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

Minutes of the meeting held on Tuesday, 8th September 2015 in Aviation House, London.

Present

Chairman:	Professor A Boobis		
Members:	Mr D Bodey		
	Dr R Brimblecombe		
	Dr J Coulson		
	Dr R Crevel		
	Dr C Harris		
	Prof D Harrison		
	Prof B Lake		
	Prof I Morris		
	Dr N Plant		
	Dr J Thompson		
	Prof F Williams		
Food Standards Agency (FSA) Secretariat:	Dr D Benford	Scientific Secretary	
	Ms R Acheampong		
	Ms L Buckley		
	Ms H Gbormittah		
	Dr D Hedley		
	Dr L Kent		
	Ms F Hill		
	Mr B Maycock		
	Ms C Mulholland		
	Ms C Potter		
	Mr A Sbaiti		
Public Health England (PHE) Secretariat:	Ms F Pollitt	Scientific Secretary	
Invited Experts and Contractors:	Dr Robert Boyle	Imperial College London	Items 5-6
	Prof Michael Coleman	Aston University	Item 8
	Dr Vanessa Garcia-Larson	Imperial College London	Items 5-6
	Mr Paul Gregory	Deenside Ltd	Item 8
	Prof Ian Kimber	University of Manchester	Items 5-6
	Dr Marialena Trivella	Oxford University	Items 5-6
	Dr Paul Turner	Imperial College London	Items 5-6

Officials:	Ms Elaine Boylan	PHE	Items 5-6
	Ms Rachel Elsom	PHE	Items 5-6
	Ms Sarah Hardy	FSA, Chemical Contaminants Branch	Items 5-7
	Ms Elizabeth Kendall	FSA, Food Allergy Branch	Items 5-6
	Mr Steven Morris	Department for Environment Food & Rural Affairs	
	Mr Will Munro	Food Standards Scotland (FSS)	
	Ms Susan Pryde	FSS	
Assessors:	Ms Michaela Benton	Health & Safety Executive (HSE)	
	Prof Tim Gant	PHE	

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Announcements

1. The Chairman, Professor Boobis, welcomed Members and assessors to the meeting.

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

3. The Chairman introduced Ms Susan Pryde from Food Standards Scotland (FSS). The FSA was reviewing the Scientific Advisory Committees for which it was the lead sponser. The review of the COT would be led by Ms Pryde and conducted until March 2016.

Item 1: Apologies for absence

4. Apologies had been received from Professors Janet Cade, Roy Harrison, Brian Houston and Robert Smith, and Dr John Thompson. Written comments had been submitted by one Member. Apologies were also received from assessor Sam Fletcher (Veterinary Medicines Directorate).

Item 2: Draft minutes of the meeting held on 30th June 2015 TOX/MIN/2015/03

5. The minutes were agreed without amendment.

Item 3: Matters arising

Item 3: Matters arising from previous meetings

6. Para 7: Members were provided with an update on the conveying of the concerns of the COT regarding inaccurate representations of its conclusions on fume events. The Department for transport (DfT) had apologised and, in future the Department for Transport (DfT) and Civil Aviation Authority (CAA) would clear any further representations of the Committee's advice with the Secretariat and Chair to ensure that they were accurate. The Chair explained that the European Aviation Safety Agency (EASA) had issued two calls for proposals for research on aircraft cabin air, the first for a pilot study assessing contaminants in cabin air and the second for a literature review and chemical testing.

7. Para 8: The Joint COT/Committee on Carcinogenicity (COC) subgroup to review the approaches to epidemiological evidence used by the COT and COC had

held its first meeting on 3rd July. The scope of review had been discussed along with how best to undertake the task. A second meeting had been scheduled for 29th October. The aim was to complete the report within a few months.

8. Para 17: Discussion was still ongoing about how to resolve the Scientific Advisory Committee on Nutrition (SACN) concerns with the draft statement on potassium-based replacements for sodium chloride and sodium-based additives and its implications. Possibly, in addition to the COT Statement in its current form, a risk-benefit analysis was required.

9. Para 18: The finalised statement on the effects of soya consumption on thyroid status would be published once the unpublished data were in the public domain.

Item 7: Histamine in cheese

10. The secretariat had requested additional information from Specialist Cheesemakers' Association (SCA) and the Provision Trade Federation (PTF), who in turn had asked for more detailed incident information from the FSA. This information was being prepared.

Item 12: The EFSA draft guidance document on uncertainty in scientific assessment.

11. This item would be discussed at agenda item 4.

12. No other matters were raised.

Item 4: EFSA consultation on draft guidance document on uncertainty in scientific assessment - TOX/2015/26

13. The Scientific Secretary, Dr Diane Benford, declared that she was a part of the European Food Safety Authority (EFSA) working group that had produced this draft guidance document. Members were content for her to field questions as appropriate. The Chair declared that he had been a partner in a previous FSA-funded research project on this topic.

14. EFSA had published its draft guidance for public consultation on 18th June 2015, with a closing date of 10th September 2015. The draft guidance described a range of approaches to the characterisation and expression of uncertainty, drawing on published work across a number of different areas including and beyond chemical risk assessment. It was recognised that the approach taken would need to be deteremined by the purpose of the (risk) assessment, the nature of the available

data, and the time/resources available. The approaches would be trialled in at least one scientific opinion per EFSA scientific panel prior to finalisation.

15. Because the deadline for submission of responses was only two days after the COT meeting, Members had been asked to provide preliminary comments in advance. The comments received had been incorporated into TOX/2015/26. Members were asked for any further comments. In addition, while the guidance was aimed at the work of EFSA panels and units, the Committee was asked whether it should review its approach to expression of uncertainty, either now, after finalisation of the EFSA guidance, or after EFSA had more experience of applying the guidance.

