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

Minutes of the meeting held on Tuesday, 22nd October 2019 in Broadway House Conference Centre, Tothill St, London, SW1H 9NQ

Present

Chairman:	Dr John Thompson (Acting Chair)	
COT Members:	Dr Phil Botham	
	Ms Jane Case	
	Dr Stella Cochrane	
	Dr James Coulson	
	Dr Rene Crevel	
	Dr Caroline Harris	
	Professor Gary Hutchison	
	Dr Sarah Judge	
	Dr Gunter Kuhnle	
	Dr David Lovell	
	Dr Mac Provan	
	Ms Juliet Rix	
	Dr Michael Routledge	
	Dr Cheryl Scudamore	
	Dr Natalie Thatcher	
	Professor Faith Williams	
	Professor Maged Younes	
	Prof Paul Haggerty	SACN liaison (via Skype)
Food Standards Agency (FSA) Secretariat:	Ms C Mulholland	FSA Scientific Secretary
	Mr B Maycock	
	Ms F Hill	
	Ms C Potter	
	Dr D Hedley	
	Dr B Dörr	
	Ms C Tsoulli	
	Dr A Cooper	
	Dr O Osborne	
	Ms F Uy	
	Dr. J Shavila	
	Ms S Thomas	
	Ms C Thomas	
	Mr F Lachhman	
Public Health England (PHE) Secretariat	Ms Britta Gadeberg	PHE Scientific Secretary
Assessors:	Dr Tim Gant	PHE
	Natalie Hough	HSE

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Officials:	Selwyn Runacres	FSA
	Mr Alan Dowding	FSA
	Mr Mark Willis	FSA
	Mr Richard Annett	FSA (via Skype)
	Daphne Duval	PHE
	Estella Hung	PHE
	Liam Johnstone	BEIS
Invited Experts and Contractors:	Dr Sarah Bull	WRc
	Dr Kate Vassaux	WRc

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Announcements

1. The Chair welcomed Members and other attendees to the meeting.

2. The Chair introduced Ms Chloe Thomas who has joined the FSA Secretariat as part of the Exposure Assessment Team.

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

4. Apologies were received from the Chair Professor Alan Boobis, and Members Professor John Foster and Professor Matthew Wright.

Item 2: Minutes from the meeting held on 17th September 2019.

5. The Minutes were accepted as an accurate record subject to the following minor changes:

Ms Juliet Rix was added to the attendance list.

Paragraph 33. Members agreed minor rewording of the final sentence to ensure clarity.

Item 3: Matters arising from the meeting held on 17th September 2019

Paragraph 17 -COT workshop - March 2020.

6. Members were informed that the March COT meeting and COT workshop would take place on 10th and 11th March at the Manchester Conference Centre and Pendulum hotel. The workshop would cover PBPK modelling and potency estimation. More details would be provided in the near future.

Paragraph 20 - Statement on phosphate-based fire retardants.

7. The Committee was informed that the statement on phosphate-based fire retardants had been published.

Update from the Committee on Mutagenicity Meeting (COM)

8. Three topics referred by the COT had been presented by the FSA Secretariat at the COM meeting held on the 10th of October. These were: “Review of

Genotoxicity of Cannabidiol", "Review of Genotoxicity of Patulin" and "Risks to human health from the use of a food additive not currently permitted in the UK (Reserved Business)." The COT would be updated on these topics once the minutes were available.

Item 4: Review of potential risks from contamination in the diet of infants aged 0 to 12 months and children aged 1 to 5 years: Mycotoxins – Aflatoxin (additional information and EFSA public consultation) -TOX/2019/56

9. A Member provided written comments.

10. Dr Michael Routledge declared an interest having been part of the EFSA working group on aflatoxins. Since this was not a commercial interest, he was free to contribute to the discussion

11. As part of the ongoing work by the COT on contaminants in the diet of infants and young children aged 0 to 5 years of age, a paper on mycotoxins was discussed at the September meeting. As a result of this discussion, Members requested some additional information on aflatoxins regarding cancer potency in newborns and adults by the same route of administration, as well as quantitative data on the activation of aflatoxins by liver fraction from newborns and adults.

12. It was noted by Members that there was surprisingly little toxicokinetic information available on aflatoxins and that the majority focused on activation with little information on detoxification being available.

