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

Minutes of the meeting held on Tuesday, 6th December 2016 in Aviation House, London.

Present

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

	Dr Vanessa Garcia-Larsen	Imperial College London	Item 5
	Ken Okona-Mensah	PHE-supported Toxicology Unit, Imperial College London	Items 3 & 8
Officials:	Elizabeth Kendall	FSA Food Allergy Branch	Item 5
	Alastair McArthur	PHE	Items 1-5
	Rachel Elsom	PHE	Items 1-5
	Alette Addison	Department of Health	Item 8
Assessors:	Prof Tim Gant	PHE	
	Michaela Benton	HSE	

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Announcements

1. The Chair welcomed Members and other attendees 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. The Chair announced that this would be the last COT meeting for Secretariat member Lily Buckley, who was leaving the FSA to take up another post, and on behalf of Members expressed his thanks for the contribution Lily had made to papers that had been put before the Committee. The Chair also welcomed back Claire Potter to the Secretariat after her absence on maternity leave.

4. Ms Britta Gadeberg was welcomed as the new PHE Scientific Secretary.

Item 1: Apologies for absence.

5. Apologies were received from Members Dr J Coulson, Prof R Harrison, Dr B Houston, Dr N Plant and Dr A Hansell. Comments were received from Dr Coulson.

Item 2: Draft minutes of the meeting held on 1st September 2016.

6. The minutes were agreed without amendments.

Item 3: Matters arising from the meeting held on 1st September 2016

Item 3: Matters arising from previous meetings

7. Para 7: The COT-COC synthesising epidemiological evidence subgroup (SEES) held its third meeting on Friday 28th October. The group reviewed the draft document that Dr Hansell had produced and circulated to sub-group members for comment in August. It was decided that an updated draft guidance document would be prepared and sent to the COT and COC at the end of February next year, in time for their meetings in March. A fourth SEES meeting would be held in early February so that the updated draft could be discussed before being sent to the Committees.

8. Para 11: The 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 and its lay summary had both been published.

9. Para 15: Interviews for new COT Members would be held over the next couple of weeks.

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

10. Para 22: The Statement had been finalised and the lay summary was in the process of being finalised. It was hoped that both would be published by the end of the week of the meeting.

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

11. Para 37: The draft Statement was still in the process of being amended ahead of being finalised by Chair's action.

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

12. The Statement addendum had been published. The lay summary was in the process of being finalised and was to be published shortly.

- **Shisha Pipes - TOX/2016/43**

13. The Chair declared that he was a members of the WHO Study Group on Tobacco Product Regulation (TobReg).

14. A COT Member had raised the question of whether there were up-to-date risk assessments for shisha smoking, including for neighbours or bystanders who may be exposed to the smoke involuntarily. It was recognised that the pattern of exposure would be more prolonged but less frequent than for cigarettes and may cover people who did not smoke cigarettes as well as those who did. It had been noted that there had been changes to the legislation on tobacco products with effect from May 2016 (the Tobacco and Related Products Regulations 2016). The Committee had presumed that shisha smoking would not be permitted in indoor public areas, as this was a product that was smoked, but that there would be no specific control on the use of shisha outdoors. Members had asked to be provided with an overview at a future meeting on what was and was not legal.

15. TOX/2016/43 contained the Chartered Institute of Environmental Health guidance on Shisha bars. This document was a supplementary guidance for local authority regulatory officers on dealing with non-compliance in Shisha bars. It was intended to support the successful implementation of the smokefree legislation which came into force in England on the 1 July 2007. This document gave a summary of the legislative controls and the health hazards associated with the use of Shisha

Pipes. The Committee had also requested a summary of the available information on exposures from shisha. This would require considerable work and would be addressed when secretariat time allowed.

16. A Member noted that while the guidance document highlighted that the use of a shisha pipe was of longer duration than smoking a cigarette, and thus exposure was higher, the smoking of a shisha pipe would be once per day and was perhaps equivalent in duration to smoking ten cigarettes. Another Member noted concern that shisha smoking might attract people who do not usually smoke.

