Minutes

Final Minutes of the 12th December 2023 COT Meeting

Meeting of the Committee at 10:00 on 12th December 2023 at Broadway House, London and on Microsoft Teams

Present

Chair:	Dr Sarah Judge

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

COT Associate Members:	Professor Jeanette Rotchell
	Dr Samantha Donnellan
	Ms Eimear O'Rourke
	Dr Ben Amies-Cull
	Dr Charlotte Mills
	Dr Tarek Abdelghany
Scientific Advisory Committee on Nutrition (SACN) Liaison	Professor Paul Haggarty

	Ms Cath Mulholland (FSA Scientific Secretary)
	Mr Michael Dickinson
	Dr David Gott
	Dr Alex Cooper
	Ms Claire Potter
	Dr Barbara Doerr
	Dr Olivia Osborne
	Dr Joseph Shavila
	Ms Emma French
	Ms Rhoda Aminu
	Ms Sabrina Thomas
	Dr Gail Drummond
	Ms Cleanncy Hoppie
Food Standards Agency (FSA) Secretariat:	Ms Jocelyn Frimpong-Manso
	Ms Sophy Orphanos
	Dr Gaetana Spedalieri
	Mr Thomas Hornsby
	Dr Emily Hudson
	Mr David Kovacic
	Dr Aaron Bradshaw
	Dr Andrew McClure
	Ms Jessica Cairo
	Dr Lorcan Browne
	Ms Natasha Adams
	Ms Abigail Smith
	Dr Katie Schulz

UK HSA Secretariat:	Ms Britta Gadeberg - (UK HSA Scientific Secretary)
Invited Contractors:	Dr Ruth Bevan - IEH Consulting
	Dr Ovnair Sepai - UKHSA
	Ms Helen Nakeeb - UKHSA
Invited Experts and Assessors	Ms Frances Hill - Department for Business and Trade (DBT)
	Ms Hannah Jones - DBT
	Ms Susannah Brown - Office of Health Improvement and Disparities (OHID)
	Ms Poornima Paramasivan - Health and Safety Executive (HSE)
	Ms Rachel Daniel - HSE
Observers	Mr Erik Prochazka - HSE
	Mr Hugh Mceneny - AgriFood and Biosciences Institute (AFBI)
	Professor Ken Ong - SACN

FSA and other Officials:	Ms Laura-Jayne Quinn - FSA NI Ms Valerie Mcfarlane - FSA NI Mr Dimitrios Maimouliotis - FSA NI Mr Vincent Greenwood - FSA Mr Krystle Boss - Food Standards Scotland (FSS) Ms Lucy Smythe - FSS Dr Marianne James - FSS Ms Rachel Elsom - OHID Ms Annabelle Hill - Department of the Environment, Food and Rural Affairs (DEFRA) Ms Holly Alpren - DEFRA Ms Akosua Adjei - Medicines and Healthcare Products Regulatory (MHRA)

Contents

Announcements

1. The Chair welcomed Members and other attendees.

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 Professors Alan Boobis, Maged Younes and Matthew Wright and Dr Mac Provan. Apologies were also received from Ms Chara Tsoulli of the Secretariat and HSE Assessor, Ms Louise Dearsley.

Item 2: Draft Minutes from the meeting held on 17th of October 2023 (TOX/MIN/2023/06)

4. It was noted that ‘reproductive toxicity’ should be replaced with ‘safety’ in the title of item 9 (Titanium dioxide).

5. The remaining draft minutes and reserved minutes were accepted as an accurate record.’

Item 3: Matters arising from the meeting held on 17th of October 2023

Joint Expert Group (JEG) update

AEJEG

6. The Additives, Enzymes and other Regulated Products JEG (AEJEG) held a meeting in October where two update papers were discussed.

7. The AEJEG working group (WG) for smoke flavourings (SFs) met on the 30th of November; there was a discussion on Quantitative Structure Activity Relationships (QSARs), with a COT Member providing support to the WG in their evaluation of the information on QSARs submitted by the applicants for SF reauthorisation. The EFSA opinions on the re-authorisation of SFs were published recently. These will be reviewed by the Secretariat and circulated for comment in due course.

