Minutes

# Draft Minutes of the 9th September 2025 COT Meeting

**Minutes of the meeting of the Committee at 10:00am on the 9th September 2025 via Microsoft Teams.**

## Present

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

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| | Professor Gary Hutchison |
| COT Members: | Professor Thorhallur Ingi Halldórsson (until Item 8) |
| | Dr David Lovell |
| | Professor Shirley Price (Deputy Chair) |
| | Dr Cheryl Scudamore (from Item 4) |
| | Professor Mireille Toledano (from Item 4) |
| | Dr Simon Wilkinson |
| | Dr Steven Enoch (from Item 5) |
| | Professor Peter Barlow |
| | Dr Chris Morris |
| | Dr Meera Cush (left the meeting for Item 5) |
| | Mr Gordon Burton |
| | Dr Andreas Kolb |
| | Dr Alison Yeates |
| | Mr Nick Richardson |
| | Dr Bryony Ross |
| | Dr Michelle Bellingham |
| | Professor Martin Clift |
| | Professor Mohammad Qasim Chaudhry |
| | Dr Tarek Abdelghany |
| | Ms Christel Wake |
| | Dr Antonio Peña Fernández |

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| Science Council: | Ms Jackie Healing |

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| Secretariat: Food Standards Agency (FSA) | Ms Cath Mulholland - FSA Scientific Secretary |
| | Dr Tahmina Khan |
| | Dr Alex Cooper |
| | Mr Barry Maycock |
| | Ms Claire Potter |
| | 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 |
| | Dr Gaetana Spedalieri |
| | Mr Thomas Hornsby |
| | Dr Emily Hudson |
| | Dr Aaron Bradshaw |
| | Dr Katie Schulz |
| | Ms Katie Wetherall |
| | Ms Rachel Jones |
| | Mr James Metcalfe |
| | Ms Yoana Petrova |
| | Ms Polly Bevan |
| | Mr Andy Axon |
| | Ms Abigail Smith |
| | Ms Alba Ureña Rusillo |

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| Secretariat: UKHSA - UK Health Security Agency | Ms Britta Gadeberg<br>Ms Sanyukta Pallavi |
| Assessors: Office of Health Improvement and Disparities (OHID) | Ms Rachel Elsom |
| UK Health Security Agency (UKHSA) | Dr Ovnair Sepai - Item 5<br>Ms Helen Hunt |
| Assessors: Department for Environment, Food and Rural Affairs (DEFRA) | Mr Leon Jackson |
| Assessors: DBT- Department of Business and Trade | Ms Frances Hill |
| Assessors:  Environment Agency (EA) | Mr Ian Martin |
| Invited experts: Bibra | Dr Daniel Threlfall<br>Ms Ese Hughes |
| FSA Officials: Food Standards Agency (FSA) | Will Smith (item 9 onwards)<br>Ms Lauren Murdie |
| FSA Officials: Food Standards Northern Ireland | Ms Catherine Hardy |
| FSA Officials: Food Standards Scotland (FSS) | Ms Krystle Boss |
| Officials from other Government Departments: UK Health Security Agency (UKHSA) | Mr Shan Zhao<br>Ms Helen Hunt<br>Oladipo Idowu (Items 5 and item 7)<br>Ms Gopika Chettuvatty - Presenting<br>Mr Stephen Robjohns - Presenting |

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| External Observers: | Dr Stephen Ruckman (Principal, Sagentia Regulatory Consultant; (Item 4 onwards)<br><br>Dr Sarah Bull, Drinking Water Quality Advisory Group (Item 5) |

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# Announcements

1. COT Members were informed that the FSA's Chief Scientific Advisor, Professor Robin May, would be stepping down in September to take up a role at the UKHSA. COT Members expressed their thanks for his support and wished him well in the future.

# 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, Professor Philippe Wilson and Dr Aravindan Veiraiah and Ms Minako Allen (Health and Safety Executive Assessor).

