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

Minutes of the meeting held on Tuesday, 4th February 2014 in Aviation House, London.

Present

Chairman: Professor D Coggon

Members: Mr D Bodey
Dr R Brimblecombe
Dr R Crevel
Dr M Graham
Dr A Hansell
Prof D Harrison
Prof R Harrison
Prof B Houston
Prof B Lake
Prof I Morris
Dr N Plant
Dr J Thompson
Prof F Williams

Food Standards Agency (FSA) Secretariat:
Dr D Benford
Ms H Gbormittah
Ms L Buckley
Mr B Maycock
Ms C Mulholland
Dr D Parker
Mr A Sbaiti
Dr J Shavila

Scientific Secretary
Administrative Secretary

PHE Secretariat: Dr Ovnair Sepai

Invited experts
Professor Glyn Lewis University College London Item 4
Dr Robert Hadden Kings College Hospital Item 4
Dr Brian Stollery University of Bristol Item 4
Professor Keith Palmer University of Southampton Item 4

Officials
Rachel Elsom Public Health England Item 4
Dr Halina Garavini PHE Toxicology Unit, Imperial College Item 4
Ken Okona-Mensah PHE Toxicology Unit, Item 4
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1. The Chairman, Professor Coggon, welcomed Members and assessors to the meeting. He also welcomed Professor Glyn Lewis (University College London), Dr Robert Hadden (Kings College Hospital) Dr Brian Stollery (University of Bristol) and Professor Keith Palmer (University of Southampton), who were members of the working group on organophosphates (OPs). A new member of the secretariat, Ms Lily Buckley, was introduced to the Committee.

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.

**Item 1: Apologies for absence**

3. Apologies had been received from three Members, Professors Cade and Smith and Dr Harris, from Professor Aggett of the Scientific Advisory Committee on Nutrition (SACN), and from the assessors, Dr Gant of Public Health England and Mr Fletcher of the Veterinary Medicines Directorate. Written comments had been submitted by two Members.

**Item 2: Draft minutes of the meeting held on 10 December 2013**

4. The minutes of the 10 December 2013 meeting were agreed subject to minor editorial amendments.

**Item 3: Matters arising**

5. The Chairman reported that he had been interviewed for the television programme Inside Out regarding aircraft cabin air.

*Item 3: Matters arising from previous meetings*

- The draft report on the project on soy phytoestrogens and hypogonadism had still not been received. It was now expected to be available for discussion at the next meeting.

- The draft statements on endosulfan isomers, pentachlorobenzene and chlordécone, on vitamin A, and on soya phytoestrogens in the infant diet were all being finalised. The draft statement on phytoestrogens in the infant diet had been submitted to the SACN’s Maternal and Child Nutrition Subgroup (SMCN) for its comments. Members confirmed that they had no additional comments on the draft vitamin A statement. This would now be finalised by Chairman’s action.
The manuscript on the aspartame study had not yet been accepted by a journal.

**Item 4: Assessment of the adequacy of the 10-fold uncertainty factor to allow for interspecies variation in developmental toxicity**

- A paper was being prepared for discussion at a future meeting.

**Item 5: Potassium salt replacers in vulnerable groups**

- Members clarified that the questions to be addressed were; a) the frequency with which patients who were not previously known to be at risk of hyperkalaemia, present to medical care with serious dysrhythmias attributable to high potassium; and b) the foods in which replacement of sodium by potassium would present particular problems for people with a medical need to follow a low potassium diet.

**Item 8: Third draft statement on potential risks of α-, β- and γ-hexachlorocyclohexanes in the infant diet**

- A fourth draft statement was being prepared for discussion at the next meeting. The Secretariat was awaiting comments from one member.

