Draft Minutes of the 21st October 2025 COT Meeting

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

Present

Chair: Reverend Professor Lesley Stanley

Deputy Chair: Professor Shirley Price

Dr David Lovell Dr Cheryl Scudamore Professor Mireille Toledano (from item 5) Dr Simon Wilkinson **Professor Peter Barlow** Dr Chris Morris Dr Meera Cush Mr Gordon Burton **COT Members:** Dr Andreas Kolb Dr Alison Yeates (from item 5) 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 Dr Susan Fairweather-Tait (from Item **SACN Liaison:** 5)

Professor Gary Hutchison

Ms Claire Potter - FSA Scientific Secretary

Dr Tahmina Khan

Dr Alex Cooper

Dr Barbara Doerr

Dr Olivia Osborne

Ms Sabrina Thomas

Dr Gail Drummond

Ms Chara Tsoulli

Ms Frederique Uy

Secretariat: Food Standards Agency (FSA)

Ms Jocelyn Frimpong-Manso

Ms Sophy Orphanos

Dr Gaetana Spedalieri

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

Dr Andy Axon

Ms Britta Gadeberg Secretariat: UKHSA - UK Health Security Agency Ms Sanyukta Pallavi **UKHSA** Contractor - bibra Mr Richard Young Assessors:Office of Health Improvement Ms Rachel Elsom (item 6) and Disparities (OHID) Assessors: Health Improvement Global Ms Neeve Pearce (Item 6). and Public Health Group Assessor: Department for Business and Ms Frances Hill Trade (DBT) Ms Chloe Thomas (Item 7) Ms Eleanor McKeegan - Presenting (Item 11) **FSA** officials: Ms Tania Haskins - Presenting (Item 11) Ms Priscilla Wanjiru (Item 8) Ms Lucy Reid (Item 8) Dr Arthur Carvalho de Silva, University of Birmingham (Item 6). Mr Alex Kallian, Kings College London. Observers:

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11).

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Dr John O'Brien, Science Council (Item

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Any other business - Presentation on FSA work to support

11 negotiations and planning for implementation of an EU-UK SPS 60-62 Agreement

Announcements

- 1. Members were informed that Professor Sue Fairweather-Tate will be the new Scientific Advisory Committee on Nutrition (SACN) liaison Member replacing Professor Paul Haggarty, who stepped down from SACN in March 2025. Professor Ken Ong would continue to provide support as necessary.
- 2. It was noted that a representative from Bibra, UKHSA's current Secretariat support contractor was present for the reserved business items. This is because their function is Secretariat support and contractual arrangements are in place to ensure confidentiality with respect to reserved materials.

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 Dr Steven Enoch and Professor Philippe Wilson, Ms Cath Mulholland and Mr Thomas Hornsby of the FSA Secretariat, Ms Jackie Healing, Science Council liaison and Ms Minako Allen, Health and Safety Executive assessor.

Item 2: Draft minutes and reserved minutes of the Tuesday 9th September 2025 meeting (TOX/MIN/2025/05)

5. The Committee reviewed the draft minutes of the meeting held on the 9th of September 2025. The minutes were accepted as an accurate record.

Item 3: Matters arising

Joint Expert Group (JEG) updates

Additives Enzymes and other Regulated Products (AEJEG)

- 6. The last meeting was held on 11th September 2025; several items were presented:
 - RP41 The JEG received an update on an extension of use application on curcumin (E100) to include a new food category "egg analogues". The progress of this application was reviewed, and the next procedural steps required to advance the evaluation were discussed by the JEG.
 - RP1457 An update was presented to the JEG on the application for the authorisation of the substance glycolipids (E 246) for use as a new food additive. The applicant had proposed conducting a new experiment designed to address and potentially alleviate the JEG's concerns regarding the impact of the additive on the gut microbiome.
 - RP1765 The JEG received an update paper on authorization of 3 flavoring substances. JEG Members were presented with the applicant's formal reply to the Request for Information (RFI) previously issued by the JEG.
 - The first draft of the Committee Advice Document (CAD) for this application (RP1765) was presented to the JEG and reviewed.
- 7. The next standard AEJEG meeting is scheduled to take place in person in London on the 2nd of December 2025 as a hybrid meeting.