8. The next AEJEG meeting will be held on the 14th of December and the next SFs WG on the 19th of December where there will be a deep dive discussion of RP1613.

FCM JEG

9. The Food Contact Materials (FCM) JEG met on the 6th December. Three recycling processes were discussed: a new application (RP1898) plus additional information and a draft safety assessment (RP53 and RP94) were presented.

10. The FCM JEG also discussed the next steps in the assessment of Ocean Bound Plastic and the FCM policy team gave the JEG an update on the Novel Technologies audit.

Chemicals Strategy

11. The Government have been developing a cross-government Chemicals Strategy, to frame the work across chemicals and to put the UK on a path for improved chemicals management. The proposed Chemicals Strategy was expected to be sent out by Defra for a targeted informal stakeholder consultation, and further details would be communicated to the Committee when available.

Subgroups

PFAS

12. The per and poly fluorinated alkyl substance (PFAS) subgroup held its second meeting on Friday 8th December where the group continued their consideration of the evidence base for PFAS.

CBD

13. The joint COT/Advisory Committee on Novel Foods and Processes (ACNFP) WG on cannabidiol (CBD) met in early November to continue reviewing CBD products, in particular those with lower proportions of CBD in their composition, along with consideration of the literature on tetrahydrocannabinol (THC).

Plant- Based drinks

14. The draft report of the SACN-COT joint working group on plant-based drinks are covered later in the meeting.

Regulation of food supplements and letter from the Council for Responsible Nutrition - TOX/2023/57

15. No interests were declared.

16. The Council for Responsible Nutrition (CRN), a trade association representing manufacturers and suppliers of food supplements, had contacted the COT Secretariat expressing concerns about the minutes related to an item on novel formulations of supplements from the May 2023 meeting. The minutes stated:

“Supplements exist in a “grey space”, Members suggested, where they are claimed to promote some benefit but do not make direct health claims and hence are currently not covered by specific legislation”.

17. The letter from the CRN setting out their concerns was attached as Annex A in TOX/2023/57. Paper TOX/2023/57 provided background information on the regulation of food supplements.

18. It was noted that the regulation of food supplements was possibly even more complex than set out in the paper, as there were a number of relevant

pieces of legislation and different policy leads involved. The policy lead for food supplements was the responsibility of DHSC in England, the Welsh Government in Wales, Food Standards Scotland in Scotland and in Northern Ireland, the FSA and the Department of Health. The FSA leads on food supplement safety across England, Wales and Northern Ireland. Nutrition and health claims in Great Britain are the responsibility of DHSC. However, claims deemed to be medicinal would be the responsibility of the Medicines and Healthcare Regulatory Agency (MHRA). In addition, supplements deemed to be novel would need to be authorised under novel foods regulations. Food supplements legislation is enforced by local authorities.

19. Members recognised the concerns expressed by the CRN but considered that it was not appropriate to amend the minutes since these accurately reflected the discussion and were not factually incorrect in that context. The minutes of the current meeting would reflect the discussion about the complexity of the topic, this would be relayed to the CRN.

20. In paragraph 6, the wording was potentially confusing, and it was noted that Department of Health in line 6 referred to the Department of Health in Northern Ireland and not the Department of Health and Social Care in England.

Publications

21. The 2022 COT/C/M Annual report has been published.

Item 4: Discussion paper on Risk of emerging marine biotoxins in British shellfish – Pectenotoxin group (TOX/2023/58)

22. No interests were declared.

23. The FSA have been considering the current advice and monitoring programme for marine biotoxins and whether there was a need to update or change existing legislative standards in the UK. The aim of the work was also to identify any emerging marine biotoxin threats in UK waters (see item 5 below). The views of the COT were therefore sought on whether any of these marine biotoxins would pose a risk to human health.