**Item 4:** Draft statement on long-term neurological, neuropsychological and psychiatric effects of low-level exposure to organophosphates in adults - TOX/2014/01

6. No interests were declared.

7. In September 2012, the Committee had considered a summary of the epidemiological literature on organophosphates (OPs) and neurological (including psychiatric) health outcomes. This had been requested by the Committee when they reviewed research that had been commissioned by Government following recommendations in a 1999 Committee on Toxicity (COT) report on OPs. It also responded to a request from the Advisory Committee on Pesticides. A Working Group of the COT had subsequently been established to evaluate the literature in depth, and to draft a COT statement, focussing on the risk of long-term adverse neurological or neuropsychological effects from exposure to cholinesterase-inhibiting OPs at levels insufficient to cause overt acute toxicity.

8. The Chair welcomed the Members of the Working Group and invited comments on the draft statement.
Mechanisms of toxicity and metabolism

9. It was agreed that more information should be included on other functions of paroxonase and their relation to human health outcomes. The Chairman explained that the statement focused on OPs and did not consider other cholinesterase inhibitors such as carbamates, or other chemicals known to cause OP-induced delayed polyneuropathy (also known as OPIDPN), but which did not inhibit acetylcholinesterase.

Other neurophysiological outcomes

10. The differences between auditory/visual event-related evoked potentials and electroencephalograms should be explained further.

Neuropsychological outcomes

11. Members suggested that there should be a clearer explanation of which studies relating to the Gulf War had been included in the review and on what basis.

Dementia

12. Members agreed that more emphasis should be given to the biological plausibility of effects on Alzheimer’s disease. The differing aetiology of different types of dementia was acknowledged, and it was agreed that the need for further research on OPs and dementia should be stressed, along with the potential value of magnetic resonance imaging as an adjunct to diagnosis.

Other neuropsychiatric symptoms

13. More reference should be made to the evidence for nocebo responses to other environmental exposures.

Conclusions and recommendations

14. The conclusions in paragraph 219 should be expanded. It was agreed that further research was of lower priority than for a number of other public health questions. One Member suggested that more evidence from animal studies should be included in the statement.

15. The statement should note that research to explore the possibility of subtle, minor effects would require studies of adequate size, incorporating rigorous assessment of exposure, and better methods for the assessment of health outcomes than are currently available. The Chairman thanked the members of the Working
Group, and agreed to redraft the conclusions and recommendations and to finalise the statement by email circulation of a version with tracked changes for agreement by Members.

16. A lay summary would be prepared explaining the scope of the statement, and making clear what was meant by “low level exposure”. The Committee considered that there was no urgent need to review potential neurodevelopmental effects of OPs, but this could be reconsidered in the future. The Chairman thanked the Members of the Working Group for their contribution.

**Item 5:** EFSA Consultation on a draft scientific opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: TOX/2014/02

17. No interests were declared by Members.

18. The Scientific Secretary declared that she had participated as a “hearing expert”, representing the EFSA Scientific Committee in several meetings of the EFSA working group which had prepared the draft opinion. She had not drafted any of the text herself, but had been in a position to influence the approach taken. In order to ensure the independence of COT comments on the EFSA opinion, it was agreed that she would be available to answer any questions but would not otherwise contribute to the COT discussion.

19. The Committee was asked to provide comments on the draft opinion, which could then be collated and submitted as a COT response to the consultation.

20. Members considered the draft opinion to be an impressive document, and generally agreed with the conclusions. Discussion focussed on changes that would improve the clarity of the opinion, and the rationale for some of the decisions that had been made in its drafting.

21. The Committee endorsed EFSA’s use of the human equivalent dose (HED) approach to extrapolate from experimental animals to humans, adjusting for the differences in toxicokinetics. A possible criticism was that the plasma Area Under the Curve (AUC) in humans had been estimated using a model, which had some uncertainties. However, the Committee considered that the approach to developing the model had been thorough, and they had no concerns about it. Plasma AUC was considered to be the most relevant dose metric, and preferable to administered dose or maximum blood level. An issue not addressed in detail was whether the lipophilicity of bisphenol A would alter the kinetics of the compound following chronic exposure, specifically with regard to the level of bisphenol A in tissues such as the
brain. Using a physiologically-based pharmacokinetic (PBPK) model, the exposure of any tissue could be considered, but it was not clear if this had been done.