Food Contact Materials (FCMJEG)

- 8. The FCMJEG meeting scheduled for the 1st October 2025 was postponed due to a light agenda.
- 9. The next FCMJEG meeting is to be held on the 3rd of December 2025 as a hybrid meeting. The JEG will be reviewing agar palmitate and will be continuing with the recycling plastics auditing.
- 10. An overview of the status of several applications was provided. There was 1 application in the suitability stage, 4 applications in the assessment stage (RP2147, RP2263, RP1415, RP1898) and one application in the process of being finalised (RP1862).

Subgroups and Working Groups (WG)

COT guidance

11. The Guidance WG met on the 19th of September and discussed the potential overall structure and outline of the guidance. The importance of distinguishing between guidance and ways of working was noted. The WG aims to present a draft document to the COT in the first half of 2026.

PFAS

- 12. COT Members were informed that work was continuing on the papers covering reproductive and developmental outcomes. This was being supported by the UKHSA's new Committee Secretariat support contractor, Bibra, with input from UKHSA staff.
- 13. It was noted that the animal/in vivo discussion papers on these endpoints were prepared by UKHSA's previous contractor (IEH Consulting). Bibra and UKHSA are currently assembling the large number of epidemiological papers to be considered for the reproductive and developmental endpoints. The next PFAS working group meeting is tentatively anticipated for Spring 2026.
- 14. COT Members were informed of an EFSA PFAS risk assessment workshop taking place in November 2025, and it was hoped that a member of the PFAS working group Secretariat would be able to attend.

Publications

15. The FSA commissioned literature review on nitrates, discussed at the May COT meeting, had now been published.

Item 4: Smoke Flavouring CADS (Reserved) (TOX/2025/37)

- 16. No interests were declared.
- 17. COT Members were presented with an update on the re-evaluation of smoke flavourings. This item is currently being treated as reserved.
- 18. The COT thanked Members who had contributed to the smoke flavourings working group.

Item 5: First draft Statement on the safety of ashwagandha in food, drinks and food supplements (Reserved) (TOX/2025/38)

- 19. No interests were declared.
- 20. A discussion paper reviewing the safety of ashwagandha in food, food supplements and drinks, along with the responses received from the FSA call for evidence on ashwagandha, was presented to the COT in March 2025. The review was undertaken at the request of FSA policy teams due to the increasing popularity of ashwagandha in food supplements and the increasing number of incidents notified to the FSA relating to food supplements containing ashwagandha.
- 21. This first draft statement contained amendments requested by COT Members, in addition to a table summarising the studies cited. A restructuring of the draft statement was requested to facilitate the review of the available data.
- 22. The COT previously identified information on the levels of potential contaminants as a potential data gap and requested any available data on this topic. This would be presented as a supplementary paper in 2026.
- 23. This item is currently being treated as reserved business as it includes confidential data.

Item 6: Artificial Intelligence in Chemical Risk Assessment (Reserved) (TOX/2025/39)

- 24. No interests were declared.
- 25. The <u>Potential future discussion items horizon scanning paper</u> was presented to COT Members in February 2025, when it was agreed that Artificial Intelligence (AI) would be a suitable topic for the next COT Annual Workshop. The proposed workshop would be a first step towards reviewing the current state of the art of AI technologies relevant to chemical risk assessment as well as discussing the opportunities and the challenges associated with the application of AI in chemical safety assessment. As part of the background to the workshop, a scoping paper on AI in risk assessment considering these points would be presented to the COT. This topic forms part of the COT's work on integrating New

<u>Approach Methodologies (NAMs) in risk assessment</u> and continuing to develop a UK NAMs Roadmap.

- 26. Paper TOX/2025/39 set out a brief history of AI, the different areas of AI and their applications in chemical risk assessment. It reviewed current state-of-the-art AI tools and discussed the opportunities and challenges of using these technologies. The paper also explored the complexity of data ecosystems which would be part of AI integration in chemical risk assessment in the regulatory setting. COT Members were informed that the scoping paper would be reworked into a state of the science report.
- 27. COT Members discussed the scoping paper.
- 28. This item is being treated as reserved ahead of possible publication.