24. Paper TOX/2023/58 provided information and data on the risks to human health associated with consumption of shellfish from UK waters, in relation to the class of marine biotoxins known as pectenotoxins (PTXs). PTXs are a regulated and monitored biotoxin group in the UK. Due to the co-occurrence of PTXs with okadaic acid (OA) and dinophysistoxins, which are linked to Diarrhoetic Shellfish Poisoning, PTXs have been included in the OA-group for the purpose of regulatory limits.

25. The maximum permitted levels for PTXs are stipulated in chapter 7 of Annex 3 in the UK's retained (EC) regulation 853/2004. However, recent amendments to the European Union (EU) legislation regarding the status of PTXs have removed PTXs from the list of monitored biotoxins in EU shellfish. The changes to the regulations are based on the conclusions and recommendations from the European Food Safety Authority's (EFSA) 2009 assessment of PTXs.

26. Paper TOX/2023/58 briefly summarised the main points and recommendations, as well as the relevant literature covered in EFSA's 2009 assessment, along with any publications produced since that time with direct relevance to the potential risk of PTXs to UK consumers.

27. The Committee agreed that the toxicological database for PTXs was limited. Of the existing acute toxicity data, most were rodent studies where PTXs was administered via intraperitoneal injection (i.p.), which was not directly relevant to assessing the risk of intoxication via shellfish consumption in humans. Overall, the Committee found the evidence was sufficient to agree that PTXs had a lower oral toxicity than OA, the toxin group it is currently regulated with. However, Members considered the evidence that PTX-group toxins do not induce diarrhoea inconclusive, with some, but not all, studies reporting diarrhoea after PTXs administration in rodents. Given this and as the PTXs have a different mode of action (MOA), the Committee agree with EFSA that PTXs should not be expressed in OA equivalents.

28. Members highlighted the limited toxicokinetic data for PTXs and agreed that to fully assess the risk of PTXs, further information on toxicokinetics and the rate of metabolism of PTXs, and specifically how it compared to OA-group toxins, would be required.

29. The Committee agreed that there were no confirmed incidents of human PTXs intoxication, but that it was difficult to assess individual cases of suspected PTXs poisoning. PTXs usually co-occur with OA-group toxins and PTXs poisoning events may go underreported as hospitals do not routinely screen for

toxins in cases where people present with shellfish poisoning symptoms. Members considered that a lack of human reports may therefore not necessarily indicate the absence of PTXs intoxication events.

30. Members also noted that there was an absence of data on co-exposure of PTXs with OA, or other toxins but considered that this information was crucial, as it would be rare that people were exposed to PTXs in the absence of other toxins. Members asked whether there was any information available on the combined effect of PTXs and OA, such as a possible synergistic effect as both PTXs and OA have the potential to damage the gut lining and hence absorption. Members also asked whether there was any information on, or considerations of, potential sensitisation and, if the effects of chronic administration had been considered in the literature. The Secretariat confirmed that to their knowledge, no data were available regarding chronic toxicity.

31. Overall, the Committee concluded that based on effects seen in animals, a toxicological risk from exposure to PTXs was plausible, albeit probably low. However due to the lack of toxicological data and occurrence data on PTXs it was currently not possible to determine the extent of any public health risk of PTXs. Members questioned if climate change and the possibility of increasing temperatures in UK waters could lead to an increased occurrence PTXs in UK shellfish.

32. As the EFSA opinion dated from 2009, Members considered it prudent to examine the current monitoring techniques and update where required in light of any new developments in analytical methods, standards and techniques since the original opinion was published.

Item 5: Scoping paper: Advice on the risk to human health from consumption of bivalve molluscs (shellfish) harvested from UK waters associated with marine biotoxins - TOX/2023/59

33. No interests were declared.

34. The FSA have been considering the current advice and monitoring programme for marine biotoxins and whether there was a need to update or change existing legislative standards.

35. The main purpose of this work was to identify any emerging marine biotoxins in UK waters, including consideration of potentially increasing occurrence due to increasing temperatures as a result of climate change. The views of the Committee were sought on whether any of the emerging marine biotoxins would pose a risk to human health.