22. It was observed that there was no information in the draft opinion on the chemistry of bisphenol A. Such information had been included in the previously published part of the draft opinion on exposure. The two parts of the opinion needed to be integrated.

23. In general, the Committee supported the weight-of-evidence approach that had been adopted. Six categories of “likeness” had been used to classify possible hazards. Hazards classed as “likely” or “very likely” had been taken forward to the hazard characterisation stage. However, the classification system used was a little unusual, and it was unclear how a hazard would be classified if there was no evidence. Where evidence was inadequate, it might be misleading to classify a hazard as being as “as likely as not”. It was unclear why a classification approach such as that used by the International Agency on Research on Cancer had not been used, which would have included a category for “inadequate evidence”. The opinion should emphasise more strongly that the classification related solely to hazard identification and not to risk assessment, since there was a danger of misinterpretation.

24. A Member noted that the conclusions regarding epidemiological data were appropriate, but the text describing the data was not always consistent with the conclusions. Furthermore in evaluating data from multiple epidemiological studies, the EFSA assessment appeared to have given much greater weight to results from prospective cohort studies than to those from case-control studies, and it was unclear if the coherence of results between studies had been taken into account. A high quality case-control study could provide more useful data than a low quality cohort study, particularly if the exposure assessment in the case-control study was not based on recollection. Furthermore, the text implied that useful information could not be obtained from cross-sectional studies, which was incorrect. The text needed to be more specific about why greater weight had not been given to data from cross-sectional studies.

25. Members had some reservations that the draft opinion had not fully explored the reasons for conflicting results in studies of reproductive effects, both for animal studies and epidemiological studies.

26. Members agreed with the conclusions that liver and kidney effects were “likely”. They broadly supported the conclusion that effects on fetal growth and thyroid function were “not likely”, but there could have been more attempt to understand the discrepancies between studies.
27. Members agreed with the conclusion that neurological and neuroendocrine effects were “not likely”. It was presumed that where the text referred to “no associations” in epidemiological studies it meant “no significant associations”. It would be helpful to provide confidence intervals when summarising the results of epidemiological studies to give an indication of whether the absence of significance could have been because the study was inadequately powered.

28. The Committee agreed with the conclusion that immunological effects were “not likely”. The text of the opinion stated that, based on recent studies, there were indications that bisphenol A exposure may be linked to immunological outcomes in humans. However, the Committee considered that the evidence was inconsistent.

29. It was observed that different epidemiological studies had assessed different cardiovascular outcomes. The Committee agreed with the overall conclusion that cardiovascular effects were “not likely”. However, the description of the epidemiological studies was unclear. The draft EFSA opinion suggested that an association in one prospective study might be due to confounding by diet. It was unclear what was meant by this, and the opinion should be explained which specific aspect(s) of diet might have accounted for the association.

30. The EFSA opinion noted that the analysis of bisphenol A in serum samples in some of the epidemiological studies may have been unreliable due to contamination by leaching from plastic equipment in which they were collected and stored. However, it was not clear whether or how this had been taken into account. The argument about the reliability or otherwise of studies because of contamination of serum samples needed to be made clearer.

31. The Committee agreed with the conclusion that metabolic effects were “not likely”. However, the criticism of cross-sectional studies was considered excessive. In addition, the wording that there was “no convincing evidence” of an obesogenic effect implied that the possibility of a hazard would be dismissed unless the evidence was overwhelming, which was not consistent with the weight of evidence approach that was being taken. Associations should not be dismissed simply because there could be confounding by other chemicals. There needed to be co-exposure to other specific chemicals that could reasonably be expected to cause the effect.

