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

Minutes of the meeting held on Tuesday 16th May 2017 in Aviation House, London.

Present

Chairman: Professor Alan Boobis

COT Members: Dr Phil Botham

Ms Jane Case Dr Rene Crevel

Professor John Foster

Dr Mark Graham Dr Sarah Judge

Professor Brian Lake

Ms Juliet Rix

Professor Faith Williams

Chair)

Dr Carol Beevers

Dr Gill Clare (also COC)

Professor Shareen Doak Via teleconference

Via teleconference

Ms Phillippa Hardwick

Professor Gareth Jenkins

Professor Francis Martin Dr Michael O'Donovan

Dr Andrew Povey

COC members Professor David Harrison

(COC Chair) Mr Derek Bodey Dr John Doe

Dr Raymond Kemp Professor Neil Pearce Dr Christopher Powell Dr Lesley Rushton

Professor Heather Wallace

Dr Rosemary Waring

Food Standards Ms C Mulholland FSA Scientific Secretary Agency (FSA) Mr B Maycock Secretariat: Ms H Gbormittah Ms F Hill Ms R Acheampong Dr D Hedley Ms K Sturgeon Ms C Potter Public Health England Britta Gadeberg PHE Scientific Secretary (PHE) Secretariat: PHE Scientific Secretary Dr Ovnair Sepai Prof Tim Gant PHE Assessors: Dr Valerie Swaine **HSE** Officials Alastair McArthur PHE Rachel Elsom PHE Dr Tim Marczylo PHE Rosanna O'Connor PHE Martin Dockrell PHE Dave Jones PHE Matthew Birkenshaw DH Other Invited Experts Prof P Aggett **SMCN** and Contractors: Professor Manuel Peitsch Philip Morris International (PMI) Dr Patrick Vanscheeuwijck Dr Serge Maeder Dr Frank Lüdicke Dr Maurice Smith Mark MacGregor Malgorzata Wronowska Andrew Zaman British American Dr Christopher Proctor Tobacco (BAT) Ken Scott Will Hill Vanita Puri **Invited Observers** Deborah Arnott Action on Smoking and Health **Professor Martin Jarvis University College**

Dr Lion Shahab

London (UCL)

UCL

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Announcements

- 1. The Chair welcomed Members and other attendees to the meeting.
- 2. The Chair announced that this was the last meeting for Karen Sturgeon of the COT Secretariat and thanked her for her contribution to the COT. The Chair also updated the Committees on the progress of recovery of Dr Diane Benford and wished her well and sorry that she had been unable to attend this meeting before she leaves the FSA.
- 3. 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 and introduction of new COT members

- 4. Apologies were received from Prof R Harrison, Prof J Cade, Dr J Coulson, Dr J Thompson, Dr M Wright and Dr C Harris of the COT and Dr D Benford, Dr D Gott and Dr J Shavila of the COT Secretariat. Apologies for absence also came from Prof S Warnakulasuriya and Dr P Greaves of the COC and from Prof H Drummond, Prof D Kirkland and Dr S Dean of the COM. Mr Ken Okona-Mensah from Imperial College London (who prepared the discussion paper) also sent apologies. Comments were received from Dr J Coulson
- 5. The Chair pointed out that the COT had a number of new members: Dr Phil Botham, Ms Jane Case, Ms Juliet Rix, Dr Sarah Judge, Prof John Foster and Dr Matthew Wright (absent). The new members present introduced themselves.

Item 2: Draft minutes of the meeting held on 28th March 2017.

- 6. The minutes were agreed with minor amendments and a change of paragraph 6 to read:
- 7. "The subgroup met on 17th March and finalised its conclusions. The COT was updated on the conclusions reached, which will be published in due course."

Item 3: Matters arising from the meeting held on 28th March 2017

- Item 3: Matters arising from previous meetings
- 8. Para 8: PBDE statement. The draft statement on PBDEs had been finalised and was ready to be cleared by Chairman's action.
- 9. Para 11: First draft addendum to the 2013 COT statement on potential risks from vitamin A in the infant diet. This addendum will be finalised shortly.

