Minutes

Draft Minutes of the 15th July 2025 COT Meeting

Minutes of the meeting of the Committee at 10:00am on the 15th July 2025 via Microsoft Teams.

Present

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

COT Members:	Professor Thorhallur Ingi Halldórsson
	Dr David Lovell
	Dr Cheryl Scudamore
	Professor Mireille Toledano (Item 4 onwards)
	Dr Simon Wilkinson
	Professor Philippe Wilson (Item 3 onwards)
	Dr Steven Enoch
	Professor Peter Barlow
	Dr Chris Morris
	Dr Meera Cush
	Mr Gordon Burton
	Dr Andreas Kolb
	Mr Nick Richardson
	Dr Bryony Ross
	Dr Michelle Bellingham
	Professor Martin Clift
	Dr Aravindan Veiraiah
	Professor Mohammad Qasim Chaudhry (until Item 6)
	Dr Tarek Abdelghany
	Ms Christel Wake
	Dr Antonio Peña Fernández
	(Items 3 & 4 and Item 6 onwards).

SACN Liaison:	Professor Ken Ong (absent during item 4)
Science Council:	Ms Jacqueline Healing Mr Tom Oliver

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

Secretariat: Food Standards Agency (FSA)

Ms Sophy Orphanos

Dr Gaetana Spedalieri

Mr Thomas Hornsby

Dr Emily Hudson

Ms Natasha Adams

Dr Katie Schulz

Ms Katie Wetherall

Ms Rachel Kerr

Mr James Metcalfe

Ms Yoana Petrova

Ms Polly Bevan

Mr Andy Axon

Ms Abigail Smith

Ms Alba Ureña Rusillo

Secretariat: UKHSA - UK Health Security Agency	Ms Britta Gadeberg Ms Sanyukta Pallavi
UKHSA Contractor – bibra	Richard Young - Presenting Pete Watts - Presenting Beth O'Connell - Presenting/ Observing Chris Waine – Presenting/ Observing Daniel Threlfall- Presenting
Assessor: Health Improvement Directorate, Global and Public Health Group. Department of Health and Social Care (DHSC)	Ms Neeve Pearce - Item 6
Assessor: Department for Business and Trade (DBT)	Ms Hannah Jones
Assessor: Medicines and Healthcare Products Regulatory Agency (MHRA)	Ms Akosua Adjei
FSA Officials:	Mr Craig Jones – Item 5
Officials from other Government Departments:	Ms Krystle Boss, Mr Lorcan Browne - FSS – Food Standards Scotland (Item 5)
Observers:	Stephen Ruckman -Sagentia Regulatory (item 5 onwards) Dr Helen Crawley -The Lizzie Vann Foundation (Item 5 onwards)

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Announcements

1. The Committee congratulated Professor Shirley Price on being awarded a well-deserved OBE in the recent King's birthday honours.

2. New co-opted Member Ms Christel Wake and new Associate Member Dr Antonio Peña Fernández briefly introduced themselves to the Committee as they had been unable to do so at the May 2025 meeting.

3. Following the recent retirement of Professor Paul Haggarty from the Scientific Advisory Committee for Nutrition (SACN), Professor Ken Ong was in attendance as SACN Liaison.

Interests

4. 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

5. Apologies were received from COT Members: Professor Gary Hutchison and Dr Alison Yeates. Apologies were also received from Dr Minako Takamiya Allen (Health and Safety Executive) and Mr Ian Martin (Environment Agency).

Item 2: Minutes of the meeting held on the Tuesday 20th May 2025 (TOX/MIN/2025/03)

6. The Committee reviewed the draft minutes and reserved minutes of the 20th of May 2025 meeting. The minutes and reserved minutes were accepted as an accurate record.

Item 3: Matters arising

7. Members were updated on the progress of the Joint Expert Groups (JEGs) with regards to the progress of regulated produce applications; a summary

table of current applications would be saved with the meeting papers in the Members' area folder for the July 2025 meeting.

Additives, Enzymes and other Regulated Products JEG (AEJEG)

8. The last standard AEJEG meeting was held on the 4th of June 2025. The COT was informed that two applications had been discussed, RP733 and RP1765. Within the meeting, AEJEG Members had concluded that further information would be required regarding RP733 and that a request for information (RFI) would be sent to the Applicant. An update paper on RP1765 had been presented and the AEJEG had agreed further information would be required and that an RFI would be issued to the Applicant.