32. The Committee agreed that genotoxicity was “not likely”. Since bisphenol A had produced negative results in tests for mutagenicity, it would be more appropriate for the text to state that “bisphenol A has been shown not to be mutagenic” rather than “bisphenol A has not been shown to be mutagenic”.

33. The Committee agreed with the conclusion that carcinogenicity was “not likely” and that the effects on mammary gland proliferation or differentiation were “likely”. 

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34. The Committee considered the proposed temporary tolerable daily intake was appropriate. The difficulty with benchmark dose (BMD) modelling of the mammary gland hyperplasia was noted. The study had not been designed for dose-response modelling and the wide range of BMDs and BMDLs generated by different models demonstrated that the data were not suitable for such modelling. It would be useful to make clear in the text that there was a wide range in the modelled BMDs as well as in the BMDLs.

35. It was queried why the data for left kidneys and right kidneys had been modelled separately, rather than together using hierarchical methods to account for similarities between two kidneys from the same animal. If that were possible, it might have resulted in tighter confidence limits around the BMD10 and thus a slightly higher BMDL10.

36. A total uncertainty factor of 25 had been used. Members agreed that adjustment of the critical BMDL10 in mice to a human equivalent dose, addressed toxicokinetic variation between mice and humans, and therefore the inter-species factor of 1 for toxicokinetics was appropriate. The factor of 25 comprised a factor of 2.5 for remaining interspecies variation, the component of the default 10-fold uncertainty factor which is assumed to allow for toxicodynamic differences, together with a full 10-fold uncertainty factor for inter-individual variation in the human population. There needed to be discussion of the adequacy of the remaining sub-factors when one of more of the sub-factors was removed from the total default uncertainty factor of 100.

37. It was agreed that the approach to modelling dermal absorption was reasonable and conservative. It was noted that absorption through the fingers may be lower due to a thicker stratum corneum.

38. The Committee discussed the recommendations in the draft EFSA opinion, and agreed that further good-quality research addressing possible non-monotonic dose-response relationships for bisphenol A would be helpful. Further work on dermal absorption, and the metabolism of bisphenol A following dermal absorption, would also be useful. One of the recommendations in the draft EFSA opinion was for further investigation of the toxicokinetics of bisphenol A in mice. The Committee considered that this should be extended to include also further investigation of the toxicokinetics of bisphenol A in humans. PBPK models could be developed to explore the time-course of bisphenol A concentrations in tissues.

39. The Committee concluded that the information in the draft EFSA opinion did not indicate a risk to UK consumers from dietary exposure to bisphenol A. However, the Committee requested confirmation that the exposure data used in the EFSA exposure opinion were relevant to the UK. Members would then consider whether there was a need for additional data on exposure of UK consumers to bisphenol A.
40. In answer to a question from the Food Standards Agency regarding the discussion of uncertainty in the draft EFSA opinion, the Committee responded that the balance of evidence as presented in the draft EFSA opinion suggested an absence of risk. However, there were some uncertainties, the main source of uncertainty being the relevance of proliferative/developmental changes in the mammary gland. This was currently being addressed by a study in the United States.

Item 6: SACN Review of vitamin D: Adverse effects of high levels

41. No interests were declared.

Item 6a: Adverse effects of single high doses of vitamin D - TOX/2014/03

42. The SACN were reviewing Dietary Reference Values for vitamin D and as part of this process, the COT had been asked to consider the potential adverse effects of high intakes. This had been discussed in a number of COT papers considered to date.