Item 7: Second draft statement on the risk for T-2 and HT-2 mycotoxins in food (TOX/2025/40)

- 29. No interests were declared.
- 30. In 2020, the European Commission (EC) 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.
- 31. Following the implementation of the new EU limits, the FSA requested that the

COT assess the potential risk to UK consumers from T-2 and HT-2 in food. In February 2023, as part of this evaluation, the COT considered the existing healthbased 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.

32. To support the COT risk assessment, the FSA and Food Standards Scotland (FSS) 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, exposure data from meat and dairy

products were not considered in this assessment.

33. A discussion paper on T-2 and HT-2 exposure was presented to the COT in

July 2024 (TOX/2024/24). A revised version, incorporating feedback from COT Members, was considered in March 2025 (TOX/2025/14).

- 34. 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 in July 2025. The first 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.
- 35. The second draft statement (TOX-2025-40) incorporated the changes requested by the COT at the July 2025 meeting. These included clearer tabulation of HBGVs, revisions to Figure 2 to show grain types individually, a more concise exposure section and an expanded discussion of the uncertainties associated with the assessment.
- 36. COT Members discussed Figure 2, raising concerns about the clarity of the data presentation. They questioned whether the graphs showed means or medians and emphasised the need for error bars to better reflect data variability. It was agreed that the figure required a clearer legend and more precise referencing in the text.
- 37. It was noted that there were inconsistencies in how vulnerable groups were described across the document, especially in relation to exposure exceedances. It was agreed that vulnerable groups should be explicitly defined within the statement, including age ranges and the food categories associated with exceedances. The Committee discussed whether to use "elderly" or "adults over 65" and agreed that aligning terminology with NDNS categories and clearly defining age groups in the document was the best approach to avoid ambiguity.
- 38. COT Members also discussed the complexity of the exposure section, acknowledging that, despite efforts to simplify it, the overlapping food categories and toxin types remained difficult to follow in places. It was suggested that a fresh perspective might help refine this section further.
- 39. The COT agreed that the statement could be finalised via Chair's action, subject to the discussed revisions. There was no need for another full Committee

Item 8: Scoping paper on the potential risk(s) of *Garcinia cambogia* (TOX/2025/41)

- 40. No interests were declared.
- 41. In March 2025, the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) published an opinion on their assessment of adverse reactions to the consumption of food supplements containing *Garcinia cambogia* (*G. cambogia*). The detailed review is in French, but the official webpage provided an English overview and also advised consumers to not consume food supplements containing *G. cambogia*.
- 42. In the UK, there are currently no safe levels or set limits established for the use of *G. cambogia* in food and drinks, including in food supplements. FSA and FSS asked the COT to perform a review of the ANSES opinion and assess the risk(s) associated with consumption of *G. cambogia* in food supplements. In addition, the COT was asked to consider whether a safe intake level or maximum limit of *G. cambogia* for use in food and drink, including food supplements, could be derived based on the available data.
- 43. In order for COT Members to make a full assessment, a translation of the ANSES opinion was commissioned by the FSA and presented to the COT as part of TOX/2025/41.
- 44. COT Members noted that there were data available on *G. cambogia*; however, they would need to be appropriately weighted before a key study and/or endpoint from which to derive a HGBV could be identified. The weight attached to human clinical case reports compared to randomised controlled trials would be particularly important.
- 45. The occasional reports of differing adverse effects from human case studies could not always be attributed to *G. cambogia* or its extract, hydroxycitric acid (HCA), alone because some individuals were taking other supplements and/or had medical conditions. There was a data gap concerning potential long-term effects. This represents a key uncertainty in the assessment. COT Members also noted that it was important to determine whether there were potential vulnerable groups.

- 46. The importance of chemical composition/identification, including an understanding of the manufacturing process, was discussed. The medicinal status of *Garcinia* food supplements containing HCA was also noted. These would not be in the remit of the FSA.
- 47. Given the limited information presented, the Committee was not in the position to agree or disagree with the conclusions reached by ANSES on the safety of *G. cambogia* food supplements. A thorough review of the data was required prior to forming conclusions. A restructuring of the scoping paper was requested to facilitate the review of the available data. Details of the manufacturing processes of *G. cambogia* food supplements were also requested. A further draft paper would be presented at a future COT meeting.

