Minutes

Final Minutes of the 26th March 2024 COT Meeting

Meeting of the Committee at 10:00 on 26th March 2024 at Clive House, London and on Microsoft Teams

Present

Chair:	Professor Alan Boobis

	Dr Phil Botham
	Professor Gary Hutchison
	Professor Thorhallur Halldórsson
	Dr Sarah Judge
	Dr Michael Routledge
	Dr Natalie Thatcher
	Ms Juliet Rix
	Dr Simon Wilkinson
	Professor Mireille Toledano
	Professor Philipe Wilson
COT Members:	
	Ms Jane Case
	Dr Gunter Kuhnle
	Professor Shirley Price
	Dr Cheryl Scudamore
	Dr Stella Cochrane
	Dr David Lovell
	Professor Peter Barlow
	Dr Steven Enoch
	Dr Mac Provan
	Professors Maged Younes

	Professor Jeanette Rotchell
	Dr Samantha Donnellan
COT Associate Members:	Ms Eimear O'Rourke
	Dr Charlotte Mills
	Dr Tarek Abdelghany

	Ms Cath Mulholland - FSA Scientific Secretary
	Ms Chara Tsoulli
	Ms Abigail Smith
	Dr David Gott
	Mr Michael Dickinson
	Ms Claire Potter
	Dr Barbara Doerr
	Dr Olivia Osborne
	Ms Sabrina Thomas
	Dr Gail Drummond
	Ms Cleanncy Hoppie
	Ms Jocelyn Frimpong-Manso
Food Standards	Ms Sophy Orphanos
Agency (FSA)	Dr Gaetana Spedalieri
Secretariat:	Mr Thomas Hornsby
	Dr Emily Hudson
	Dr Aaron Bradshaw
	Dr Lorcan Browne
	Ms Natasha Adams
	Dr Katie Schulz
	Ms Katie Wetherall
	Mr Barry Maycock
	Ms Frederique Uy
	Dr Rachel Kerr
	Mr James Metcalfe
	Ms Yoana Petrova

UK HSA Secretariat:	Ms Britta Gadeberg - UK HSA Scientific Secretary
Assessors:	Dr Ovnair Sepai - UK Health Security Agency (UKHSA)
	Ms Frances Hill - Department for Business and Trade
	Ms Susannah Brown - Office of Health Improvement and Disparities (OHID)
	Mr Ian Smith - Environment Agency (EA)
	Mr Gordon Burton - Independent consultant
	Dr Meera Cush - Ramboll
	Mr Nick Richardson - Defence Science and Technology Laboratory (Dstl)
	Dr Chris Morris - University of Newcastle
	Dr Andreas Kolb - Rowett Institute, Aberdeen
	Mr Kevin Hughes - Colorcon Ltd
Observers:	Dr Emma Bradley - Food Contact Materials Joint Expert Group Member (FCM JEG)
	Dr Gill Clare - FCM JEG Member
	Professor Susan Lanham-New - Member of Plant-based Drinks Working Group
	Professor Tim Key - Member of Plant-based Drinks Working Group
	Professor Gareth Jenkins - Committee on Mutagenicity (COM)

FSA and other Officials:	Mr Allan Shivembe - FSA Dr Mindy Dulai - FSA Ms Lucy Reid - Food Standards Northern Ireland (FSA NI) Ms Lucy Smythe - Food Standards Scotland (FSS) Ms Krystle Boss - FSS Ms Sanyukta Pallavi - UK HSA Ms Rachel Daniels - Health & Safety Executive (HSE)

Contents

Announcements

1.The Chair welcomed Members and other attendees.

2. This was the last meeting for COT Deputy Chair Dr Sarah Judge and COT Members Dr Phil Botham, Professor Matt Wright, Ms Jane Case and Ms Juliet Rix. The Committee thanked them for all their hard work over the years and wished them well in the future.

3. The Chair welcomed new COT Members Dr Chris Morris, Dr Alison Yeates, Dr Andreas Kolb and Dr Meera Cush and new lay Members Mr Nick Richardson and Mr Gordon Burton, who were in attendance as observers before joining the Committee in May, and briefly introduced themselves to the Committee.