43. The SACN Working Group had asked COT to comment on whether any recommendations could be made regarding the safety of single, high doses of vitamin D, which are sometimes used as an alternative to daily dosing where compliance with the latter may be poor. This request was made in the light of a paper by Sanders et al. (JAMA, 303:1815-22, 2010) which suggested that a single annual oral dose of 12,500 µg vitamin D was associated with an increased risk of falls and fractures, largely occurring in the first few months after dosing. Since there were relatively few studies in which single large oral doses of vitamin D had been administered, the paper also summarised data from studies involving single high intra-muscular (i.m.) doses or several high oral or i.m. doses over a short time period. Data from case reports of vitamin D intoxication were also provided, but where dose information was known, exposures appeared to have been considerably higher than the dose used in the study by Sanders and colleagues.

44. It was noted that the study by Sanders used an intention to treat analysis, and that it would have been helpful also to present a per protocol analysis. Although the dose used was non-physiological, the finding of increased falls and fractures was unexpected. It was noted that there were some differences in the baseline characteristics between the treatment groups which, although not significant, could have caused some bias.

45. It was unclear from the paper whether the reported increases in risk were independent of serum calcium. Mean serum calcium concentrations increased in
some of the studies of high dose calcium supplementation but did not exceed the normal range. In contrast, hypercalcaemia was frequently observed in the case reports of vitamin D toxicity.

46. It was suggested that hypercalcaemia might affect muscle strength, and this might explain a relationship of vitamin D with falls. However, it was also possible that vitamin D could affect balance directly.

47. The findings of controlled studies using lower single doses than that studied by Sanders et al. (although still high) were inconsistent, showing both positive and negative associations with fracture risk, or an absence of association in either direction. It was unclear whether these discrepancies occurred by chance or for other reasons.

48. The finding in the study by Sanders et al. that the increased risk of fracture was higher in the first three months after treatment was considered to be plausible but not convincing.

49. Members agreed it would not be possible to establish a safe upper limit for a single dose of vitamin D from the information presented, since findings were too inconsistent. Instead, it might be helpful to set the data that were available on serum 25-hydroxyvitamin D levels following different single doses of vitamin D alongside the steady state serum levels that occurred when daily exposures were close to the proposed Tolerable Upper Level. Members agreed to assist the secretariat with this.

Item 6b: Draft COT conclusions on a tolerable upper level for vitamin D - TOX/2014/04

50. The SACN vitamin D working group secretariat would be preparing a draft report on revised Dietary Reference Values for vitamin D in spring/summer 2014. To assist them with this task, the Committee was asked to consider and agree some provisional conclusions, prior to preparation of a final COT statement. A paper, TOX/2014/04, was provided to the Committee, which summarised the key points of the COT discussions to date, and set out some draft conclusions for consideration.

51. Members discussed the provisional conclusions and made a number of suggestions regarding wording. It was agreed that any conclusions regarding high single doses of vitamin D would need to be reviewed following further examination of data on blood 25-hydroxyvitamin D levels following high doses of vitamin D.

52. The revised document would be made available to the SACN Working Group.
Item 7: Second draft statement on the potential risks from perfluorooctane sulfonate (PFOS) in the infant diet - TOX/2014/05

53. No interested were declared.

54. The Committee discussed a second draft statement on potential risks from perfluorooctane sulfonate (PFOS) in the infant diet. Members indicated that they were content with the overall format and proposed several editorial changes. They sought clarification on the source of the fish from which the data on occurrence that had been considered previously by the EFSA were derived. The levels of PFOS in breast milk had been measured within several European countries and the Committee asked whether any temporal trends were apparent.

55. The Committee requested some clarification of the study by Llorca et al. (2009) concerning infant formulae. Members agreed that the authors of the study should be contacted to establish whether the measurements of “T-PFOS”, would have included precursors as well as PFOS itself. They asked that consideration of PFOS precursors be added to the section on risk characterisation.

56. Once these actions and editorial changes had been completed, the third draft would be sent to SMCN for comments. Depending on the extent of revision required, the statement would then be agreed by chairman’s action or returned to COT for confirmation.

Item 8: Potential future discussion items – horizon scanning

57. Members noted the list of agenda items that were planned or underway for 2014, and discussed several other topics that might also be considered.