13. The Committee noted that there was a potential for different susceptibility to aflatoxins in children compared to adults, however, the currently available data did not allow any conclusions to be drawn on the magnitude of any such difference. The Committee asked for these uncertainties to be reflected in the subsequent text in the Addendum.

14. Members also asked for more detail on the MOEs and a more detailed risk characterisation in the final text for the Addendum.

15. The Committee was made aware of EFSA's public consultation on the risk to public health related to the presence of aflatoxins in food and were provided with a brief summary of the new data/information as well as differences from the previous assessment. Members noted that little had changed since the last risk assessment provided by EFSA.

16. Members were asked to provide any written comments they might have om the EFSA document to the Secretariat by the 31st of October 2019.

Item 5: Toxicological interactions between xenobiotics and the human microbiota – a scoping paper - TOX/2019/57

17. A member provided written comments.

18. Professor Boobis declared that he regularly participated/chaired meetings of the JECFA veterinary residues committee and had contributed to the development of the decision tree for assessing the antimicrobial effects of residues of veterinary drugs. Since this was not a commercial interest, his comments on the paper were discussed and incorporated into the minutes as appropriate.

19. The paper summarised recent data on the effects of xenobiotics (metals, pesticides, organic contaminants and food additives and components) on the structure and function of the microbial community in the digestive tract of, largely, experimental animals, and the effects of the microbiota on ingested xenobiotics. A few examples of how effects on the gut microbiota might be considered in the risk assessment for oral exposure to xenobiotics were also given.

20. Regarding the possibility of extending the establishment of microbiological ADI values beyond veterinary drugs, Members discussed the possibility of extrapolating from animal data to human responses, given the variability of the microbial populations between individuals, let alone between species. Being able to develop a model for the behaviour of the fluctuations in the GI microbiota that would differentiate between adaptive and toxicological responses would be challenging. The concept of microbiological health-based guidance values (HBGVs) had been extended to pesticides at the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), although for many compounds there was a lack of any relevant information. At least the two key endpoints should be considered: disruption of the intestinal colonisation barrier and selection of drug resistant species, for all chemicals. Careful consideration needed to be given not only to microbial sensitivity but also to how much of the chemical would be bioavailable to the microbial population, particularly at environmentally/dietary relevant levels, since many would be absorbed to a greater or lesser extent in the small intestine.

21. The Committee also contemplated the potential for the use of selected probiotic species to mitigate the toxicity of xenobiotics in humans. Some Members questioned the need for this, due to the paucity of evidence that probiotics were effective in modifying the population structure of the gut microbiota. The Chair pointed out that a number of products were marketed on their purported ability to do this, particularly in the case of “resetting” the gut flora in children with diarrhoea. The Committee regarded this as a potential attempt to promote the purchase of these products and blurred the line between food and medicinal use, which would require precise wording to clarify. On the basis of current knowledge and the probiotics available, this use would seem unlikely.

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22. The Committee decided that long-term prospective studies across different age groups would be required to address effects of xenobiotics on the human microbiota. These studies would have to target specific parts of the GI tract since the composition of the flora varied naturally along its length. Another option would be to identify individual metabolic pathways that might be disrupted or specific microbial species, although this would reveal only a small part of the interactions that could potentially occur. A Member suggested that the later-life health consequences of caesarean section birth relative to vaginal birth could be amenable to research.

23. The Committee agreed for a statement to be prepared as an overview of the current state of knowledge in this area, with an emphasis on relevance to humans. It would need to highlight where the knowledge gaps were and critically address the extent to which the literature might apply to the work of the COT.

Item 6: Potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes)

a) Paper 10d: Toxicity assessment of flavourings used in E(N)NDS: Menthone -TOX/2019/58

24. Professor Maged Younes stated he is the Chair of the Panel on Food Additives and Flavourings Food Additives and Flavours at EFSA, but it was agreed that did not prevent him being involved in the discussion of this item. No further declarations of interest were presented in addition to those already declared at the meeting in December 2018.

25. Paper TOX/2019/58 presented the limited amount of published data available on the toxicity of menthone via inhalation exposure. Only the predominant types of menthone; L-menthone and D-menthone were addressed in this paper.

26. The Committee commented that there was an absence of data on acute toxicity, a lack of knowledge on potential reproductive effects similar to that discussed for menthol at the previous meeting, and very limited data on immunotoxic effects. The Committee highlighted that the biggest data gap was repeat dose inhalation toxicity studies.