36. The marine biotoxins discussed in paper TOX/2023/59 were selected based on published assessments and reports on emerging marine biotoxins by other regulatory authorities, as well as a brief literature search. Brief summaries of toxicological information, occurrence data, with an emphasis on UK waters, and any additional relevant information, such as proposed or current limits/monitoring and considerations in other countries were provided, where available.

37. The Committee noted that the scoping paper provided a substantial amount of data on a number of marine toxins, most of which were familiar and had the potential to be very hazardous. However, the potential risk of these toxins depended on the exposure to the toxins, hence the importance of reliable occurrence data. Members therefore enquired whether any of the emerging biotoxins presented were currently monitored in the UK and if so, what levels were being detected in UK shellfish. It was noted that it cannot be excluded that these toxins are already present in UK waters. The Secretariat highlighted that all available information on UK occurrence had been captured in the paper, but would check with policy colleagues whether there were any monitoring or other occurrence data that may have been missed to assist the Committee.

38. Members agreed that data on human intoxication was scarce, either due to limited exposure or underreporting of incidents. The general consensus in the literature or from other regulatory authorities was that human cases were underreported, especially for diarrhetic toxins, as people were unaware that they had eaten contaminated shellfish or their symptoms were not severe enough to require medical assistance. Even in cases where intoxication has been reported, it was often difficult to retrieve samples or identify the exact toxin responsible. Additional information on exposure patterns, i.e. acute, intermittent or chronic, would be useful to identify likely risks where emerging biotoxins were of concern. Members discussed whether screening of patients would be an option.

39. The Committee asked it would be possible to identify some potential toxin threats by investigating the occurrence of algal blooms. It was noted that there was generally little information on the factors influencing the formation of blooms. Members highlighted that sewage has been linked to increased appearance of algae blooms and asked for further information/data on water

quality in the UK, and the potential effects of sewage on rates of algae blooms.

40. In addition to the potential effects of sewage, Members also highlighted that increased nutrients and higher temperatures could lead to the increased presence of algae and subsequently toxin producing algae in UK waters. As climate change could also lead to rapidly changing occurrences of algae and marine biotoxins Members further queried whether there was a need for EU or UK recommendations to monitor these changes and regularly update advice.

41. Most recent information on individual marine toxins was predominantly based on work by the French authorities. Members were therefore interested in the differences between the UK and French diet, as well as a clearer definition of the shellfish included in the review, e.g. bivalves/mussels, crustaceans. The Committee also asked whether any information was available on how much shellfish was excluded from entering the market each year, either due to harvest site closures or reported biotoxin levels above the regulatory limits.

42. Members noted that information on the chronic effects of marine biotoxins was limited.

43. To assist in reaching a conclusion on which of the marine biotoxins discussed would be of potential risk to UK consumers, Members asked for a table to be included, summarising the toxicological endpoints, the lethal doses along with information on occurrence. Ideally the table should also include information on marine biotoxins that are already monitored and regulated to assist with putting the potential risk of these emerging toxins into perspective. It could also prove helpful to identify what criteria need to be fulfilled for a toxin to raise concern and consider how the emerging toxins align with these criteria.

44. Members were not aware of any additional emerging biotoxins.

Item 6: Second Draft Statement on the Safety of Ginger Supplement Use in Pregnancy Ginger (Maternal diet) – TOX/2023/60

45. No interests were declared.

46. In May 2021, the Committee considered the potential effects of ginger and ginger supplements during pregnancy and lactation as part of the current

work programme on the maternal diet being conducted with SACN. Paper TOX/2021/26 reviewed the available data on toxicity to the mother, effects on the development of the fetus or embryo, and possible interactions with drugs as well as data on potential exposure.

47. Overall, it was concluded that there were limited data available on ginger. The human data were not strongly indicative of any significant toxicological concern but there were some indications of possible adverse effects and a lot of uncertainties. Ginger did not appear to be systemically toxic but did appear to have reprotoxic effects at high supplemental doses. The Committee suggested examining the animal data in more detail to determine if a point of departure could be identified to compare against the potential exposure from supplements to determine whether there was any cause for concern.

