Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Minutes of the meeting held on Thursday, 1st September 2016 in Aviation House, London.

Present

Chairman:	Professor A Boobis		
Members:	Mr D Bodey Prof J Cade Dr R Crevel Dr M Graham Prof D Harrison Prof R Harrison Prof B Lake Prof I Morris Dr N Plant Prof F Williams		
Food Standards Agency (FSA) Secretariat:	Ms C Mulholland Mr B Maycock Ms H Gbormittah Dr D Benford Dr D Gott Ms F Hill Ms R Acheampong Ms L Buckley Dr D Hedley Dr J Shavila Mr A Sbaiti Ms K Sturgeon	Scientific Secretary	
Public Health England (PHE) Secretariat:	Dr O Sepai	PHE Scientific Secretary	
Invited Experts and Contractors:	Prof P Aggett Dr P Turner (by phone)	SMCN Imperial College London	Item 5-6

	Prof I Kimber	University of Manchester	Item 5-6
Officials:	Elaine Boylan	PHE	Items 5-6
	Michaela Benton	HSE	
	Elizabeth Kendall	FSA Food Allergy Branch	Items 5-6
	Ian Smith	FSA Contaminants	Item 4
	Mark Willis	FSA Additives	Item 4

Assessors:

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Announcements

1. The Chair welcomed Members and visitors to the meeting.

2. The Chair reminded those attending the meeting to declare any commercial or other interests they might have in any of the agenda items.

3. Members were informed that the respected toxicologist Dr Cliff Elcombe, who was a COT Member from 2008 to 2010, had died recently. Members expressed their sadness at this news and asked that their condolences be sent to his widow Barbara,

4. The Chair announced that this would be the last COT meeting for Secretariat member Azmi Sbaiti, who was leaving the FSA to take up another post, and on behalf of Members expressed his thanks for the contribution Azmi had made to papers that had been put before the Committee.

Item 1: Apologies for absence.

5. Apologies were received from Members Dr J Coulson, Dr C Harris, Prof B Houston, Prof R Smith, Dr J Thompson and Dr A Hansell. Apologies were also received from Prof T Gant from PHE.

Item 2: Draft minutes of the meeting held on 5^{h} July 2016.

6. The minutes were agreed with minor amendments.

Item 3: Matters arising.

Item 3: Matters arising from previous meetings

7. Para 5: An update on the COT-Committee on Carcinogenicity (COC) Synthesising Epidemiological Evidence Subgroup was provided. Dr Hansell had produced a draft document based on discussions to date, and further contributions from members of the subgroup were being sought before meeting to discuss a final draft.

8. Para 6: The next meeting of the COT/SACN potassium working group was scheduled for 27th September.

9. Para 8: The finalised addendum to the 2013 COT statement on the potential risks from aluminium in the infant diet had been published, together with a combined lay summary.

10. Para 10: The finalised addendum to the 2013 COT statement on potential risks from lead in the infant diet had been published, together with a combined lay summary.

11. Para 12: First draft statement on the potential risks from arsenic in the diet of infants aged 0 to 12 months and young children aged 1 to 5 years. The statement had been cleared by Chairman's action and had been passed to SMCN for comment. A lay summary would be prepared and circulated to members for comment soon.

Item 5: Scoping paper on the potential risks from electronic nicotine (or non-nicotine) device systems in users and non-users (bystanders): a focused overview-TOX/2016/25.

12. Para 26: A discussion paper would be prepared for a future meeting of the COT.

Item 9: Discussion paper on the results of the 2014 survey of metals and other elements in infant foods-TOX/2016/29.

13. Para 54: A brief discussion paper would be prepared for the October COT meeting.

Item 11: Any other business.

14. Para 67: Shisha (Hookah/water pipe) smoking: a paper setting out the relevant legislation would be prepared for the October COT meeting.

15. Para 69: COT recruitment: The advert for new COT members was launched on 22 July, with a closing date of 16 September. As of 24 August, 5 completed applications had been received. Members were invited to encourage suitable contacts to apply.

Item 4: First draft statement on potential risks from acrylamide in the diet of infants and young children – TOX/2016/31.

16. Dr Benford declared that she had been the Chairperson of the European Food Safety Authority's (EFSA) Panel on Contaminants in the Food Chain (CONTAM) when the scientific opinion on acrylamide had been adopted.