*Risks associated with the consumption of Lactobacillus rhamnosus GG (LGG) as a component of fully hydrolysed infant formula by cows’ milk-allergic children under 6 months of age*

58. The FSA had been asked to consider potential risks from the addition of LGG to infant formula, and the proposed claim that consumption would reduce the risk of developing cows’ milk allergy. Members were asked to advise whether it was within the remit of the Committee to assess such risks, and to suggest an alternative Committee if they judged it was not.

59. It was proposed that an ad hoc Working Group be set up to evaluate the evidence for risks and benefits, and that relevant expertise would include allergy, diet, paediatrics and microbiology. The FSA would provide the Secretariat.
Update on Tox21 and ToxCast

60. A brief overview of recent developments in these American initiatives was presented. Members were asked for their thoughts on the topics, which they had considered in previous years. The Committee noted the major challenges faced by the Tox21 project. In particular, there had been poor progress in the integration of metabolism with in vitro assays.

61. The Committee supported the objective of ToxCast to prioritise substances for in vivo testing, which otherwise would not be tested. The Committee indicated that it would welcome a presentation on progress in this area in due course, although it was not considered a priority in the short term. It was noted that PHE would be interested in presenting detailed results of the ToxCast project to the Committee in the future.

Modelling kinetics

62. Recent publications stemming from European-wide cooperation in the areas of physiologically-based toxicokinetic modelling were presented. These covered: available (including freely-available) models; the generation of supporting data for such models; and the use of such models to aid the incorporation of in vitro data into risk assessment.

63. Members had not had experience with the freely-available models but speculated that they may be rather complex for inexperienced users. The Committee agreed that a presentation on developments in the field would be interesting, and that it would be useful if such a presentation provided examples of different methods with their pros and cons. However, this was not viewed as a high priority.

Guidance on COT procedures

64. Members were advised that the sister Committees on Carcinogenicity and Mutagenicity had produced guidance statements on the approaches they follow in risk assessment. Those guidance statements had taken the form of an overall strategy with more detailed guidance on individual aspects published as separate web-based documents.

65. It was noted that in general, the COT follow WHO principles and methods for risk assessment (EHC 240, 2009). They consider a wider variety of questions than the other two Committees, covering more diverse topics, and often have incomplete data on which to draw in making risk assessments. This impacted on the approaches used. Members considered that drawing up guidance statements on their methods might in theory have benefits in transparency and promoting
consistency, but that because of the complexity, the benefits would in practice be limited and insufficient to justify the use of Committee time.

Balance of expertise on the Committee

66. It was noted that the Committee lacked specific expertise in paediatrics, and that this gap had been covered on a case-by-case basis by a Member of SACN. The need for expertise in predictive toxicology and psychology was also considered, but it was agreed that Members had sufficient knowledge to identify when further expertise in these areas was needed on an ad hoc basis.

67. It was noted that the current Chair would be standing down in March 2015, and that it would be helpful for the next Chair to be appointed in time to allow for a period of transition over several meetings.

68. In response to a question about possible FSA research to improve future COT risk assessments, a member had suggested improvements to the food databases used in exposure assessments. The Committee was informed that a project to update the compositional data for recipes was underway and a paper for information would be prepared for a future meeting. As noted in paragraph 16, potential neurodevelopmental effects of OPs would be considered in 2015 as a possible priority.

Item 9: 2013 Annual report of the COT – TOX/2014/07

69. Due to time constraints, members were asked to submit any comments via email. Any issues would be raised at the following meeting

Item 10: Paper for Information: Update on actions taken subsequent to COT advice – TOX/2014/08

70. This was paper was provided for information only

Item 11: Any other business

71. There was no other business.

Item 12: Date of next meeting
72. Date of next meeting – 18 March 2014, Conference Rooms 4 & 5, Aviation House, 125 Kingsway, London WC2 6NH.