- 10. Para 12: Potassium based replacements for sodium chloride and sodium based additives. The draft final report of the joint COT/Scientific Advisory Committee on Nutrition (SACN) working group on potassium based replacements is largely complete and will be published along with the accompanying statements from COT and SACN after the General Election.
- 11. Para 15 (reserved business): Draft statement on a new formulation of PAVA irritant spray (reserved business). The draft statement on TW1000 irritant spray had been finalised and will be sent for clearance by Chairman's action.
- Item 4: Reports of the COT-COC Synthesising Epidemiological Evidence Subgroup (SEES) TOX/2017/13
- 12. Para 16: The changes suggested by COT and COC were being incorporated into the document and a revised version will be presented to the Committee at a future meeting.
- Item 5: Discussion paper on the potential risks from cadmium in the diets of infants aged 0 12 months and children aged 1 to 5 years TOX/2017/14
- 13. Para 31: The second draft of the cadmium paper will be discussed at the July COT meeting.
- Item 6: Second draft statement to the potential risks from iodine in the diets of infants aged 0 12 months and children aged 1 to 5 years TOX/2017/15
- 14. Para 39: The draft statement on iodine was awaiting clearance by Chairman's action and will be published shortly.
- Item 7: Second draft addendum to the potential risks from nickel in the diets of infants aged 0 12 months and children aged 1 to 5 years TOX/2017/16
- 15. Para 43: The revised statement will be presented to the Committee at the July meeting.
- Item 8: Updated discussion paper on the result of the 2014 survey of metals and other elements in infant foods TOX2017/18
- 16. Para: 49: The revised statement will be presented to the Committee at the July meeting.
- Item 10: EFSA consultation on draft guidance on the risk assessment of substances present in food intended for infant below 16 weeks of age TOX/2017/17
- 17. Para 55: The Committee's comments were forwarded to EFSA.

- Item 12: EFSA consultation on draft guidance on biological relevance— TOX/2017/20
- 18. Para 66: The Committee's comments were forwarded to EFSA.
- Item 13: EFSA consultation on draft guidance on the use of the weight of evidence approach in scientific assessments TOX/2017/21
- 19. Para 79: The Committee's comments were forwarded to EFSA.

Item 4: Novel tobacco products – joint COT, COM and COC discussion (TOX/2017/25)

- 21. Declarations of interest were made by Professor Alan Boobis (COT) as he is a member of the WHO Study Group on Tobacco Product Regulation (WHO TobReg) and Chair of the ISO TC126 Working Group 10 on an "Intense Smoking Regime". Dr Carol Beevers (COM) declared a non-personal specific interest as her employer has been involved in the mutagenicity testing of these products. Dr Gill Clare (COM and COC) declared a personal specific interest as she may have analysed anonymised slides relating to the mutagenicity testing of these products. Professor Faith Williams (COT) declared a personal non-specific interest as her brother-in-law is a retired senior manager from British American Tobacco. None of these declarations were considered a conflict of interest and all members were able to participate fully in the discussion.
- 22. The COT, with support from COM and COC, had been requested to assess the toxicological risks from novel heat-not-burn tobacco products, and to compare these risks to those from conventional cigarettes. The purpose of the assessment was to provide DH and PHE with a general opinion on the toxicological risks of these types of product, rather than a view on any specific product, and was not intended to address any regulatory function of PHE. At the February 2017 COT meeting, it was agreed that the two manufacturers of these products notified to DH would be invited to present their data to address a list of data requirements collated based on the comments provided by all three Committees.
- 23. The Chairman thanked Members of the COC and COM, the invited observers nominated by Action on Smoking and Health and the two manufacturers for attending.
- 24. The two companies were invited to present separately to the participants at the meeting.

Presentation by manufacturer: Philip Morris International (PMI)

- 25. PMI presented on their product, IQOS, addressing the list of data requested by the Committees.
- 26. The Members asked a number of questions related to the presentation. As this contains commercially confidential information and unpublished data, the minutes are reserved. The publicly available part of the presentation is included in TOX/2017/25.

Presentation by manufacturer 2: British American Tobacco

- 27. BAT presented on their product, iFuse, addressing the list of data requested by the Committees.
- 28. The Members asked a number of questions related to the presentation. As this contains commercially confidential information and unpublished data, the minutes are reserved. The publicly available part of the presentation is included in TOX/2017/25.

Reflections on presentations and question sessions from invited observers

29. The invited observers nominated by Action on Smoking and Health were invited to comment on the presentations and discussions on the heat-not-burn (HNB) products. The observers discussed whether the HNB products were less hazardous than cigarettes and what information or analyses might be useful. As this discussion considered the commercially confidential information and unpublished data presented earlier in the meeting, the minutes are reserved.

COT/COC/COM discussion

- 30. Members of the three committees discussed the data that had been presented. As this discussion considered commercially confidential information and unpublished data, the minutes are reserved.
- 31. A draft statement would be prepared for discussion at the July meeting.

Item 5: Paper for information: FSA Scientific Advisory Committees (SACs) update – TOX/2017/12

32. This paper had been provided for information.

Item 6: Any other business

33. No other business was raised.

Date of next meeting

Tuesday 4th July 2017 in Conference Rooms 4&5, Aviation House, 125 Kingsway, London, WC2B 6NH.