27. It was noted that the positive Ames test result obtained in the 1984 study by Andersen and Jensen[1], described in paragraph 31, was not repeated in a study conducted in 2018[2].

[1] Andersen, P.H. and Jensen, N.J. (1984) Mutagenic investigation of peppermint oil in the Salmonella/mammalian-microsome test. Mutation Research/Genetic Toxicology, 138, 17-20.
[2] Unnamed study report, 2012 cited in ECHA (2019a) REACH registration dossier. L-Menthone *https://echa.europa.eu/registration-dossier/-/registered-dossier/12246/1 Accessed September 2019*.

28. Clarification was provided on the differences between CLP and REACH and it was suggested to add a more detailed explanation on this in paragraph 49. It was confirmed that CLP self-classification was based on manufacturer and importer opinions and that no classification agreed by EU Member States had been produced.

29. The Committee suggested that all flavourings should be assessed using the framework for risk assessment of flavouring compounds via inhalation exposure (awaiting publication - see TOX/2019/49).

30. Finally, the Committee noted that a large number of people are now using E(N)NDS which could provide useful information on the potential health effects of exposure to E(N)NDS, rather than relying on animal data.

b) Potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes). Follow up to paper 13: Tabulation of user exposure -TOX/2019/59

31. Paper TOX/2019/59 presented a tabulation of user exposure to the constituent ingredients present within E(N)NDS focussed on the highest mean and lowest exposure values previously reported in TOX/2019/39.

32. It was noted that the available data were highly variable and inconsistent across the scientific literature. Subsequently, more standardisation in the experimental methodology was recommended to facilitate comparisons between different study reports and across products.

33. It was agreed that there needed to be better quantification of E(N)NDS user exposure to the basic ingredients in order to assess the health risk better. The inhalational exposures calculated from E(N)NDS use generally exceeded the available guideline values for the constituent ingredients. The relevance and limitations of comparing E(N)NDS user exposures that would occur over a long-term, as short duration individual peak exposures, to the guideline values which were based on continuous exposure were discussed. It was suggested that a pharmacokinetic approach could be used of calculating the maximum plasma concentration (Cmax) and the area under the concentration-time curve (AUC) to assess which better reflects the exposure and predicts potential health-based outcomes. Based on the available information in the published literature and the uncertainties over the real-world human exposure profile, any statement would need to flag that there could be a potential for health effects.

34. It was noted that PBPK models were available through the U.S. EPA for pesticide crop sprayers which had been developed for assessing short-term intermittent human exposures; these could be helpful for assessing exposure of E(N)NDS users. It was suggested that these matters could be further discussed at

the potency/PBPK workshop scheduled for March 2020, and additionally what the key data requirements might be for existing models.

35. An outline of the MHRA notification process was provided. E(N)NDS do not need to be registered as medical devices but fall under “tobacco-related products” regulation and require notification. There was no legislative requirement for manufacturers of E(N)NDS to conduct toxicology research on the constituent ingredients, but instead to review the current scientific literature on all ingredients, though this literature was sparse. They are required to report the ingredients and to conduct emissions testing, however the results vary considerably due to different set up conditions for the products and as some e-cigarette devices are customisable. Subsequently, it is difficult to ascertain what typical user exposure would be.

36. For the upcoming draft statement, the Committee agreed that the following aspects should be covered: standardised testing, including standard coils, heating temperature where feasible but accepting continuing product development as well as user customisation of devices; utilising the cohort of data on existing users and obtaining more real-world human exposure data; the need to consider information becoming available from North America on the health effects seen there; the uncertainties of differences in exposures between proprietary products and customisable devices where home mixing of fluids is utilised, including noting potential for use of illicit substances; and all of which would be need to be as a balanced discussion compared to ongoing smoking. Finally, it would be important to be clear to the public what the safety of these devices was and to keep a watching brief on information on any increase in *de novo* use.

c) Follow-up to Literature update to mid-2019 – further details of publications in TOX/2019/50 (TOX/2019/60)

37. At the COT meeting in September this year, the Committee discussed publication abstracts, providing an update on the literature relating to the potential toxicological risk from E(N)NDS (TOX/2019/50). The paper presented at this meeting (TOX/2019/60) provided summaries of ten papers, for which the Committee had requested more detail, including information on the choice of liquids tested (Angerer et al., 2019), second-hand aerosol exposure (Bayky et al., 2019) and on the combination of CC and E(N)NDS (Osei et al., 2019).