17. A discussion paper was presented to COT in April 2016 and it was agreed that a draft statement should be produced.

18. Members were provided with additional information about the main food groups contributing to dietary exposure, and other sources of exposure. Information was also provided in respect of the COC approach to interpretation of Margins of Exposure (MOEs). This information had been incorporated into the draft statement.

19. Members made a number of comments on the wording and structure of the draft statement. Further clarification on the interpretation of the MOEs that had been derived in the statement was requested.

20. Members were informed that acrylamide had been detected at low levels in uncooked foods in which it was not expected to be present. These levels were unexplained but were possibly due to low level contamination; this would not significantly affect exposure estimates based on the much higher concentrations of acrylamide measured in cooked and processed foods.

21. Following a question by a Member, the Committee were informed about a number of current and future risk management options in respect of acrylamide levels in food, including a code of practice that was being discussed at EU level. Other initiatives included educating consumers and small businesses about ways to reduce levels further. The possibility of modifying plants to reduce one or more precursors of acrylamide was also being explored.

22. It was agreed that that the statement would be finalised by Chairman's action.

Item 5: Third draft statement on the introduction of allergenic foods to the infant diet and influence on the risk of development of atopic outcomes and autoimmune disease (reserved business) – TOX/2016/32.

23. The Chair declared a non-personal, non-specific interest in this item as he is employed at the same institution as the contractors who had performed the review.

24. Professor Ian Kimber was present at the meeting and Dr Paul Turner (Imperial College London) was available via teleconference for the discussion, to provide advice to the Committee on this topic.

25. Members made a number of comments on the wording and structure of the draft statement; it was agreed that a final draft would be cleared by Chairman's action and published to coincide with a paper in the peer reviewed literature, in due course.

26. The final statement and minutes of this item from previous meetings were currently reserved as they included pre-publication data. These would be published as soon as practicable.

Item 6: Second draft statement on evidence regarding maternal and infant dietary exposures and risk of atopic outcomes and autoimmune disease. - (reserved business) - TOX/2016/33.

27. The Chair declared a non-personal, non-specific interest in this item as he is employed at the same institution as the contractors who had performed the review.

28. Professor Ian Kimber was present at the meeting and Dr Paul Turner (Imperial College London) was available via teleconference for the discussion, to provide advice to the Committee on this topic.

29. Members made a number of comments on the wording and structure of the draft statement; it was agreed that a revised draft would be considered at the next meeting.

30. The draft statement and minutes of this item from previous meetings were currently reserved as they included pre-publication data. These would be published as soon as practicable.

Item 7: First draft addendum to the 2015 COT statement on potential risks from PBDEs in the infant diet – TOX/2016/34.

31. The Chair and Dr Benford both declared that they had been members of the EFSA CONTAM panel that had adopted the scientific opinion on PBDEs in 2011.

32. A discussion paper was presented to COT in May 2016 and it was agreed that a draft statement should be produced.

33. Members were provided with additional information regarding levels of environmental PBDEs in European Union countries with particular reference to whether there was any trend for an increase or decrease in levels. This information had been incorporated into the draft statement.

34. Members pointed out that the risk characterisations were only for the four congeners that had reference values and discussed the reasons for BDE-209 being treated differently from the other congeners. They concluded that information on this should be included in the addendum along with some further information on the different types of PBDEs.

35. The EFSA had concluded that for these PBDEs a MOE of greater than 2.5 indicated that there was unlikely to be a health concern; Members noted that this indicated a low level of concern as opposed to a reassurance of safety.

36. Members made a number of comments on the wording and structure of the draft statement.

37. It was agreed that that the statement would be finalised by Chairman's action.

Item 8: First draft addendum to the 2015 COT Statement on potential risks from hexabromocyclododecanes in the infant diet – TOX/2016/35.

38. The Chair and Dr Benford were members of the EFSA CONTAM panel involved in the 2011 EFSA review on hexabromocyclododecanes (HBCDD).

39. This addendum to the 2015 COT statement on the potential risks of HBCDDs in the infant diet was requested by Members following a discussion paper, presented to the Committee in July 2016, which provided estimated HBCDD exposures for children in the UK aged one to five years and also provided an update on exposures for infants aged 0-12 months, as new data on exposure had become available since the 2015 COT statement.