# Item 2: Minutes of the meeting held on the Tuesday 15th July 2025 (TOX/MIN/2025/04)

4. The Committee reviewed the draft minutes and reserved minutes of the meeting held on the 15th of July 2025. These were accepted as an accurate

record.

# Item 3: Matters arising

## Joint Expert Group (JEG) updates

### AEJEG

5. The most recent meeting of the main Additives, Enzymes and other Regulated Products Joint Expert Group (AEJEG) was held on 17th of July 2025 and one item was presented. This was a cover paper for an application on the modification of specifications for enzymatically produced steviol glycosides as a food additive to include Rebaudioside E (RP2120). It was agreed by the AEJEG that a request for further information (RFI) would be sent to the Applicant.

6. The next main AEJEG meeting would take place on 11th September 2025.

### FCMJEG

7. The most recent meeting of the Food Contact Materials JEG (FCMJEG) was held on the 27th of August 2025. The FCMJEG reviewed a novel recycling technology application for the competent authority auditing process and a draft Committee Advice Document (CAD) for a plastic additive (RP2147 chopped carbon fibre). The FCMJEG also reviewed additional data received regarding a plastic additive application on Agar Palmitate (RP2263). FCMJEG Members agreed to request a further clarification from the applicant on the data provided.

8. The FCMJEG discussed a guidance document prepared by the Waste and Resources Action Programme (WRAP) for evaluating the performance of polyolefin decontamination processes; feedback would be collected by the FCMJEG Secretariat and relayed back to industry. The industry guidance document would be circulated to the COT for review once available.

9. Of the FCMJEG’s current applications, one is at the suitability assessment stage, four are undergoing assessment and one is near finalisation; work on the recycled plastics audit is also continuing.

10. The next FCMJEG meeting was scheduled to take place on 1st of October 2025.

## Subgroups and working groups (WG)

### COT Guidance WG

11. The COT Members were informed that the first full meeting of the COT Guidance WG was scheduled for the 19th of September 2025, following an earlier mapping session. The Committee thanked the Members who have kindly agreed to support this work

### ACNFP/COT working group on CBD

12. COT Members were informed that, although the Advisory Committee on Novel Foods and Processes (ACNFP)/COT working group on Cannabidiol (CBD) had concluded its initial programme of work earlier in 2025, some *ad hoc* work had continued during the summer. The Chair thanked the COT Members who participated.

### PFAS Working Group

13. The PFAS Working Group had not met since 2024 due to the end of the contract with their contractor and a subsequent change of provider. However, the new contractor (Bibra) had now started work and it was hoped that the next WG meeting would be held either later in 2025 or early 2026. Future topics to be discussed included reproductive and developmental toxicity.

## Update from COC

14. COT Members discussed the Committee on the Carcinogenicity of Chemicals in Food, Consumer Products and the Environment's (COC) new guidance statement:

A case for change: the challenge to develop a better approach to assessing risk of cancer caused by chemicals - GOV.UK, a call for proposals on improving the assessment of chemicals for carcinogenicity. COT Members were content with the COC report.

15. The Chairs of COT and COC had met to discuss future collaborations. It was hoped that a new COC Chair would be appointed in March 2026. Future liaison would likely be with the new COC Chair.

# COT Workshop

16. Speakers for the October COT Workshop had now been confirmed, and Members were invited to submit any suggestions for round table questions or topics by the 19th of September.

## Publications

17. Members were informed that the Joint SACN COT WG report on plant-based drinks was published on the 16th of July. There was some media coverage of the report, but this largely focussed on nutritional aspects such as equivalence to cows' milk. In general, the feedback from the media was broadly positive.