48. A follow-up paper (TOX/2021/51) provided further information with respect to animal studies, contaminants and exposure to ginger supplements, primarily centred on the effect of ginger on prostaglandins, reproductive and developmental toxicity and the possible contaminants present in ginger. Members noted that although different ginger extracts were not comparable, they did appear to exhibit some biological activity in the early stages of pregnancy. However, it was reiterated that there was no indication of general systemic toxicity from the use of ginger.

49. A draft statement was considered in July 2022, drawing on the information provided in the previous discussion papers to form an overall conclusion on the safety of the use of ginger and in particular ginger supplements in the maternal diet. Members made a number of comments and suggestions to be incorporated into the second draft of the statement.

50. The revised statement (TOX/2023/60) included additional studies identified by the COT to further inform the database on the possible influence of ginger components on cyclooxygenase (COX) and prostaglandin activity. A summary of all the studies considered was also tabulated in Annex B for reference.

51. The Committee asked for an introductory paragraph on the maternal diet to be added to the statement. It was suggested that the NHS’s recommendation on ginger supplement use during pregnancy should also be included for context.

52. The Committee considered there needed to be greater clarity on whether a no observed adverse effect level (NOAEL) or NOAELs could be established for ginger.

53. Members noted that the Norwegian Food Safety Authority have advised against ginger shots during pregnancy and requested for this additional information to be added to the conclusions of the statement.

54. It was highlighted that the statement does not address the physicochemical effects of ginger nor the effect of high doses of ginger combined with fat-soluble vitamins. The Secretariat was also asked to address any potential interaction with anticoagulant drugs such as warfarin and any antihistamine effects directly related to ginger consumption and their implications in pregnancy.

55. The Committee noted that there needed to be a clearer distinction on the different types of ginger (i.e., ginger in the form of food (e.g. biscuits) and food supplements or shots).

56. Members suggested the addition of a paragraph on the rate of spontaneous abortions observed in the *in vivo* toxicological studies and noted that not all of the increases in the incidence of spontaneous abortions were statistically significant: the normal rate for spontaneous abortions should be noted to aid comparison. It was noted that there was no evidence in the UK teratology service database linking ginger shots and fetal malformations.

57. The Committee considered that the median inhibitory concentration values of 10.95 and 53.15 µg/ml discussed in paragraph 22 needed further clarification. The Committee asked for clarification on what the 1 mg/ml value obtained from the Lantz *et al.* study (cited in paragraph 101) referred to.

58. Members also asked for data on studies where the animals had been pre-treated to be omitted to avoid difficulty with interpretation.

59. Members noted that endpoints in adult males had been included as this could indicate potential mechanism, but this needed to be clearly explained as the review was on maternal exposures and end points.

60. The Committee asked for the NHS and NICE references for the statement “1 g ginger per day has been recommended” to be checked to establish what this was based on. Members also questioned the NHS’s recommendations for the use of ginger during pregnancy since anecdotally, reflux

was associated with the use of ginger when reflux was already a common issue for pregnant women. It would be useful to know how this common gastrointestinal side effects would affect appetite and nutrient absorption in pregnant women.

61. Members suggested a number of minor editorial changes to be made throughout the paper.

62. Overall, the Committee stated that the additional information provided did not change their final conclusions that the traditional culinary uses of ginger are not of health concern, but there is some uncertainty on the safety of ginger supplements. Final requests from the Committee were to reflect this difference in separate conclusions for ginger in culinary use and ginger supplements.

63. A third draft of the statement will be presented to the Committee in due course.

Item 7: Bisphenol A

a) Discussion paper/Paper for information: Bisphenol A: The Dutch National Institute for Public Health and the Environment (RIVM), BPA Part 2 TOX/2023/61

64. Professor Thorhallur Ingi Halldórsson 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.

65. Dr Stella Cochrane and Dr Natalie Thatcher declared non personal specific interests, as their employers would have an interest in the use of BPA in packaging.