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 Matthew Wright, Dr James Coulson, Dr Stella Cochrane and Dr Silvia Gratz, Associate COT Member Dr Ben Amies-Cull and Dr Alex Cooper of the Secretariat.

Item 2: Draft Minutes from the meeting held on 6th of February 2024

(TOX/MIN/2024/01)

6. The Committee reviewed the draft minutes and the reserved minutes of the 6th February 2024 meeting (TOX/MIN/2024/01).

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

Item 3: Matters arising from the meeting held on 6th of February 2024

Joint Expert Group (JEG) update

Additives, Enzymes and other Regulated products - AEJEG

8. The AEJEG met in February and provided a toxicology update for the opinion on RP507. Two Requests for Information (RFIs) were discussed (RP1245 and RP42). The Advisory Committee on the Microbiological Safety of Food (ACMSF) provided the JEG with an update on the microbiological risk associated with nisin. The AEJEG would meet next on the 16th of April 2024.

9. The AEJEG working group (WG) for Smoke Flavourings (SFs) met face to face on the 6th March and discussed the weight of evidence and Quantitative Structure Activity Relationship (QSAR) summary documents, and, the discrepancies between different applications. The second round of RFIs will be sent out at the beginning of April. The SFs WG will next meet on the 15th May to start Phase 3 of the assessment: this is the conclusions on genotoxicity and the start of the assessment of the general toxicity/new Extended One Generation Reproductive Toxicity (EOGRT) data expected later in the year.

Food Contact Materials - FCMJEG

10. The FCMJEG met on the 28th February where they discussed the updated statement on Ocean Bound Plastics, to be covered later in this agenda, the first draft safety assessment for a recycling process (RP53) and the second draft assessment for a plastic additive (RP1702).

11. The next FCMJEG meeting will be face-to-face on the 10th April where the JEG will discuss a new dossier for a plastic additive (chopped carbon fibre, RP2147) and potential additional information on recycling processes.

12. The JEG will also be informed about the new abbreviated processes (ABBs) and use of other regulators opinions (OROs) for responding to applications.

The potential human health risks of bamboo bio-composites in food contact materials – TOX/2024/09.

13. No interests were declared.

14. Paper TOX/2024/09 provided an update on the use of bamboo composites in biologically based food contact materials (FCMs) which had been discussed by the Committee in 2021, with a position paper being published in 2022, which stated that there were insufficient data to conclude on the safety of bamboo based FCMs. Paper TOX/2024/09 contained a summary of the responses obtained from manufacturers following a 2022 FSA call for information. It was noted that Members had been circulated with a reserved version of the paper, while a non-reserved version had been published on the website with any information that could identify individual companies being removed. An additional report containing relevant analytical data was also provided but was treated as reserved as it contained commercially confidential information.

15. Members noted there was a potential cause for concern with respect to the levels of contaminants seen with some bamboo-based FCMs, particularly considering that some of these products were intended for children.

16. It was considered that the companies' responses were of only limited use, and the Secretariat confirmed that only a relatively small amount of data had been submitted to the FSA, these were generally short documents, and analytical test reports.

17. A representative from the FCMJEG informed the Committee about the test procedures often used in the assessment of FCMs and noted that some products could give higher measurements of melamine and formaldehyde due to hydrolysis of the polymer. This could be related to an incorrect ratio of monomers used in production, but the issue was not clear cut.

18. The Committee emphasised the need for monitoring of melamine and formaldehyde in these products. Attempting to establish the magnitude of the potential problem in the UK was difficult due to the lack of data. Currently, testing was required on only 10% of products, meaning that most products reach the market untested.

19. It was noted that current FSA advice was that these products should not be used for hot or acidic drinks, but consumers had not been advised to dispose of these products.

20. Overall, the Committee agreed that the conclusions of the Interim Position paper did not need to be amended following consideration of the new evidence submitted to the FSA by manufacturers. It was agreed that there was still insufficient exposure data on which to perform a complete risk assessment.