40. Members suggested a number of changes to the text to improve clarity of meaning.

41. Regarding HBCDD exposure via dust and soil, Members requested that the combination of the exposure data from Abdallah *et al* (2008)[1] and Kuang *et al* (2015)[2] be presented as median, maximum and 97.5th percentile values, with the margin of exposure values amended accordingly.

42. A Member brought to the Committee's attention data on HBCDDs in topsoil, showing that the median concentration in soil was lower than that in dust, whereas the assumption used in the assessment was that they were the same. In light of this, Members concluded that the use of the concentrations in dust for both dust and soil was conservative.

[1] Abdallah, M.A., Harrad, S., and Covaci, A. (2008). Hexabromocyclododecanes and tetrabromobisphenol-A in indoor air and dust in Birmingham, UK : implications for human exposure. *Environ Sci Technol*. 42: 6855-61.

[2] Kuang, J., Ma, Y., and Harrad S (2016) Concentrations of "legacy" and novel brominated flame retardants in matched samples of UK kitchen and living room/bedroom dust. *Chemosphere 2016* 148:224-230.

43. Members agreed that the addendum could be finalised by Chairman's action.

Item 9: EFSA consultation on draft guidance document on the use of the benchmark dose in risk assessment – TOX2016/36.

44. Dr Benford declared that she was a member of the EFSA Scientific Committee which produced the draft guidance document, which had been released for public consultation.

45. The Committee was asked if it had any comments it wished to submit to EFSA, and more generally if it had any comments on the benchmark dose approach and its implications for the work of the COT.

46. The draft guidance document was an edited update of the previous EFSA guidance document on benchmark dose modelling which had been published in 2009. The key changes were largely to the methodology, and were primarily on the way that models were used and assessed for goodness of fit; the use of model averaging; and describing how to use either the benchmark dose software (BMDS) developed by the United States Environmental Protection Agency, or PROAST which was developed by the Netherlands National Institute for Public Health and the Environment (RIVM).

47. Members considered the document clear and useful to understand how benchmark dose modelling results were calculated and used. Members recognised that benchmark dose modelling was scientifically superior to the use of the no-observed-adverse-effect-level (NOAEL). However, one advantage of the NOAEL approach was that since the NOAEL had to be one of the dose levels tested, most experts would agree the same value for the NOAEL. Since different benchmark dose models might be used, with different judgements on whether to constrain the models, and different uses of model averaging, different scientific committees and bodies might arrive at different reference points, losing consistency between these committees/bodies. Transparency was needed, and it was pointed out that the draft guidance document provided a template for reporting benchmark dose modelling results.

48. A Member asked whether efforts were continuing to compare NOAELs to benchmark dose lower confidence limits (BMDLs) calculated from the data sets. However, this had been a one-off exercise for production of the original guidance document.

49. The Committee noted the conclusion of the document that study guidelines should be changed to increase the number of dose levels tested without increasing

the total number of animals used in the experiment. It had been argued that no statistical power is lost when using the same number of animals over more dose groups. However, while this was the case for dose-response modelling, the power would be reduced for hazard identification in the case of low potency substances. In addition, if no effects were observed then benchmark dose modelling could not be performed whereas it would still be possible to identify a NOAEL.

50. One Member noted that NOAEL identification was not based only on statistical analysis and expressed the reservation that benchmark dose modelling could become a purely statistical exercise.

51. It was agreed that the Committee itself would not submit a response to the consultation. However, Members were encouraged to respond to the consultation individually if they had any comments.

Item 10: Paper for information: FSA Scientific Advisory Committees (SACs) update – TOX/2016/37.

52. This paper was provided for information only. The Chair commented that GACS was being replaced by a high-level Science Council, although the Chairs of committees were still available for consultation.

Item 11: Any other business

53. Members were informed that Professor Frank Woods who had chaired the COT from 1992- 2002 had died earlier this year. The Chair noted that the COT and the various Working Groups in which Prof Woods had been involved expressed their regret at his passing.

54. Neither the Committee nor the Secretariat had any other business to discuss.

Date of next meeting

55. The next meeting was to be held on Tuesday 25th October 2016 in Conference Rooms 4&5, Aviation House, 125 Kingsway, London, WC2B 6NH.