38. The Committee were informed that the choice of liquids tested in the Angerer et al. 2019 paper was purely based on the availability of liquids from the vendor and the Committee noted that some contained synthetic cannabinoids. Members noted that in paragraph 6, endotoxin and glucan presence was reported as above the LOD in some samples, but no actual concentrations were provided nor what the LOD was.

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39. The Committee also noted that the levels of toxic metals reported were below the respective guidelines, however that the exposures could not be separated from the overall inhalation exposure. Members noted that as discussed earlier in the meeting, pesticide inhalation modelling approaches could be useful to apply in these scenarios to look at the exposure from all the different components.

40. A discussion was held about the quality of the epidemiological studies and Members noted that dual use of CC and E(N)NDS may have more severe adverse effects, such as cardiovascular effects, than E(N)NDS alone. Members furthermore queried if there was any information regarding the duration of dual use, especially in light of attempting to quit smoking. Members were informed that approximately 40% of users are dual users, however that the levels were declining. The Committee concluded, information on real world use and combined use of CC and E(N)NDS as well as general habits of individuals were areas of interest and where further studies/publications would be useful.

41. With respect to developmental effects, the NHS currently recommended quitting smoking entirely during pregnancy or alternatively using nicotine replacement therapy. However, ENDS were noted to be a safer option than continuing to smoke. The Committee noted that additional reproductive studies/publications would be useful as there is very limited information available to support this advice.

42. There were large evidence gaps within the literature/information available and this is reflected in the different policies on E(N)NDS across different countries. Members discussed that it might be useful to inform the public just how little is known, even if no direct conclusions could be drawn.

43. The Committee agreed that the information and science relating to E(N)NDS is changing rapidly and therefore the statement on E(N)NDS when published would need to be revisited on a regular basis, so advice given to the general public would be as up to date with current information as possible.

44. Since preparing the paper for this meeting, the Secretariat had become aware of a more recent paper on induction of lung adenocarcinoma and bladder urothelial hyperplasia in mice. The Committee asked for COC to review this and provide an opinion.

Item 7: Introduction to the discussion paper for the development of methods for potency estimation- TOX/2019/61

45. Dr Stella Cochrane stated that her company was undertaking a lot of work in this area and had just held a workshop for which there may be potential commercial interest for developing methods. This was considered to be a specific non-personal interest and did not prevent her contributing to the discussion of this item. No other interests were declared.

46. Members were informed that paper TOX/2019/61 was an introduction to the forthcoming scoping paper planned for December which would review various potency estimation methods as well as previewing the planned COT combined workshop with PBPK modelling in March 2020.

47. Potency estimates can be used to directly compare chemical profiles and prioritize modelling and association mapping. These would be important in risk assessment scenarios where limited or no specific information is available on the toxicity of a chemical.

48. The Committee was reminded that in 2009, they had held a workshop on 21st century toxicology which had addressed the United States (US) National Academy report “Toxicity Testing in the 21st Century: A Vision and a Strategy”. The report called for accelerated development and adoption of human cell *in vitro* and *in silico* methods for the prediction of hazards, the determination of mechanistic information, and the integration of data. The report had set out a 10-20 year strategy in which the goal would be to develop and validate toxicological protocols that enable predictions of human responses to chemicals in a high-throughput and cost-effective manner, with a reduction in the use of experimental animals. The Committee agreed that as it was now half way through the period covered by the vision and strategy, it would be apt to review the current methodologies available and how they might be applied in case studies as well as applied in risk assessment.

49. The Committee agreed that a tiered testing approach, read across, Quantitative Structure Activity Relationships (QSARs) including nano-QSARs (QSARs for nanomaterials), chemical prioritisation through high throughput screening (HTS), organ on a chip as well as free dose/fixed dose *in vitro* should be included in the paper.

50. It was noted that there was a lack of metabolic capacity in the almost all *in vitro* tests and that what default assumptions could be made and what tools were available to overcome this limitation should be considered.

51. The Committee emphasised that *in vitro* extrapolations to organs in situ would have to be carefully considered due to changing factors such as exposure time and the media used.

52. Some speakers for the March workshop were suggested by the Committee as well as topics for discussion such as adverse outcome pathways, PBPK in food matrices and method validation.