Item 4: Safety Advice Document on the evaluation of the recycled poly(ethylene terephthalate) decontamination process operated by LINPAC for use in the manufacture of articles in contact with food (Reserved) (TOX/2024/10)

21. No interests were declared.

22. An FCMJEG safety advice document on the evaluation of the recycled poly(ethylene terephthalate) decontamination process operated by LINPAC for use in the manufacture of articles in contact with food 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 paper.

Item 5: Committee Advice on the safety of the Application to modify the conditions of use of E401 (sodium alginate) for use as a surface treatment in entire fruits and vegetables (Reserved) (TOX/2024/11)

25. No interests were declared.

26. A confidential AEJEG safety advice document on the safety of the application to modify the conditions of use of E401 (sodium alginate) for use as a surface treatment in entire fruits and vegetables was presented to the COT.

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

28. Members reviewed and commented on the paper.

Item 7: Fifth draft interim position paper on bisphenol A (TOX/2024/13)

36. Professors Thorhallur Halldórsson and Maged Younes of the Committee and Dr David Gott of the Secretariat were Members of the EFSA CEP panel and BPA Working Group. They were able to answer questions and provide clarification on the EFSA opinion but could not otherwise take part in the discussion.

37. Dr Natalie Thatcher declared a non-personal specific interest, as her employer would have an interest in the use of BPA in packaging. No other interests were declared.

38. In April 2023, the EFSA CEP Panel established a new tolerable daily intake (TDI) of 0.2 ng BPA/kg bw per day. Following the Committee's discussion of the EFSA opinion, a draft interim position paper by the COT was presented to the Committee in May, September and October 2023.

39. Along with the European Medicines Agency, the BfR (the German Federal Institute for risk assessment) published a diverging opinion alongside the final EFSA opinion. Following the publication of their diverging opinion, BfR then published a full assessment of BPA in late 2023, establishing a TDI of 0.2 µg/kg bw per day (equivalent to 200 ng/kg bw per day); this was discussed at the December 2023 meeting of the COT and it was agreed that it could be adopted as an interim TDI while the Committee undertook its own review of BPA. An updated draft of the interim position paper was then presented at the February 2024 meeting.

40. At the February 2024 meeting, the Committee agreed to fully adopt the BfR TDI. The draft interim position paper was therefore updated to reflect the COT's conclusion and to include further detail underpinning the conclusion and presented to the present meeting.

41. At the present meeting, the Committee discussed the draft position paper, particularly the updated text in the "Conclusion and Next steps" section. Members suggested a number of editorial changes to strengthen the conclusions and clarify the Committee's views. It was agreed that the text should emphasise that the new evidence had been considered in detail and that the COT considered the BfR's assessment scientifically more robust than EFSA's, hence the COT's decision to adopt the BfR TDI. It was noted that a detailed statement setting out the Committee's approach would be prepared later in the year.

42. The revised draft will be discussed at the next COT meeting in May.

Item 8: Fourth draft statement on the safety of Titanium Dioxide (E171) as a Food Additive (TOX/2024/14)

43. Professor Alan Boobis declared an interest that dated back to 2019. He is a member on the External Advisory Committee of the Centre for Research on (Food) Ingredient Safety at Michigan State University. One of their research groups had undertaken research on titanium dioxide, published in 2019, which was partly funded by industry. This was not a direct interest and would not preclude

Professor Boobis from contributing to the discussions, but the item was chaired by the Deputy Chair, Dr Sarah Judge.

44. Professor Shirley Price declared an interest as she is a member of the JECFA group on titanium dioxide and would be attending the next JECFA meeting in October 2024 to discuss it. Dr Natalie Thatcher declared a non-personal specific interest as her employers may use titanium dioxide in their products. These interests did not preclude these Members from contributing to the discussion of this item. No other interests were declared.

45. Professor Gareth Jenkins, Chair of the Committee on the Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM), and Dr Ovnair Sepai of the COM Secretariat were in attendance for this item. Mr Kevin Hughes from the company Colorcon was present as an external observer for this item.