Item 4: A review of potential risks from iodine in the diets of infants aged 0 – 12 months and children aged 1 to 5 years – TOX/2016/38

17. One Member declared that they were a co-applicant for a Department of Health funded study on iodine in pregnancy.

18. The SACN had been undertaking a review of scientific evidence that would inform the Government's dietary recommendations for infants and young children. The SACN was examining the nutritional basis of the advice. The COT had been asked to review the risks of toxicity from chemicals in the diet of infants, most of which had been completed, and now on young children aged 1 to 5 years.

19. A paper for the 'COT contribution to the SACN review of complementary and young child feeding; proposed scope of work for 1-5 year old children' (TOX/2015/32) had been considered by the Committee in October 2015 and Members had requested further exposure assessments for infants and young children aged 1-5 years for a number of chemicals including iodine. At that meeting the COT decided that a full review of the exposures to iodine should be performed for infants and young children aged 0 to 5 years as a review of the exposures in 0 to 12 month olds had not yet been completed.

20. Members discussed the available data and concluded that the difference between adequate iodine intakes and intakes that may result in effects that could be considered adverse was very small and that there was a lack of good biological markers of excess iodine intake. Caution was therefore required with any advice, as deficiency could cause significant adverse effects on development in young children.

21. Members considered whether it would be appropriate to use the basal metabolic rate to calculate appropriate intakes for children using data from studies in adults. They concluded that there was no strong basis to use anything other than bodyweight to extrapolate from adults to children.

22. The Committee noted that there were differences between the health-based guidance values set by different bodies (European Food Safety Authority, Joint

FAO/WHO Expert Committee on Food Additives and the UK Expert Group on Vitamins and Minerals) and that these differences were likely to be due to a lack of accurate markers of excess iodine and limited data, especially in children. Members concluded that since the end points used to derive the health-based guidance values were relatively minor changes in thyroid hormone levels, this would result in conservative values. Members noted, however, that the implications of suppressed thyroid hormone production in children were as yet unknown. The EFSA Tolerable Upper Level (TUL) was the most conservative of available values and the Committee considered that this would be the most appropriate value with which to compare estimated intakes at this time. However, Members also considered that exposure in the region of 5-17 µg/kg bw/day (the range of health-based guidance values available) would not be expected to cause adverse effects in the majority of infants and young children.

23. The Committee concluded that better data on iodine levels in breastmilk would help to more accurately assess intakes in very young children. Current figures were based on a pooled sample from a small number of mothers whose iodine intakes were not recorded.

24. Members requested that a statement be drafted for consideration at a future meeting.

Item 5: Third draft statement on evidence regarding maternal and infant dietary exposures and risk of ectopic outcomes and autoimmune disease (reserved business) – TOX/2016/39

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

26. Dr Robert Boyle and Dr Vanessa Garcia-Larsen (Imperial College London) were available at the meeting to answer questions on this topic.

27. 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.

28. 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: A review of potential risks from vitamin A in the diets of children aged 1 to 5 years and updated exposures for infants – TOX/2016/40

29. No interests were declared.

30. This topic was part of the review of the risks from chemicals in the infant and young child diet in support of a review by the SACN of Government recommendations on complementary and young child feeding.

31. This discussion paper provided estimates of vitamin A exposures for children in the UK aged 1 to 5 years, and also an updated exposure assessment for infants aged 0 to 12 months. In 2013 (Statement 2013/03) the infant age intervals used for expressing exposure were those from the Diet and Nutrition Survey of Infants and Young Children (DYNSIYC, 2013). However, since individual consumption data had become available from DNSIYC, the infant age ranges had been updated to reflect those in more recent COT papers.

32. Members agreed that the statement would need to explain the basis of the COT setting an infant specific TUL using bulging fontanelles as the endpoint, and why raised intracranial pressure in older children, which would not be apparent from bulging of the fontanelles, as these would have fused by this time, had not been considered as a possible endpoint in this age group. Members considered that hepatotoxicity would be relevant for children aged one to five years, as it had been reported in case reports for that age group, but concluded that there was no suitable TUL for this age group due to the limited data available.

33. Members observed that current Government advice was to limit liver consumption by infants and children but also that all children aged one to five years be given a multivitamin supplement containing vitamin A, which appeared contradictory.