# Item 4: Mercury in the maternal diet – second draft statement (TOX/2025/30)

18. No interests were declared.

19. For the benefit of new COT Members, the Secretariat provided a brief background to the COT's work on chemicals in the maternal diet. This was a long-standing programme of work initiated a few years ago by the UK Department of Health and Social Care (DHSC) as part of their review of guidance to pregnant women. DHSC asked the Scientific Advisory Committee on Nutrition (SACN) to conduct a risk assessment on the maternal diet. In turn, SACN requested that COT evaluate chemicals of potential toxicological concern for pregnant women; these included both contaminants and naturally occurring constituents. Following the COT's consideration of several scoping papers, a preliminary list of chemicals for review was assembled, noting that this could be amended as needed (for example, tea and liquorice had been added to the initial list). Some of these substances would have a detailed review and their own statement, whilst others would need a lighter touch review and be grouped together in an overarching statement containing a detailed introduction. Cross-cutting topics such as pica behaviour would also be considered. The Secretariat was currently working to standardise the papers, and include a common annex with background information and a representation of the programme's timelines. This annex would be presented to Members at a future COT meeting. The Secretariat added that the programme was expected to be completed within the next few years, although this timeline would be affected by the addition of further chemicals to the list.

20. The first draft statement on the effects of mercury on maternal health was presented to the Committee (TOX/2025/22) at the May 2025 COT meeting. Overall, COT Members had been content with the risk characterisation and conclusions of the statement but had some comments on the structure and content of the Absorption, Distribution, Metabolism and Excretion (ADME), Toxicity and Derivation of health-based guidance value (HBGV) sections.

21. To address these comments, additional primary literature had been included and to improve the flow and clarity of the document, the statement's structure amended to separate out the discussion on inorganic mercury and methylmercury and their respective effects on adults, children and laboratory animals. It was also made clearer which text in the section on the Derivation of the health-based guidance value (HBGV) reflected the opinions of other authorities and, the primary evidence their opinions were based upon.

22. Additional changes had been made to the exposure assessment section to clarify pica behaviour as an uncertainty in the exposure assessment and to note the known under-estimation of energy intake in the National Diet and Nutrition Survey (NDNS) data.

23. COT Members were asked for their overall comments on the scientific content of the statement and asked to send minor editorial comments to the Secretariat by the 19$^{th}$ September.

24. COT Members agreed that the terms "mercuric" and "mercurous" in relation to mercury should be defined in the paper and added to the glossary.

25. COT Members recommended replacing the term "heavy metals" as this was not scientifically accurate. A more appropriate term would be "metals and metalloids" or "trace elements."

26. COT Members noted that it was difficult to compare doses between animal studies as some authors reported the concentration in the diet but did not provide the dose on a per kg bodyweight basis in the animals. However, COT Members advised against estimating the dose using default intake values as this would introduce additional uncertainty to the assessment; only the information that authors had reported should be quoted in the statement. A recommendation could be added to the conclusions section of the statement for researchers to always estimate consumption in mg/kg bodyweight/day to allow for comparison between studies. The COT guidance WG was invited to consider including this in the Committee's updated guidance.

27. COT Members were informed that the FSA Exposure Assessment Team had identified some additional uncertainties with respect to the exposure assessment. These were identified after preparation of the draft statement and related to whether information from the Total Diet Survey (TDS) adequately captured potential mercury exposure from large, predatory fish. This would not affect the exposure assessment as set out in the statement but needed to be captured in the uncertainties section. Members were content to add this point to the draft statement.

28. It was noted that canned tuna tends to contain lower levels of mercury and dioxins than fresh tuna as the less valuable, smaller tuna were normally canned.

29. An expert Member agreed to collaborate with the Secretariat to review the papers referenced in paragraph 28 of the draft statement and revise the wording to reflect that mercury can cross the placental barrier, although current evidence may be insufficient to determine the extent to which this occurs.

30. Overall, the Committee agreed that the statement was clear. Only minor editorial changes were required. COT Members agreed that the statement could be finalised by Chair's action.

## Item 5: Deriving a health-based guidance value for boron to support development of UK Drinking Water Standards (TOX/2025/31)

31. Dr Meera Cush declared a personal specific interest which was determined to represent a potential conflict; Dr Cush therefore withdrew from the meeting whilst this item was considered.