46. Titanium dioxide (TiO2) is an authorised Food Additive (E171) in the EU and currently remains authorised in the UK, under Retained EU Regulation No. 1333/2008 and Retained EU Regulation No. 231/2012. It is used in food as a colour to make food more visually appealing, to give colour to food that would otherwise be colourless, or to restore the original appearance of food. It is commonly used in products such as bakery products, soups, broths, sauces, salad dressings, savoury sandwich spreads, processed nuts, confectionary, chewing gum, food supplements and cake icing.

47. Titanium dioxide has been the subject of multiple safety evaluations. The most recent EFSA Opinion was published in 2021, in this, the EFSA Food Additives and Flavourings (FAF) Panel considered that some findings regarding immunotoxicity, inflammation and neurotoxicity with respect to TiO2 nanoparticles may be indicative of adverse effects. On the basis of the currently available evidence and the uncertainties, in particular a concern regarding genotoxicity which could not be resolved, the EFSA Panel concluded that E171 can no longer be considered as safe when used as a food additive.

48. In 2021 the COT published an interim position on titanium dioxide (COT 2021) capturing the outcomes of their discussions and outlining the next steps. Members had been asked to evaluate the EFSA Opinion and comment on whether they agreed with EFSA’s conclusions and to provide further guidance on the next steps that should be taken; it was agreed to produce an opinion paper following a review of the new EFSA opinion and the extended one generation reproductive toxicity (EOGRT) study data by both the COT and COM.

49. Paper TOX/2024/14 was an updated version of the statement, which covered the COT conclusions to date on the following topics and endpoints: Absorption, Distribution, Metabolism, Excretion (ADME), Aberrant Crypt Foci as a marker for Carcinogenicity, Allergenicity, Reproductive and Developmental Toxicity, potential evidence of Immunotoxicity, Inflammation and Neurotoxicity, along with discussion of the review and the conclusions on the genotoxicity endpoints, conducted by the COM. It also included a characterisation section. The narratives produced by COM on in vitro and in vivo genotoxicity had been provided to COT Members for information. It was noted that they would be finalised shortly but were currently still draft documents and should be treated as confidential.

50. Members discussed the characterisation section; it was noted that the section highlighted that there was no defined boundary between food grade and nanoparticle titanium dioxide. It was also stated that there can be a degree of variability in the levels of nanoparticle within food-grade titanium dioxide, although it was noted that within food-grade the number of nanoparticles would be minimised. It was suggested that the terms micro-sized and nanoparticles should be defined.

51. A minor revision was requested for the text discussing the Rompelberg et al study as it was noted that the estimated mass (weight %) of the nanoparticles went up to 12.5%, however in the previous paragraph it had been written that the percentage number was 1% or less. The Secretariat agreed to check the numbers.

52. COT members suggested that a section on how the health-based guidance value was derived should be added to the report.

53. It was suggested that the EFSA summary on the Pele et al, 2015 study should be included in the statement.

54. Members agreed that it should be clear that the recent European Commission ban on titanium dioxide would not be reflected in the available exposure data used by the Committee, which was from several years ago.

55. The draft COM conclusions were presented to Members. The COT requested that it be made clear which sections in the draft statement were quoted from the COM.

56. COT Members noted that the COM report had stated there were a lack of studies using E171 titanium dioxide, therefore it was asked if there was still uncertainty about the conclusions due to the lack of appropriate studies. It was

explained that within the COM conclusions it was noted that more studies would be ‘welcomed’, however, conclusions were drawn based on the available data. The COM noted that studies that had used micro-sized titanium dioxide, similar to E171, tended to yield negative results and that studies using nanosized particles did not show convincing evidence of hazard. Overall, there was limited evidence of genotoxicity for micro or nano sized titanium dioxide.

57. The COT Members agreed with the overall draft COM conclusions on genotoxicity.

Item 9: FCM JEG position statement on Ocean Bound Plastic (accompanied by Reserved background paper) (TOX/2024/15)

58. Professor Boobis declared that he was a nominal Member of the Imperial Network of Excellence on Ocean Plastic Solutions but had not undertaken any activities. No other interests were declared.