Food Contact Materials JEG (FCMJEG)

9. The COT was informed that the previous FCMJEG meeting was held in May 2025, as the June meeting was cancelled. During the May meeting, the FCMJEG reviewed two polypropylene recycling process applications, for which the FSA is the competent authority. Members of the FCMJEG had highlighted areas where clarification and additional information were required, and it was agreed that this information would be requested via an RFI. The FCMJEG was presented with RFI responses on an ongoing plastic additive application and additional information on a recycling process application. The FCMJEG agreed that the additional information on the recycling process was sufficient and a CAD would be prepared by the FCMJEG Secretariat. However, Members of the FCMJEG had agreed that further points of clarification were required on the plastic additive application. It was agreed that that this additional information would be requested via an RFI.

10. The COT were informed that the next FCMJEG meeting would be held on the 27th of August and would focus on two novel technology recycling process applications.

Smoke Flavours

11. COT Members were updated on the reauthorisation of Smoke Flavours. This matter is currently being treated as reserved.

UKHSA Contract

12. An introductory presentation was given to COT Members by bibra Toxicology Advice and Consulting Limited, an external contractor who would be providing Secretariat support to the UKHSA.

COT guidance working group

13. COT Members were reminded that Dr Mac Provan had stepped down from the COT and the Guidance Working Group (WG). Given the already small size of the WG, the Secretariat and current Members were keen to expand its Membership. The Secretariat thanked everyone who had already volunteered and invited other COT Members who might be interested to contact them. The most recent COT discussions on updating the guidance were covered in TOX/2024/46. The first phase of the work would be to develop the overarching principles underpinning the guidance.

14. COT Members agreed that, due to other commitments, it might not be possible for some individuals to join the WG as permanent Members. Such individuals could be involved in discrete sections within their areas of expertise.

15. It was hoped that a meeting of this Working Group would be scheduled in the near future.

Plant-based drinks working group

16. COT Members were informed that the joint SACN/COT report on the benefit- risk assessment of plant-based drinks would be published on the 16th of July.

Publications

17. COT Members were informed that the FSA had recently published a rapid risk assessment on glycerol in slushed ice drinks.

Calcidiol

18. COT Members were informed that the group of rapporteurs had met with the Secretariat and a representative from SACN to discuss how to take forward the paper on calcidiol in the maternal diet. The group recommended that the COT should develop an overview of calcidiol in the maternal diet, taking into account naturally- occurring calcidiol that is consumed in the diet or formed within the body as a result of metabolism as well as calcidiol taken in supplement

form. This would be presented in the form of a brief position paper which clearly signposted all the previous COT work on vitamin D/calcidiol, together with a succinct supplementary report which specifically addresses the issue of calcidiol in the maternal diet. The exposure assessment would include dietary intakes and supplements as well as natural forms of the vitamin.

Other discussions

19. Some COT Members asked if papers could be made available as shared documents in a Word format so that comments could be made ahead of the meetings. The Secretariat agreed to look into this suggestion but noted that new security features in how papers are accessed by Members could make this challenging.

AI in risk assessment workshop

20. A draft agenda for the upcoming workshop **Exploring the future of AI in Risk assessment** was shared with COT Members who were invited to suggest ideas for speakers and agenda topics. COT Members were content with the logo, title of the workshop, and the outline agenda.

Item 4: Committee Advice on the Authorisation of the extension of use of curcumin (E 100) to a new food category “egg analogues” (RP41) (Reserved) (TOX/2025/25)

21. No interests were declared.

22. A confidential AEJEG Committee Advice Document (CAD) for the extension of use of ‘curcumin’ (E 100) to a new food category ‘egg analogues’ to be included under category 12.9 ‘protein products’ excluding category 1.8 was presented to the COT.

23. The item is currently being treated as reserved as it is developing policy. The minutes will be published once confidentiality agreements have been finalised.

24. Members reviewed and commented on the draft CAD.

Item 5: T2 HT2 first draft statement on the risk for T-2 and HT-2 mycotoxins in food) (TOX/2025/26)

25. No interests were declared.

26. The mycotoxins T-2 and HT-2 were previously evaluated by the COT in 2018 and again in 2021. The 2018 review had focused on their presence in the diets of infants and young children, while the 2021 assessment had examined the potential risks associated with combined exposure to multiple mycotoxins.