32. As part of a Drinking Water Inspectorate (DWI) post-EU exit review of regulatory standards for certain chemicals in drinking water, the UKHSA, which advises the DWI on the health risks of chemicals in drinking water, requested advice from the COT with respect to an appropriate health-based guidance value (HBGV) for boron. Paper TOX/2025/31 summarized the available toxicity studies on boron and the evaluations of various authoritative bodies.

33. The COT last reviewed the available toxicity data on boron and boric acid in 1994 and 1995 (COT, 1995). It determined a No Observed Adverse Effect Level (NOAEL) of 9.6 milligrams per kilogram body weight per day (mg/kg bw/day)

– rounded up to 10 mg/kg bw/day – for reduced fetal weight and skeletal effects in rats. These were identified as the critical adverse effects in developmental studies. A total default uncertainty factor of 100 was applied to give a Tolerable Daily Intake (TDI) of 0.1 mg/kg bw/day.

34. COT Members noted that most of the published oral toxicity data on the effects of boron in laboratory animals dated back to the 1970s to 1990s. There was very little relevant human or epidemiological data. One Member highlighted that a study conducted in Turkey (Col & Col, Food and Chemical Toxicology 41, pp.1417-1420, 2003) had reported no obvious adverse effects in humans following relatively high environmental exposure to boron.

35. COT Members discussed the oral repeat dose toxicity study in dogs reported by Weir and Fisher in 1972 (Toxicology and Applied Pharmacology, 23, pp.351-364) which was used by Health Canada (Health Canada, 2023) to derive its health based guidance value for boron. The 1960s Borax Research Corporation data cited in the discussion paper and by Health Canada were not publicly available to access and thus could not be further evaluated, while concerns were raised with respect to the Weir and Fisher 1972 paper. Lack of information on the age of the dogs used in this study impaired the interpretation of the reported atrophy of the testes because the testicular epithelium could be incompletely developed in immature dogs and this can be difficult to distinguish from testicular atrophy. Additionally, the small group sizes in this study – approximately four, and at the highest dose only two, dogs per group – limited its value for benchmark dose modelling. Overall, the dog oral toxicity study was considered inadequate and unsuitable for identifying a point of departure (POD).

36. COT Members considered that the developmental toxicity study in rats by Price et al. (Fundamental and Applied Toxicology, 32, pp.179-193, 1996) was a good and well conducted study. It identified a NOAEL of 9.6 mg/kg bw/day for reduced fetal body weight and skeletal malformations.

37. In general, toxicity data were consistent across the available studies and species in identifying reduced fetal body weight, adverse effects in the testes and developmental malformations (e.g., skeletal malformations). COT Members also noted several later research studies (Chapin et al 1997, Yoshizaki et al 1999 and Sabuncuoglu et al 2006) which, while not conducted according to conventional toxicity study protocols, reported NOAELs which were broadly consistent at approximately 10.0 mg B/kg bw/day, as far as could be determined.

38. There was a broad consensus among authoritative bodies on using the Price et al study published in 1996 as the basis for the POD (ECETOC, 1995; EFSA, 2013; EVM, 2003; WHO, 2009). Some authoritative organizations had used benchmark dose (BMD) modelling of the Price at al., (1996) study data. COT Members noted that changes in BMD modelling approaches since the mid-1990s had made little difference to the resultant BMDL, which usually coincided closely with the study NOAEL. A dose of 10.0 mg B/kg bw/day was identified as an appropriate POD, consistent with the COT's previous assessment in 1995.

39. It was noted that several authoritative bodies had applied an uncertainty factor of approximately 60 in deriving a HBGV for boron; COT Members, however, did not identify any reason to depart from the default uncertainty factor of 100. This would encompass the severity of the toxicity endpoints (reduced fetal weight and skeletal malformations), reflect the uncertainty of extrapolating from animal to humans, and allow for differences in blood concentrations of boron following similar intakes of boron from different boron compounds. Applying a total uncertainty factor of 100 to the selected POD of 10.0 mg/kg bw/day would result in a TDI of 0.1 mg/kg bw/day.