59. Dr Emma Bradley and Dr Gill Clare of the FCMJEG were in attendance for this item.

60. In 2021, the FSA became aware of environmental plastic and/or plastic materials intercepted within a certain distance of the ocean, thereby potentially entering the oceans (referred to as ocean bound plastic), being used in food contact applications on the UK market. Colleagues in the FCM policy team sought an initial opinion from the FCMJEG as to whether ocean bound plastic (OBP) could safely be utilised in food packaging, either directly in contact with food or behind a functional barrier. They were especially concerned regarding substances that are mutagenic, carcinogenic or toxic to reproduction (CMR) and whether their absence could be guaranteed.

61. Following discussions held by the FCMJEG in 2021 a draft interim position paper was prepared, which was reviewed by the COT at their meeting in May 2021. This was accompanied by a discussion paper on OBP, providing background on the concept of OBP, its current uses on the UK market, and the potential safety implications for human health. The COT were updated on progress in July 2021. The FCMJEG interim position paper on OBP was published in February 2022.

62. To aid the FCMJEG with their assessment of environmental and OBP, the FSA undertook a call for evidence between March and October 2022, which was

followed by FCMJEG requests for further data from the companies that engaged with the call. Additional companies identified as suppliers of these materials between November 2022 and January 2024, were also contacted for any information they might hold.

63. Paper TOX/2024/15 presented the draft position paper prepared by the FCMJEG. All information submitted to the FSA by end of January 2024 was considered in their evaluation of environmental and OBP.

64.An additional background paper (TOX/2024/15A) was also circulated to the Committee. This provided details on the data received from the call for evidence and the considerations of this data by the FCMJEG. As the information provided was commercially confidential, this background paper was reserved.

65.The Committee asked whether, given the source(s) of environmental and OBP, would it, in general, be possible to obtain the data required to assess the safely of these materials for use in FCMs. It was explained that no recycling process was capable of removing 100% of contamination but the current regulation and requirements for PET recycling processes were based on a large European study conducted several years ago, assessing potential contamination and misuse of PET FCMs. Therefore, the aim of the legislation was to ensure that any remaining contamination was below a level that would raise safety concerns. For environmental and OBP the dataset on potential contamination (i.e. type of contaminants, concentrations) was currently extremely limited. Hence it was unclear whether the current recycling processes were capable of reducing any potential contamination in these materials to sufficiently low (legally required) levels. Members further noted that there remained significant uncertainty over the source of OBP, specifically regarding the degree of environmental exposure.

66. In contrast to recycling of non-PET/other plastics, it is not a requirement for PET recycling operators to routinely test the output material, the onus lies on the manufacturer of the final product. The same applies to non-intentionally added substance (NIAS) testing. However, most recycling operators and manufacturers test their output materials for due diligence purposes and any material used for FCMs has to comply with general food law, ensuring that that any material in contact with food is safe.

67. Members asked whether there was any information on how recycled environmental or OBP used in FCMs would respond to further recycling. It was noted that this was one of the uncertainties and that to date, no data/information on this had been provided. Members noted that the use of OBP in products other

than FCM, where human exposure is of less concern, and hence with different regulatory standards, may be more appropriate.

68. Overall, the COT was content with the position statement of the FCMJEG.

Item 10: Draft 2023 COT Annual Report (TOX/2024/05)

69. This item was postponed from the February 2024 meeting.

70. Paper TOX/2023/05 presented the draft text of the COT section of the 2023 Annual report. It was noted that Members' comments have been incorporated from the previous version shared.

71. Members were invited to comment on the report and to consider how the COT has performed during 2023 against the Good Practice Guidelines for committees advising the FSA, which were attached at Annex 4 to the Annual report. It was agreed that in general, the Committee had performed well against the guidelines, but noted that on occasion there needed to be clarification with respect to problem formulation.

72. Members were asked to send in any additional questions or comments on the document to the Secretariat and to ensure their interests were up to date.

Item 11: Update on the work of other FSA Scientific Advisory Committees - for information (TOX/2024/16)

73. This paper was circulated largely for information and Members were asked to send in any questions or comments to the Secretariat.

Item 12: Any other business

74. There was no other business.

Date of next meeting

75. The next meeting of the Committee will be at 10:00 on the 21st of May 2024 at Broadway House, London and via Microsoft Teams.