66. No other interests were declared.

67. Following discussions of the 2023 EFSA re-evaluation of the risks related to bisphenol A (BPA), by the Committee at the September COT meeting, Members enquired about health-based guidance values (HBGVs) established by European or international authorities. The available HBGVs and other relevant information were presented at the October 2023 meeting.

68. One of the authorities which recently (2016) published information on BPA was the Dutch National Institute for Public Health and the Environment (RIVM). Part 1 of their report on BPA was published in 2014, providing an overview of the current state of knowledge about BPA. Part 2 of the report aiming to evaluate the scientific knowledge and discuss possible health risk was not available to the Secretariat at the time. Since then, RIVM has kindly provided the link to Part 2 (Recommendations to risk management) and paper TOX/2023/61 provided a very brief summary of the main points. The Secretariat also drew Members attention to Section 6 of the report which focused on alternatives to BPA.

69. While the Committee considered it useful to have the second part of the RIVM's assessment on BPA, Members noted that the report was from 2016. Hence it did not address either the selection of the critical endpoint nor the approach taken by EFSA. With the report being seven years old, it would have fed into the new EFSA opinion, but it would also be unable to provide answers to the current questions being posed by the COT.

70. Members acknowledged the section on alternatives but did not further discuss the information provided as they have not been given a mandate to consider alternatives to date.

b) Discussion paper: Bisphenol A (BPA): Additional information TOX/2023/62

71. No additional interests were declared to those given above.

72. In April 2023, the European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) established a new tolerable daily intake (TDI) of 0.2 ng BPA/kg bw per day. This new TDI would mean that both mean and high-level consumers of all age groups would exceed the new TDI by 2-3 orders of magnitude.

73. At the September COT meeting, Members enquired about health-based guidance values (HBGVs) established by European or international authorities. The available HBGVs and other relevant information were presented at the October 2023 meeting. Following discussions at that meeting, paper TOX/2023/62 provided information on the derivation of a TDI by EFSA (2023) and by the Bundesinstitut fuer Risikobewertung (BfR) (2023), including detail of the Benchmark Dose (BMD) modelling conducted and the derivation of the human equivalent dose (HED), as well as brief detail on the study selection. However, a

direct comparison of the studies assessed by EFSA and BfR was not included.

74. The Committee reiterated that they did not agree with EFSA's conclusion that the change in Th17 cells would necessarily result in an adverse immune effect/inflammatory response. Hence, Members did not consider it an appropriate endpoint to derive a point of departure and subsequent TDI/HBGV. As stated in their diverging view and assessment, the BfR concurred with this view and instead used reproductive effects, i.e. sperm mobility/mortality in rodents, in their BMD modelling and derivation of a point of departure. This was in agreement with the critical endpoint used in previous COT assessments. The BMD value calculated by the BfR for sperm mobility/mortality was higher than the one EFSA derived for Th17 cells.

75. In addition, both EFSA and the BfR calculated human equivalent dose factors (HEDF) to convert the applied doses in animals to equivalent doses in humans, using toxicokinetic data. Members noted that sufficient data were available on the toxicokinetics of BPA, and while EFSA and the BfR applied the same human data, the animal studies used differed. Hence, EFSA and the BfR derived HED values differing by two orders of magnitude. Members noted that the information, specifically for EFSA's approach was difficult to tease apart but that it was the difference in HED and approaches for the derivation of the TDI that led to the difference in magnitude of the resulting HBGVs. Members would have considered it helpful to be able to see the APROBA spreadsheet and underlying considerations the BfR applied in the IPCS/WHO approach they used for the BMD modelling.

76. Overall, the Committee agreed that while the BfR still added a significant level of conservatism to the derivation of the TDI, the overall assessment avoided unnecessary conservatism. The critical effect applied in the assessment was that used previously in COT assessments. Hence, Members approved the endpoint selected by the BfR and the overall assessment, and the Committee agreed to apply the TDI of 0.2 ug/kg bw per day derived by the BfR as an interim HBGV until they have undertaken their own assessment/can reach a more considered position.