40. It was agreed that a statement would be prepared for discussion at a future meeting. COT Members also requested a literature search to check whether there were any human epidemiological studies with exposures similar to those occurring from drinking water.

## Item 6: Citrinin in the maternal diet - second draft statement (TOX/2025/32)

41. As part of its work on the maternal diet, SACN is reviewing the scientific evidence that supports the Government's dietary recommendations. As part of this, SACN have requested that COT review the risks of toxicity from chemicals in the maternal diet, including the mycotoxin citrinin.

42. The potential risk from citrinin in the maternal diet was discussed by the COT in October 2024. It was concluded that citrinin would not have adverse effects on maternal health at levels of exposure likely in the UK.

43. The draft statement sets out the advice of the COT on whether exposure to citrinin would pose a risk to maternal health. It builds on the initial COT discussion paper (TOX/2024/39) which drew on the EFSA opinion from 2012, where appropriate, as well as studies published since 2012.

44. The first draft statement was considered at the July 2025 COT meeting. In response to comments from COT Members, the statement was restructured, additional uncertainties in the assessment were highlighted and additional detail was added to the descriptions of the studies, where applicable. In addition, a separate uncertainties section was added.

45. COT Members had requested that details of the risk assessment carried out by the National Institute for Public Health and Environment (RIVM) and commissioned by the Netherlands Food and Consumer Product Safety Authority (NVWA) be included in the statement. In addition, the Secretariat contacted RIVM to request further details on a biomonitoring study which was referred to in the risk assessment. RIVM had intended to use this to compare the level of citrinin determined in the Dutch total Diet Study (TDS) to urinary levels of citrinin in the Dutch population; however, RIVM responded to confirm that this study had not been carried out and so this has not been included in the statement.

46. COT Members discussed the second draft statement presented in TOX/2025/32.

47. COT Members noted that some information was missing from the paragraph describing the Lee et al. (2010) study. The species used, length/duration of the study and the route of administration should be added to the document.

48. COT Members requested that the conclusions state that citrinin is nephrotoxic rather than acutely nephrotoxic.

49. It was noted that where the statement referred to the benchmark lowest dose (BMDL) it should be changed to the lower 95% confidence bound of the BMDL (BMDL5) in the document to better reflect the methods used.

50. COT Members suggested a number of additional minor editorial changes to the document. It was agreed that the statement could be finalised by Chair's action.

# Item 7: EFSA Draft opinion on $\Delta^8$ THC – Derivation of a Health Based Guidance Value (TOX/2025/33)

51. No interests were declared.

52. The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) was asked by the European Commission (EC) to review the existing scientific evidence and all new relevant studies on $\Delta^8$ -tetrahydrocannabinol ($\Delta^8$-THC) and provide a scientific opinion on deriving a Health-Based Guidance Value (HBGV) for $\Delta^8$-THC in food. The Panel was also asked to assess the occurrence of $\Delta^8$-THC in food, consider co-occurrence with $\Delta^9$ -tetrahydrocannabinol ($\Delta^9$-THC) and evaluate the available toxicological and pharmacological data on $\Delta^8$-THC.

53. EFSA launched a public consultation on the “Derivation of a health-based guidance value for $\Delta^8$-THC and its occurrence in food” on 31st July 2025. COT Members were asked to review the draft opinion and provided comments to be submitted to the EFSA consultation.

54. COT Members noted that the EFSA document presented more evidence relating to $\Delta^9$-THC than $\Delta^8$-THC; this was not the stated aim of the evaluation.