16. Members considered the document to be well-balanced, describing a range of qualitative and quantitative approaches for the assessment of uncertainty. Concerns were raised about putting specific numbers to certain terms and what the public perception/understanding of these would be, and about how it might sometimes be difficult to explicitly reflect fully the expert judgement that is a vital part of the assessment process.

17. It was noted that the banding of uncertainties assumed a symmetrical distribution, which was very rarely the case, and that high uncertainty meant high risk. In reality, the standard approach to risk assessment was to be conservative. While the draft guidance stated that assessors should avoid using words with risk management connotations, a margin of exposure (MOE) of 10,000 had been agreed as “low concern” as a matter of risk assessment policy. It was also noted that some of the most important uncertainties were often not quantifiable.

18. The COT agreed to revisit the topic to consider whether there should be any changes to how the COT expressed uncertainty once the EFSA guidance had been finalised and experience had been obtained from its application by the Panels.

19. Members agreed that Dr Benford should collate their opinions and feed back to EFSA. An information paper containing the feedback submitted to EFSA would be provided at the COT meeting in October.

Item 5: Review of risks arising from the infant diet and the development of atopic and autoimmune disease: Systematic review C Part I – the role of hydrolysed cows’ milk formula in influencing the development of atopic or autoimmune disease – TOX/2015/24 – RESERVED BUSINESS

20. 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. This was not considered a conflict and Members were content for him to chair this item.

21. This item was considered as reserved business because the results of systematic review C part I had yet to be accepted for publication in the peer reviewed literature.

22. The FSA had commissioned Imperial Consultants to carry out a systematic review of the literature looking at the role of hydrolysed cows' milk formula in influencing the development of atopic and autoimmune disease. This had been carried out alongside, but separate to, three further reviews looking at the infant diet and the development of atopic and autoimmune disease. These had been commissioned in support of the SACN subgroup on Maternal and Child Nutrition (SMCN) review of UK government recommendations on breastfeeding and the introduction of solid foods in the diet.

23. Professor Ian Kimber and Dr Paul Turner were present to provide the Committee with additional expertise on allergic and atopic disease. The contractor who had prepared the review, Dr Robert Boyle from Imperial College London, was also present to advise the Committee, along with his colleagues Dr Vanessa Garcia-Larsen and Dr Marialena Trivella.

Item 6: Review of risks arising from the infant diet and the development of atopic and autoimmune disease: Systematic review C Part II – avoidance or exposure to specific dietary patterns, food groups or nutrients during infancy, pregnancy and lactation and the risk of developing atopic or autoimmune disease (intervention studies) – TOX/2015/25 – RESERVED BUSINESS

30. 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. This was not considered a conflict and Members were content for him to chair this item.

31. This item was taken as reserved business because the results of systematic review C part II had yet to be accepted for publication in the peer reviewed literature.

32. The COT had been asked by the Department of Health (DH) to provide advice on the risks arising from the infant diet that are related to the development of atopic and autoimmune disease. This was in support of a review being undertaken by the SMCN of the UK government recommendations on breastfeeding and the introduction of solid foods in the infant diet.

33. To facilitate the COT assessment, the FSA had commissioned Imperial Consultants to conduct three separate systematic reviews to assess comprehensively and systematically, the existing literature on the relationship

between early dietary exposures and the risk of developing atopic and autoimmune disease. The first of these reviews, which had reported on timing and duration of breastfeeding, had been considered at the COT meeting in June 2015. Systematic review C part II explored the evidence concerning the avoidance or exposure to specific dietary patterns, food groups or nutrients during infancy, pregnancy and lactation and risk of developing atopic and autoimmune disease. The report assessed was on intervention studies. A later report would address observational studies.

34. Professor Ian Kimber and Dr Paul Turner were present to provide the Committee with additional expertise on allergic and atopic disease. The contractor who had prepared the review, Dr Robert Boyle from Imperial College London, was also present to advise the Committee, along with his colleagues Dr Vanessa Garcia-Larsen and Dr Marialena Triella.

Item 7: Final report of the Lead Ammunition Group – TOX/2015/27 – RESERVED BUSINESS

43. Members were informed that Dr Benford was a member of the EFSA CONTAM panel at the time lead was being discussed and that Professor Boobis was the Chair of the lead sub-group.

44. This item was taken as reserved business as the Lead Ammunition Group (LAG) report had not yet been published.

45. The LAG was an independent body which had been established in 2010 to advise the FSA and Defra on the risks to wildlife and to human health of spent lead ammunition. The final report of the LAG had now been received. The COT was asked to comment on the human health aspects of the LAG report; the wildlife aspects of the report were separately being peer-reviewed via Defra.

Item 8: Further submission for a reformulation of PAVA irritant spray – TOX/2015/30 – RESERVED BUSINESS

56. No conflicts of interest were declared.

57. One Member had sent written comments. Paul Gregory, an incapacitant consultant for the applicant, Deenside Ltd., and Professor Michael Coleman, a toxicologist at Aston University who had prepared a risk assessment of the reformulation for the applicant, attended to answer the Committee's questions.

58. This item was reserved business as it contained commercially-sensitive information.

Item 9: Paper for information: Rebuild of the Food Standards Agency Recipes Database – TOX/2015/28

67. This paper was provided for information only.

Item 10: Paper for information: FSA Scientific Advisory Committees (SACs) update – TOX/2015/29

68. This paper was provided for information only.

Item 11: Any other business

69. A poster summarising the COT symposium held in March 2015 had been prepared for presentation at EuroTox 2015. A copy of the poster was tabled. No other business was raised.

Item 12: Date of next meeting

70. Date of next meeting – Tuesday 27th October 2015, Conference Rooms 4&5, Aviation House, 125 Kingsway, London, WC2B 6NH