34. Members concluded that an addendum to the statement 2013/03 should be drafted and that the exposure and effects should be discussed without reference to a TUL. Members requested that summaries of the review of hepatotoxicity in adults by the former Scientific Committee on Food (SCF), and the dose and duration reported in the case reports of hypervitaminosis A in children, be included in the addendum.

Item 7: A review of potential risks from nickel in the diets of infants aged 0 – 12 months and children aged 1 to 5 years – TOX/2016/41

35. Dr Diane Benford declared that she had been a member of the EFSA CONTAM panel that had adopted its opinion on nickel in 2015.

36. This topic was part of the review of the risks from chemicals in the infant and young child diet, in support of a review by the SACN of Government recommendations on complementary and young child feeding.

37. This discussion paper provided estimates of nickel exposures for infants and young children in the UK aged 0 to 12 months and 1 to 5 years, respectively. There were currently no Government dietary recommendations for infants and young children which related to nickel.

38. The Committee concluded that the tolerable daily intake (TDI) that had been established by EFSA was not applicable to these age groups because it was based on embryo/fetal toxicity, an effect that is possible only when exposure occurs prior to birth. In order to establish a TDI specific to these age groups, Members requested further information on the results of an existing 3-generation toxicity study and other available multigeneration toxicity studies, particularly on any adverse effects reported in offspring. If there were no adverse effects in offspring observed in these studies then the TDI could be based on systemic toxicity in older animals. Some clarification around the bioavailability of nickel was also requested.

39. In order to determine whether acute exposures should be considered for this age group, Members requested that information be provided on the proportion of infants and young children likely to be pre-sensitised to nickel.

40. The Committee requested that breast milk values for nickel be representative of the whole breastfeeding period and that further consideration be given to concentrations in breast milk to reflect the range of possible estimates of intake.

Item 8: Toxicological evaluation of novel heat-not-burn commercial products: Overview summary of data submitted (reserved business) – TOX/2016/42

41. The Chair, Professor Boobis, declared that he was a member of the WHO TobReg.

42. This item was taken as reserved business as it considered commercially confidential information.

Item 9: Final draft Statement on potassium-based replacements for sodium chloride and sodium-based additives: Revised version – TOX2016/44.

43. Dr Crevel declared a non-personal specific interest in that colleagues in his organisation worked on potassium-based replacements for sodium chloride.

44. In 2013, the Department of Health (DH) asked the Scientific Advisory Committee on Nutrition (SACN) to review current recommendations on the use of potassium-based replacements for sodium chloride and sodium-based additives as part of measures to reduce sodium intakes in the population.

45. The COT was asked by the SACN to advise on the possible adverse effects of increased potassium intakes as a consequence of sodium replacement, since there were concerns regarding vulnerable individuals, notably those with undiagnosed kidney disease who might be at risk of hyperkalaemia-related adverse effects from increased potassium intakes. The COT statement on potassium based replacements for sodium chloride and sodium-based additives was finalised, but not published, in May 2015.

46. As the SACN was reviewing the potential benefits of increasing the use of potassium based replacements for sodium, it was agreed that there should be a formal risk benefit assessment so that unified advice could be given to risk managers. A joint COT/SACN working group was established to undertake this task. It is hoped that the risk benefit assessment report will be considered by the COT and SACN at their February meetings with the final report and accompanying individual committee statements being published in spring 2017. However, as a result of the risk-benefit analysis conducted by the working group, some new data had been identified which could be usefully included in the COT statement. This had resulted in some additional text on the prevalence of hyperkalaemia in different populations and on the potential effects of the rate of increase of serum potassium levels with accompanying references; the estimates of hyperkalaemia prevalence were also updated. The exposure assessment for increasing levels of potassium was also expanded and updated for the joint Working Group report and these more recent estimates have been included in the draft COT statement.

47. Members considered the new text and agreed that it should be included. Members further agreed that the new text did not affect the conclusions that had been drawn previously.

Item 10: Paper for information: FSA Scientific Advisory Committees (SACs) update – TOX/2016/45

48. This paper was provided for information only.

Item 11: Any other business

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

Date of next meeting

50. Date of the next meeting – Tuesday 7th February 2017 in Conference Rooms 4&5, Aviation House, 125 Kingsway, London, WC2B 6NH.