55. COT Members were reminded that the joint Advisory Committee on Novel Foods and Processes (ACNFP) and COT WG had previously considered $\Delta^9$-THC and its precursors as contaminants in hemp-derived products, including Cannabidiol (CBD) novel foods. A joint position paper had been published, establishing a safe upper limit of 1 µg/kg bw/day for $\Delta^9$-THC and its precursors (Advisory Committee on Novel Foods and Processes & Committee on Toxicity, 2025. “Joint position paper on establishing a Safe Upper Limit for delta-9-tetrahydrocannabinol (Δ9-THC) and its precursor as contaminants of hemp-derived products including CBD novel foods”). It was noted that the EFSA draft opinion considered both $\Delta^9$-THC and $\Delta^8$-THC in the derivation of the HBGV, whereas the joint ACNFP/COT paper had focused solely on $\Delta^9$-THC and its precursors. COT Members noted that taking a similar approach could potentially require reconsideration of the HBGV for $\Delta^9$-THC to include $\Delta^8$-THC.

56. COT Members noted the absence of references to UK assessments. For context, the joint ACNFP/COT position paper had endorsed the EFSA Acute Reference Dose (ARfD) value of 1 µg/kg bw/day but had specified that this included both $\Delta^9$-THC and $\Delta^9$-tetrahydrocannabinol acid ($\Delta^9$-THCA). Additionally, the Advisory Council on the Misuse of Drugs (ACMD) had recommended that the dose of each controlled phytocannabinoid should not exceed 50 micrograms per unit of consumption, including total $\Delta^9$-THC and $\Delta^9$-THCA (Home Office (2023) “Government response to the ACMD’s advice on consumer cannabidiol ( CBD) products”. London: GOV.UK.).

57. Concerns were raised about the absence of robust and accurate detection methods for $\Delta^8$-THC; there is a particular lack on methods with low limits of detection and quantification. COT Members noted that this limitation undermined the reliability of exposure and occurrence data, especially given the difficulty in distinguishing between $\Delta^8$-THC and other cannabinoids and precursors. COT Members also noted the challenge of distinguishing between the pharmacological effects of $\Delta^8$-THC and $\Delta^9$-THC within complex mixtures.

58. COT Members highlighted significant data gaps regarding the pharmacokinetics of $\Delta^8$-THC, particularly with respect to its metabolism and the potential accumulation of metabolites due to their lipophilic nature; these gaps should be considered when evaluating uptake via the food matrix.

59. The bioavailability of $\Delta^8$-THC and $\Delta^9$-THC was discussed. The draft EFSA opinion stated that there were no major differences in the toxicokinetics between the two compounds. However, COT Members concluded that there was insufficient evidence to determine whether the disposition of $\Delta^8$-THC differed from that of $\Delta^9$-THC due to the lack of human bioavailability studies. It was further noted that if $\Delta^8$-THC was present in a food matrix, particularly a fatty food, its absorption could be significantly increased.

60. It was noted that the potency factor estimate was based on limited data from a single human study involving 19 healthy adults and that, while $\Delta^8$-THC appeared slightly less potent than $\Delta^9$-THC, the relative potencies were essentially unknown. COT Members identified an error in the summary paper, which had stated that the relative potency of $\Delta^8$-THC to $\Delta^9$-THC was very likely within the range of 1 to 1.6 (90–95% certainty). The EFSA opinion had instead reported a point estimate for **$\Delta^9$-THC to $\Delta^8$-THC** of 1 to 1.4, with 95% confidence intervals of 1 to 1.6.

61. COT Members discussed the parameters used by the Panel to derive the ARfD, which was now described as applicable to the sum of $\Delta^9$-THC and $\Delta^8$-THC. This grouping did not include precursors (such as $\Delta^9$-THCA) or other cannabinoid compounds that may arise. It was noted that the inclusion of $\Delta^8$-THC in the group ARfD implied a lowering of the $\Delta^9$-THC ARfD.

62. COT Members considered that the Lowest Observed Adverse Effect Level (LOAEL) of 2.5 mg/kg for $\Delta^9$-THC identified by the Panel and used to set the HBCV was potentially too high, and that additional studies had suggested a lower threshold. It was recommended to provide a comment to EFSA that dose-ranging studies be conducted to establish more accurate LOAELs for $\Delta^8$-THC and $\Delta^9$-THC

separately.