27. In 2020, the European Commission (EC) had proposed setting maximum levels (MLs) for T-2 and HT-2 mycotoxins in food. These new legal limits, which were lower than the indicative levels outlined in Commission Recommendation 2013/165/EU, came into effect across the European Union (EU) on July 1, 2024. The established MLs apply to the combined total of T-2 and HT-2 toxins only. Modified forms of these toxins—such as neosolaniol (NEO) and 4,15-diacetoxyscirpenol (DAS)—were excluded due to limited data on their occurrence and the lack of a reliable routine analytical method.

28. Following the implementation of the new EU limits, the FSA requested that COT assess the potential risk to UK consumers from T-2 and HT-2 in food. As part of this evaluation, in February 2023 COT had considered the existing health-based guidance values (HBGVs) for these mycotoxins (TOX/2023/04), as established by the European Food Safety Authority (EFSA) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2017.

29. To support the COT risk assessment, the FSA and Food Standards Scotland (FSS) had conducted a call for evidence between July and October 2023. This initiative aimed to gather data across the cereal supply chain from production to retail. Although T-2 and HT-2 have been found in products of animal origin (probably due to contaminated feed as noted by EFSA in 2017), the data call did not include such products. Consequently, meat and dairy data were not considered in this assessment.

30. A discussion paper on T-2 and HT-2 exposure was presented to COT in July 2024 (TOX/2024/24) and again in March 2025 (TOX/2025/14), incorporating feedback from COT Members.

31. A first draft statement (TOX/2025/26 Annex A) bringing together the contents of the three previous discussion papers and the outcomes of the COT discussions was presented. This draft statement outlined the risks associated with T-2 and HT-2 mycotoxins in food, with a focus on exposure through the consumption of cereal grains and related products where data were available. Detailed exposure tables referenced in the statement were included as supplementary material in Annex B to the paper.

32. It was requested that the basis for the various HBGVs be clearly tabulated using the original units specified by the respective authoritative bodies, with an accompanying explanation making it clear that the values were essentially equivalent. The table should include the key outcomes considered critical to the risk assessments by both EFSA and JECFA. It was noted that both organisations concurred that the toxic effects of T-2 and HT-2 mycotoxins cannot be differentiated.

33. The COT suggested revising Figure 2 of the Draft Statement to show time trends for each type of grain individually, rather than aggregating them. Including the number of samples in the figure would also be beneficial; however, if this was not feasible, the information could be tabulated separately. The COT also recommended including a discussion of whether the data reflect a genuine time trend. If so, potential real and artefactual contributing factors, such as climate change, legislative changes, modifications in sampling and analytical methodologies, sample numbers and seasonality (e.g., the timing of sample collection) should be explored.

34. The section on exposure was lengthy and should be condensed where possible, reference being made to the relevant tables in the appendix to aid in streamlining the content. The age ranges used in the exposure assessment for children and younger age groups, which came from the National Diet and Nutrition Survey, should be clearly stated in the document.

35. COT Members suggested that the exposure assessment should acknowledge exposure to other mycotoxins as a source of uncertainty.

36. The COT agreed that it would be helpful to have more detail In the Toxicology section, with paragraphs 22 to 24 being expanded and any available information on mechanisms of action being incorporated.

37. A number of other changes to the wording were suggested by COT Members.

38. A second draft of the statement would be presented to the COT in due course.

Item 6: Citrinin in the maternal diet first draft statement (TOX/2025/27)

39. No interests were declared.

40. The Scientific Advisory Committee on Nutrition (SACN) is reviewing the scientific evidence supporting the Government's dietary recommendations for women of childbearing age. The SACN have asked the COT to review the risks of toxicity from chemicals in the maternal diet, including that of the mycotoxin citrinin.

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

42. The draft statement evaluates risks to maternal health as a consequence of exposure to citrinin. Studies on the immunotoxicity of citrinin published since the last EFSA opinion in 2012 were requested by the COT at the October 2024 meeting. These were included as Annex B to the draft statement and summarised in its text.