Item 8: Review of the potential risks from α-, β- and γ-hexachlorocyclohexanes in the diet of children aged 1-5 years TOX/2019/53

53. Dr Sarah Judge declared that she had released a publication on lindane 3 years ago that was not commercially funded. Since this was not a commercial interest it did not prevent her contributing to the discussion. No other interests were declared.

54. This paper followed an earlier COT paper; TOX/2014/12 and reviewed the risk of toxicity of hexachlorocyclohexanes (HCHs) in the diets of children aged 1-5 years addressing changes in HBGVs, exposure and toxicity data.

55. Members made a number of suggestions on the content of Table 4 to improve clarity.

56. It was suggested that it would be helpful to explain how the Brouwer et al[3]., 2017 study cited in paragraph 11 was performed, whilst acknowledging issues with the epidemiological methodology.

57. The committee questioned why a worst-case scenario using both maximum and 97.5th percentile levels were not used in the exposure assessment, as done in the earlier COT statement. The exposure assessment team clarified that a worst-case scenario was not used in this current review, as breast milk feeding was not exclusive for the age group being assessed (i.e. children aged 1-5 years), whereas the previous COT statement assessed infants aged 0-12 months, for whom breast milk feeding was exclusive.

58. Members requested confirmation on the age ranges of children used in the GEMS/cluster diets.

59. The committee commented that β-HCH levels in breast milk had an unusual distribution; the Kalanatiz et al., 2004 study cited in the earlier COT statement demonstrated this unusual distribution, with one participant's breast milk containing high levels of β-HCH and skewing the data. The committee recommended that this

[3] Brouwer, M., Huss, A., van der Mark, M., Nijssen, P.C., Mulleners, W.M., Sas, A.M., Van Laar, T., de Snoo, G.R., Kromhout, H. and Vermeulen, R.C. (2017). Environmental exposure to pesticides and the risk of Parkinson's disease in the Netherlands. *Environment international*. 107:100-110.

observation should be included in the current review as it might influence risk assessment outcomes.

60. Members noted that the conclusion in this review might differ from those on β-HCH in breast milk presented in the earlier risk assessment; TOX/2014/12.

61. It was also commented that use of the NOAEL given in paragraph 55 in the risk characterisation of β-HCH could be conservative.

62. The Committee also suggested including information on the historical decline of the use of HCHs in the final statement.

63. The committee considered it sufficient to include the key points of the paper in the addendum to the overarching statement and agreed that HCHs were not of toxicological concern.

Item 9: Scoping paper on the potential risks from exposure to microplastics- TOX/2019/62

64. A Member provided written comments for this item. Professor Booobis declared a personal non-specific interest as he was a member of a WHO expert group undertaking an assessment of the human health risks to micro- and nano-plastic particles, as a follow-up to their drinking water assessment. He was also involved in an ILSI Europe-convened round table discussion to identify data gaps in the assessment of the risk to human health of microplastics. No other interests were declared.

65. The importance of good physicochemical property data of micro- and nanoplastics, as well as the necessity to generate a more refined exposure dataset were discussed. It was acknowledged that for both data requirements, existing methodology was not readily available, and in terms of generating good exposure data sets, gathering information on total dietary intake of microplastics would be difficult.

66. It was highlighted that exposure to microplastics via inhalation might be easier to assess compared to oral exposure as occupational data from synthetic textile workers were available, however, the context should be considered. The concentrations present in food and water, compared to airborne exposure to microplastics was thought to be lower.

67. Based on the available data, it was considered that microplastic exposure via oral exposure did not indicate a concern for human health. Similarly, based on the available data, adsorbed compounds on microplastics, did not seem likely to pose a health concern to humans via the dietary route as the concentrations involved would

be low. Chemicals leaching from microplastics could originate from other sources and not just microplastics alone, therefore their contribution to the overall exposure may range from not of significance – to a level that would cause adverse human health effects.

68. In terms of nanoplastics, it was asked whether there were existing pathophysiological data on human health – as these would provide better understanding on molecular interactions and which cells and organs were sensitive. However, proving an organ level effect was difficult. Furthermore, *in vitro* to *in vivo* extrapolation had limitations and conclusions were often non-transferrable.

69. It was noted that there was a great variability in the definition of microplastics and to define this would be a challenge However, it was acknowledged that in the context of nanomaterials in food, a definition has been set out by the EFSA.

70. It was proposed that an initial risk assessment could be based on microplastic exposure from tyre wear. The Committee expressed a preference for UK data in risk assessment models. However, if unavailable, non-UK data with the appropriate conversion factors if needed would be considered appropriate.