63. Evidence of reproductive and developmental toxicity in both males and females was discussed. COT Members noted that this area had been insufficiently explored and should be highlighted as a concern, particularly given the evidence in animal studies that $\Delta^8$-THC may show greater potency in females. This was an important data gap.

64. Concerns were also raised regarding potential drug interactions, specifically due to Cytochrome P450 (CYP)-mediated oxidation of $\Delta^8$-THC. COT Members noted that individuals taking medication may be at increased risk and should be considered a vulnerable population in future evaluations.

65. COT Members supported the recommendations made by the EFSA CONTAM Panel and agreed that these would be valuable for future investigations into $\Delta^8$-THC. However, it was concluded that the current evidence base was insufficient to confidently establish an ARfD for $\Delta^8$-THC.

66. COT Members agreed that the final opinion should be reviewed once available.

67. COT Members were asked to send any additional comments to the Secretariat. These would be collated and fed back to EFSA via the public consultation process.

# Item 8: EFSA Draft scientific opinion on the evaluation of the safety of preparations from the fruits of sweet and bitter fennel (TOX/2025/34)

68. No interests were declared.

69. The EFSA Panel on Nutrition, Novel Foods and Food Allergens was asked by the EC to assess the safety of preparations derived from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C.Presl). The EC request followed safety concerns raised by the German Federal Institute for Risk Assessment (BfR) in relation to possible adverse effects associated with the consumption of fennel fruit preparations by infants and young children due to the presence of estragole, a known genotoxic carcinogen.

70. COT Members were asked to review and provide comments on the draft EFSA opinion on the safety of fennel fruit preparations. The Secretariat would then submit the Committee's comments to the EFSA consultation.

71. Overall, COT Members concluded that the draft opinion contained all the relevant information; however, the structure of the opinion could be clearer, and some sections would have benefitted from more information and clarification.

72. It was noted that it was difficult to distinguish between the compounds originating from fennel and those from other dietary components and that the dietary habits of different EU populations had a significant influence on the assessment. There was, therefore, significant uncertainty in what other dietary habits would influence exposure to genotoxic *p*-allylalkoxybenzenes; it would be useful to see this aspect discussed in more detail.

73. COT Members highlighted that variation in the diet of different ethnic groups was another exposure scenario that could influence fennel exposure; however, this was considered out of scope by EFSA, whose assessment focused exclusively on herbal infusions/tea.

74. COT Members discussed to what extent fennel consumption/exposure would be relevant to the UK population. Overall, consumption of fennel tea/infusions is not as common in the UK as in other European countries. While there may be pockets of higher exposure among the population, general consumption is probably low.

75. EFSA's margin of exposure estimations were generally high, which was reassuring, however, they were less than 10,000 in some population groups.

76. COT Members noted that some fennel products were marketed to pregnant women as galactagogues (lactation inducers) for breastfeeding and as a 'safer' alternative to caffeine. Fennel infusions/tea were also generally marketed as aids to digestion. It was highlighted that there was also NHS advice on the use of herbal teas and fennel consumption for pregnant women in the UK.

77. It was agreed that the provision of additional information on the chemistry of estragole, methyleugenol, safrole and other *p*-allylalkoxybenzenes would be useful in linking their structures and toxicological effects. The literature contains little data on estragole, the main component of interest; data on similar compounds was therefore used to develop the EFSA opinion. COT Members recommended the use of formal read-across techniques to investigate the relationship between structure and mechanism of action among the *p*-

allylalkoxybenzenes.

78. It was observed that the draft opinion did not identify any epidemiological evidence linking consumption of fennel fruit preparations to a higher mutagenicity rate in populations. The risk of harm in vulnerable groups with higher consumption of fennel fruit preparations remained uncertain.

79. COT Members highlighted that the EFSA opinion's discussion of the influence of potential interindividual variability on metabolism could be strengthened. The draft opinion provides some information on pharmacogenetic variation and possible CYP-mediated effects, but additional information on potential pharmacogenetic variation in estragole metabolism and estragole-food/estragole-drug and possibly estragole-ethanol interactions due to induction or inhibition of CYPs would also be beneficial.