43. The first draft statement on citrinin in the maternal diet (TOX/2025/16) had been on the agenda for the March 2025 COT meeting but due to time limitations it was not discussed. However, COT Members had made a number of comments which were incorporated into the statement presented in TOX/2025/27.

44. The COT commented that the studies were not uniformly described across the statement. For consistency the discussion of each study should summarise its quality, its design and its key outcomes with additional detail being provided where relevant.

45. COT Members discussed whether there should be more emphasis on the risk to consumers of red yeast rice (RYR) contaminated with citrinin, particularly in the unregulated supplement market, but agreed that the text currently used in the statement was sufficient. The exposure and prevalence of use of such supplements in the UK was unknown and this should be acknowledged in the uncertainties section.

46. The COT agreed that the assumptions made in the assessment, including the decision not to account for carryover of citrinin from animal feed to food were appropriate but should be clearly itemised in the uncertainties section.

47. COT Members questioned whether the title of the paper fully reflected its content. The Secretariat noted that the programme of work on the maternal diet had been in progress for several years and the papers had evolved during that time. Work was underway to ensure standardisation, and a paper providing a general overview of the programme and additional background information – to include definitions of relevant terminology – was being drafted. From a SACN prospective, it was noted that either Maternal Diet or Maternal Nutrition was an appropriate title.

48. The COT commented that the data described in the section summarising EFSA's opinion (2012) the genotoxicity of citrinin was of poor quality. It was possible that a well-conducted genotoxicity study might become available in the future, but for now the lack of good quality genotoxicity data should be noted in the uncertainties section.

49. The COT observed that the details provided on the Arai (1983) study (Cancer Letters 17: 281-287) were not directly from the published paper but represented EFSA's interpretation of the study. COT Members requested that this be clarified. The poor quality of the paper should be noted in the uncertainties section. COT Members commented that renal adenomas, which were reported at increased incidence in the study, are uncommon in rat kidney; this was a significant finding even in the absence of malignancy. The presence of adenomas was of concern regardless of whether or not carcinomas would have been seen with a longer study duration. This finding, when considered with additional findings in the more recent literature, add to the weight of evidence that there might be a concern for carcinogenicity.

50. The Committee noted that the study describing immunomodulation (Islam et al, 2012. Food and Chemical Toxicology, 50:3537-3547) did not include a description of organ and body weight changes. Members discussed the importance of this information but acknowledged that there was not enough data in the study and histopathology results were not included. Due to the short duration of the study, conclusions could not be drawn from it.

51. COT Members suggested the studies be summarised, grouped and tabulated to aid comparison of the data cited by EFSA.

52. One of the studies described in the statement (Kuroda et al, (2013) Toxicology 311, 216–224) discussed potential mechanisms of citrinin-induced renal carcinogenicity. The studies conducted by Kuroda et al (2013) were, however, short term (maximum of 28 days' exposure in rats) focussing on genotoxicity, cell proliferation and changes in gene expression. They did not demonstrate actual carcinogenicity. This needed to be made clear in the draft statement. The COT further questioned the relevance of some of the other studies included in the carcinogenicity section of the report.

53. Decreases in body weight were noted in the summary of the Kuroda et al (2013) study. This could be due to reduction in food intake due to the unpalatability of high doses of citrinin, but it would be useful to have more detail on the cause in order to exclude overt toxicity as a factor.

54. The COT questioned the quality of the epidemiology data. It was agreed that it should be clearer which population groups some of the data were referring to. COT Members noted that sources of exposure to citrinin could vary between ethnicities and cultures. This should be included in the uncertainties section.

55. In the risk characterisation section, the COT requested that nephrotoxicity is clearly stated as the identified critical endpoint and the level of no concern was set on that basis. Any other adverse effects that were seen occurred at higher doses of citrinin.

56. COT Members noted the potential for mixed mycotoxin exposure and potential additive effects which should be listed as an uncertainty.

57. A COT Member had provided a risk assessment on citrinin which was requested by Netherlands Food and Consumer Product Safety Authority (NVWA) and performed by the National Institute for Public Health and the Environment (RIVM). This gave a different level of no concern and would be included in the second draft of the statement.

58. Members made a number of other minor comments on the structure and wording of the draft statement.

59. Overall, Members agreed that the conclusions reached were appropriate and based on the evidence provided; however, they requested the addition of a section listing the large number of uncertainties associated with this risk assessment.