Item 9: Summary of the European Food Safety Authority's scientific opinion on the guidance on the use of read-across for chemical safety assessment in food and feed (TOX/2025/42)

- 48. Professor Mohammad Qasim Chaudhry declared an interest as he is an author of the Scientific Opinion under discussion. He was able to answer questions and provide clarification, but not to be further involved in the discussion. No other interests were declared.
- 49. The European Food Safety Authority (EFSA) Scientific Committee recently published guidance on the use of read-across for chemical safety assessment in food and feed. Paper TOX/2025/42 provided a brief overview of this guidance. COT Members were invited to share any comments or feedback with a view to determining whether they would be content to use the guidance.
- 50. Members were invited to comment on: (1) the structured workflow proposed to standardise and justify the read-across approach, (2) the content of the guidance, and (3) the applicability of the guidance.
- 51. COT Members noted that the structured workflow was clear when approached as a review. However, no standard operating procedures were included in the guidance, which appeared to be intentionally flexible.
- 52. COT Members argued that, in order to consider the validity of the use of NAMs or read across there needed to be validated experimental data to make

the comparisons and to consider the validity of the methods being used.

- 53. Professor Chaudhry, as co-author of the Scientific Opinion, provided a brief explanation of the guidance. He emphasised the importance of fully characterising the target compound and setting boundaries for the read-across, as well as defining what was acceptable in terms of uncertainties, e.g. in situations where no data were available and further data cannot be requested, a higher level of uncertainty may be acceptable. Uncertainties would be introduced at each step of the workflow, and they must be collated and evaluated. If read-across was based on Good Laboratory Practice-compliant studies, uncertainties were inherently low. Where uncertainties were moderate, additional supporting evidence from NAMs may be used to reduce them. If this was not possible, the scope of read-across may be widened, or testing may be required.
- 54. Regarding expert judgement within the read-across workflow, Professor Chaudhry explained that while experts may identify analogues based on structural or functional similarity, independent and unbiased evidence was essential to support such claims, ideally from high-quality databases. However, concerns were raised about some applicants relying on proprietary databases without providing sufficient explanation or transparency. It was concluded that, if the established procedure was followed, the read-across was likely to be accepted.
- 55. COT Members noted that while the aim of the guidance was to streamline processes, the quality of input data must be carefully considered, as it directly affects the quality of the output. The COT reflected on how to judge the quality of data, particularly in studies using NAMs and read-across.
- 56. COT Members highlighted that the guidance did not clearly state that readacross may not be accepted for certain substances such as plant protection products, whose active substances are subject to legal requirements to provide toxicological studies whereas metabolites or contaminants are not. Read-across is therefore only acceptable for the latter. The guidance did not make this sufficiently clear. Read-across should be used as a supporting line of evidence only when permitted by the relevant regulatory framework. Only in certain cases, such as when no applicant is present and uncertainties are high, may it be accepted as the sole source of evidence.
- 57. It was noted that read-across is a significant component of Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which is managed within the EU by the European Chemicals Agency (ECHA). COT

Members asked how the EFSA guidance aligned with ECHA's. Professor Chaudhry confirmed that experts from ECHA contributed to the drafting of the guidance.

58. COT Members commented on the guidance document and suggested it should be reviewed by the COT Guidance Working Group to avoid duplicating existing work. The Committee asked the Secretariat to include this guidance as a topic for consideration by the Working Group, specifically to assess whether the guidance should be fully adopted or whether deviations were warranted. Given that the COT's remit extends beyond food, it was agreed that relevant guidance from other regulatory contexts should also be reviewed to ensure broad applicability.

Item 10: Update on the work of other FSA Scientific Advisory Committees - for information (TOX/2025/43)

59. This item was presented for information. If Members had any questions they should contact the Secretariat.

Item 11: Any other business - Presentation on FSA work to support negotiations and planning for implementation of an EU-UK SPS Agreement

- 60. No interests were declared
- 61. A presentation on the FSA work to support negotiations and planning for implementation of an EU-UK SPS Agreement was given to Members.
- 62. This item is being treated as reserved as it relates to developing policy.

Date of next meeting

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

Secretariat

October 2025