80. Given the lack of available information, COT Members were not confident that taking the BMDL for methyleugenol as a reference for the whole *p*-allylalkoxybenzenes group was the most scientifically robust approach for a risk assessment of fennel and would have liked to have seen a broader discussion and/or consideration of other studies/BMDLs.

81. COT Members were asked to send any additional comments to the Secretariat. These would be collated and fed back to EFSA via the public consultation process.

# Item 9: EFSA Draft opinion on risks to human health from lectins in food (TOX/2025/35)

82. No interests were declared.

83. The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) was asked by the European Commission (EC) to assess the risk of plant lectins within the diet. This followed a statement from the BfR which highlighted the potential allergy risk of lectin consumption.

84. COT Members were asked to consider the EFSA CONTAM Panel's draft statement on the risk of plant lectins in the diet. Feedback would be submitted to EFSA as part of their consultation process.

85. COT Members agreed that the EFSA draft opinion was detailed and highlighted several areas of importance including potential autoimmune and

allergenic effects of lectins.  A number of data gaps were, however, identified.

86. The draft EFSA opinion correctly noted the limited number of human studies available in terms of exposure to purified and non-purified lectins and recognised that the studies were not quantitative and that there was a lack of relevant controls.

87. COT Members highlighted that the Panel’s exposure assessment and risk characterisation focussed mainly on Phytohaemagglutinin (PHA) because this was the lectin that was considered to be the most toxic.

88. It was agreed that clarification of EFSA's discussion of correct and incorrect processing would be of benefit for consumers and other readers. Differences in cooking – one kind of processing method – can greatly affect lectin levels within foods. For example, the reviewed studies suggested that if raw beans, specifically of the *Phaseolus sp.,* were not adequately cooked, gastrointestinal issues were exacerbated because the lectins were not denatured.

89. COT Members agreed that, based on the current scientific data, there was not enough information to derive a health-based guidance value. They therefore agreed with the Margin of Exposure (MoE) approach used by the Panel to determine the risk associated with exposure to lectins in food. The Panel concluded that an MOE of >100 would not raise a health concern and that if beans such as kidney beans were cooked properly there was no appreciable risk. However, if the exposure assessment assumed that 50% of the lectins remain active in food matrixes, this resulted in an MOE of 0.3, which COT Members noted was highly unusual for a commonly consumed food product. COT Members agreed that further clarification on the derivation of the 50% value was needed.

90. It was further noted that, absorption of lectins was low, and while a high percentage of lectins remain unchanged following digestion, there was a paucity on data on the fate of lectins that had been absorbed. While adverse effects were associated with intact lectins in the gastrointestinal tract, it was commented that lectins which were absorbed may be broken down into peptides and may induce an allergic reaction.

91. COT Members suggested that, due to the number of reported adverse gastrointestinal effects, the EFSA Panel should consider the effect(s) of plant lectins on the gut microbiome. They further suggested that the exposure assessment should also consider vulnerable population groups such as those with irritable bowel syndrome (IBS), Crohn’s disease, ulcerative colitis and coeliac

disease.

92. The COT agreed with the Panel’s recommendations for further work.

93. COT Members were asked to send any additional comments to the Secretariat. These would be collated and fed back to EFSA via the public consultation process.

## Item 10: Update on the work of other FSA Scientific Advisory Committees - for information (TOX/2025/36)

94. This paper is provided for information, but Members can contact the Secretariat for further information if needed.

## Item 11: AOB

95. There was no other business.

## Date of next meeting

96. The next meeting of the Committee will be at 11:00 on Tuesday 21st October 2025 at Broadway House, London and via Microsoft Teams. The COT workshop on artificial intelligence (AI) will be held on the 22nd of October 2025 at Broadway House and online via Microsoft Teams.

**Secretariat**

**September 2025**