77. The draft position paper discussed at previous meetings would be redrafted to reflect the discussions and conclusions and presented to the Committee at a future meeting.

Item 8: Draft EFSA Opinion EFSA consultation on a draft opinion on risks from polychlorinated naphthalenes in food and feed (TOX/2023/63)

78. No interests were declared.

79. EFSA released a draft opinion on risks from polychlorinated naphthalenes (PCNs) in food and feed, for public consultation. Members were asked to provide comments on the draft opinion to be submitted to EFSA, and also to advise whether they agreed with EFSA's evaluation.

80. Members noted the limited evidence upon which the opinion was based, including the limited occurrence data for the exposure assessments. However, Members largely agreed with the opinion and with the recommendations made. Members agreed that dietary exposures to hexaCNs are not a concern.

81. The recommendations could have been structured in a more logical order, though Members recognised that they were ordered based on the structure of the opinion. Any information on production, environmental persistence and trends in occurrence levels over the last 10-20 years would be useful. One of the recommendations, in recommending non-animal methods, was open ended, and it was noted that recommendations should be made that can be implemented. However, it was recognised that this may be because it is not possible to specify possible new approach methodologies (NAMs) available in the future.

82. While Members agreed that dietary exposures to hexaCNs are not a concern, it was not clear how the conclusion of 99% certainty had been arrived at. Expert knowledge elicitation had been used but some clarity and explanation would be useful.

83. The draft opinion had concluded that it was not possible to carry out risk characterisation of PCNs for any food producing or non-food producing animals exposed via feed because of a lack of studies in these species from which points of departure could be identified. The draft opinion had not attempted to use the toxicology data in laboratory animals to characterise the risks to animals exposed via feed, and the Committee were asked whether they agreed with this, since toxicology data in laboratory animals are used in assessing risks from feed additives by EFSA's Panel on Additives and Products or Substances used in Animal (FEEDAP). Members could not see why the toxicology data in laboratory animals

could not be used, with the application of uncertainty factors, as it is used in human health risk characterisation.

84. Members were asked to provide any additional comments for submitting to EFSA to the Secretariat by 10th January 2024.

Item 9: Plant-based drinks Working Group- first draft report (Reserved). TOX/2023/64

85. No interests were declared.

86. The COT was asked to review an overview of this SACN/COT draft report, which included comments received from SACN from their November 2023 meeting. This draft report was attached as Annex A to Paper TOX/2023/64.

87. The item is currently being treated as reserved.

88. Members reviewed and commented on the first draft report.

Item 10: Draft advice of the AEJEG on steviol glycosides (E 960) produced by fermentation (Rebaudioside M) using Saccharomyces cerevisiae (RP1112) (Reserved) TOX/2023/65

89. No interests were declared.

90. A confidential AEJEG draft opinion paper on steviol glycosides (E 960) produced by fermentation (Rebaudioside M) using Saccharomyces cerevisiae was presented to the COT.

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

92. Members reviewed and commented on the draft paper.

Item 11: Committee Advice on the safety of the Application to Request the approval of 2-

Hydroxy-4 methoxybenzaldehyde for use as a new flavouring substance in or on foods (RP1466) (Reserved) TOX/2023/66

93. No interests were declared.

94. A confidential AEJEG draft opinion paper on the new flavouring 2-Hydroxy-4-methoxybenzaldehyde for use as a flavouring substance in or on foods was presented to the COT.

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

96. Members reviewed and commented on the draft advice.

Item 12: Update on the work of other FSA Scientific Advisory Committees - for information (TOX/2023/67)

97. This paper was circulated for information. Members were asked to send in any questions or comments on the document to the Secretariat.

Item 13: Any other business

98. There was no other business.

Date of next meeting

99. The next meeting of the Committee will be at 10:00 on the 6th of February 2024 on Microsoft Teams.