71. The Committee agreed that a risk assessment could not currently be performed due to the lack of relevant human or related data.

72. The Committee agreed that a draft statement should be prepared by the Secretariat, highlighting other sources of exposure and key research needs.

Item 10: Risk assessment of residues of a group of veterinary products - TOX/2019/63 (Reserved Business)

73. Dr Thompson declared that he was a member of the Veterinary Products Committee at the time it adopted its report on these veterinary products in 2006. Professor Boobis declared that was a member of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) when it evaluated some of these veterinary products in 2000-2008. No other interests were declared.

74. This item was discussed as Reserved Business.

Item 11: Review of potential risks from cyclopiazonic acid in the diet of infants aged 0 to 12 months and children aged 1 to 5 years- TOX/2019/64

75. No interests were declared.

76. This discussion paper formed part of the ongoing work on the diets of infants and young child feeding. A scoping paper (TOX/2015/32) “COT contribution to Scientific Advisory Committee on Nutrition (SACN) review of complementary and young child feeding; proposed scope of work for 1-5 year old children” was reviewed by the COT in 2015. A further scoping paper on mycotoxins was presented to the COT in 2017 and an initial discussion paper on cyclopiazonic acid (CPA) (TOX/2019/18) was reviewed in May 2019.

77. The Committee discussed the use of the Nuehring et al. (1985) study, in which dogs were treated for 90 days with CPA, as the possible basis of the margin of exposure (MOE) for risk characterisation with Members having some concerns about the quality of the study. A study by Lomax et al. (1984) was available, however this was only a 14-day study. The difference in NOAEL values between these two studies was 10-fold. A third study by Voss et al. (1990) was also considered. The NOAEL in this 13-week study in SD rats was 0.2 mg/kg bw/day, which was very similar to that of the Nuehring et al. study (0.1 mg/kg bw/day). Due to the similar NOAEL values from the Voss et al. and the Nuehring et al. study, the Committee agreed that UK exposures could be compared to the NOAEL from the Nuehring et al. study as the basis of the MOE approach.

78. Members agreed that given the toxicological profile of this compound, an MOE of 1000 or more using the above NOAEL should be adequate to provide assurance of low toxicological concern.

79. CPA will be added to the “Draft Addendum to the Overarching Statement on the potential risks from contaminants in the diet of infants aged 0 to 12 months and children aged 1 to 5 years”. This would be presented at the December meeting.

Item 12: Discussion paper on soya drink consumption in children aged 6 months to 5 years of age -TOX/2019/65

80. No interests were declared.

81. Soya drinks are a popular alternative to dairy products and their use is becoming more widespread. The Department of Health and Social Care (DHSC), Public Health England (PHE) and the FSA are receiving an increasing number of enquiries regarding the use of plant-based drinks in the diets of infants and young children. Therefore, the COT were asked to consider the potential health effects of soya drinks in the diets of children aged 6 months to 5 years of age.

82. Soya products contain isoflavones, which are phytoestrogens, and they have been shown to have development and reproductive effects in animal studies, although human epidemiological studies have not produced conclusive results. The COT considered the safety of soya phytoestrogens in 2003 and in 2013. In the

statement from 2013, the Committee concluded that there was no substantive medical need for, nor health benefit arising from, the use of soya-based infant formula and it should only be used in exceptional circumstances to ensure adequate nutrition.

83. Levels of phytoestrogens in soya-based infant formula and soya drinks although variable are comparable, but with soya drinks generally having higher levels.

84. The WHO state that soya-based drinks are unsuitable as a major source of nutrients in non-breastfed children aged 6-24 months of age and therefore Members were asked to consider differences between this population group and those aged 2 to 5 years of age.

85. The Committee identified a more relevant source of information on isoflavone levels in foods than that used in the discussion paper and so the secretariat agreed to recalculate the potential exposures and bring a revised paper back to the Committee in December. Concerns were raised about wider soya consumption and therefore a broader range of food sources would be presented in the revised exposure assessment.

Item 13: Update paper for information: FSA Scientific Advisory Committees (SACs) – TOX/2019/66

86. This paper was tabled for information.

Item 14: Any other Business

87. No other business was discussed.

Date of Next Meeting

88. Date of next meeting: Tuesday 3rd December 2019 at Amba Hotel Charing Cross, The Strand, London, WC2N 5HX

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