAP had utilised the SETE approach not to consider the potential for nano- and micro-plastics to cause health impacts, but rather to assess the potential for population risk from environmental exposure. The axes of the SETE chart had been amended accordingly. This was considered by COMEAP to be more useful to represent the evidence base to its audiences.

72. The Committee had no specific comments, but the materials were welcomed as useful information.

Item 10: Update on the work of other FSA Scientific Advisory Committees - for information (TOX/2025/50)

69. This item is for information, but if Members have any questions, they were advised that they could contact the Secretariat.

Item 11: Any other business

70. There was no other business.

Date of next meeting

71. The next meeting of the Committee will be at 10:00 on Tuesday 3rd February 2026 via Microsoft Teams.