60. A revised version of the draft statement would be presented at a future meeting.

Item 7: First Draft statement of advice on the risk to human health from consumption of bivalve molluscs (shellfish) harvested from UK waters associated with marine biotoxins (TOX/2025/28)

61. The Chair declared attending meetings by the Scottish Food Advisory Committee at which marine biotoxins monitoring data were discussed. No other interests were declared.

62. Based on a scoping paper (TOX/2023/59) and discussion paper (TOX/2024/25) the COT had previously concluded that there were significant data gaps for emerging marine biotoxins, including a lack of information on the presence and concentrations of emerging marine biotoxins 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. Due to these data gaps COT Members had been unable to conclude on the potential risks of the emerging marine biotoxins to human health and derive HBGVs.

63. Therefore, to assist in prioritising the emerging marine biotoxins, the COT had discussed the scope for risk ranking based on a numerical scoring system. Such an approach had previously been applied to score the relative risk of mycotoxins. To develop the risk ranking system a small working group of Members was formed. The resulting approach and outcomes of the risk ranking were presented to the COT at the March 2025 meeting (TOX/2025/15).

64. The risk ranking approach proposed scores for each group of biotoxin according to four categories of evidence: toxicological data, occurrence data, human case reports, and regulation/monitoring. COT Members had concluded the approach was successful in differentiating some biotoxins as higher or lower risk and agreed that the narrative alongside the scoring was essential for clearly depicting how the data was weighed. However, several changes had been requested by the COT to finalise the ranking.

65. COT Members had suggested that biotoxins with identical scores should be prioritised by giving most weight to human data, followed by animal toxicological data and occurrence data. Hazard-based prioritisation was considered the most conservative approach for protecting public health. The human case reports scoring category was originally scored 1-3; however, the COT requested this be changed to 1-5 to ensure equal weighting of all categories. It was concluded that information on regulation should be considered separately because the risk ranking was for emerging biotoxins and those that were regulated in the UK (i.e., saxitoxin) were out of scope. The COT had noted that the analogue approach suggested for ranking biotoxins with extremely limited information was not suitable especially for the non-hazard categories. While this conclusion has been noted in the Statement the analogue approach itself is not further discussed.

66. The statement presented in paper TOX/2025/28 was a final version of the risk ranking, addressing previous suggestions alongside background information on emerging marine biotoxins and discussions of the risk ranking approach and its underlying uncertainties.

67. COT Members agreed that it was a well written Statement. The pragmatic risk ranking approach it proposes would be informative to risk managers, its target audience; in addition, given that the Statement aims to support risk management decisions, it would be a helpful tool for communication with interested parties such as politicians, policy decisionmakers, and the general public.

68. The proposed scoring system for toxicity focused on acute effects only. The COT discussed the risk from potential chronic effects and noted that, based on the available evidence, chronic effects appear always to be secondary to acute exposure. It was, therefore, agreed that the Statement should capture the fact that protective measures against acute effects would also be protective against chronic effects. An additional ranking was not considered necessary.

69. Climate change and rising sea temperatures may affect the distribution of marine biotoxins; however, due to the extremely limited available data, especially for the UK, the extent of this influence remains unknown. The COT requested that this uncertainty be clearly reflected in the relevant section.

70. Overall, the Committee were content with the first draft Statement but suggested some additional minor editorial changes. It was agreed that the Statement could be finalised by Chair’s action.

Item 8: Update on the work of other FSA Scientific Advisory Committees - for information (TOX/2025/29)

71. This paper was provided for information. Members could contact the Secretariat if they had any questions.

Item 9: Any other business

72. Members were informed that the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) had very recently published its new guidance statement:

A case for change: the challenge to develop a better approach to assessing risk of cancer caused by chemicals - GOV.UK This highlighted the COC's aim to identify approaches which allow better prediction of human cancer risk, which is not necessarily achieved with the current approach that often relies on long-term animal studies. It also invited interested parties to send in proposals to the Secretariat with approaches in this area, or to present cases studies where alternative methodology has been used to select candidate compounds before full regulatory testing, so any COT members aware of such are invited to get in contact via COC@ukhsa.gov.uk.

Date of next meeting

73. The next meeting of the Committee will be at 10:00 on Tuesday 9th September 2025 via Microsoft Teams.

Secretariat

July 2025