RESERVED BUSINESS

Item 4: First draft statement on the EFSA Opinion on "Risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food" -TOX/2018/37

1. Prof Foster declared that he had read the pathology slides for some of the investigative studies on perfluorooctane sulfonic acid (PFOS) conducted at CXR Biosciences Ltd, Dundee, and was an author on some papers on PFOS published prior to 2012. This was noted, and Prof Foster was allowed to contribute as the interest period had expired.

2. EFSA were shortly to publish an Opinion, "Risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food". New health-based guidance values had been established for both PFOS and perfluorooctanoic acid (PFOA).

3. A brief overview of the EFSA Opinion was provided in the draft statement. UK exposures were provided in order to compare with the HBGV for an updated risk assessment. This statement addressed the comments from the Committee on the discussion paper seen by them in September.

4. Members would have liked to have seen more robust evidence synthesis and critical appraisal of this complex set of data.

5. EFSA were currently evaluating the other perfluoroalkyl substances in a separate Opinion and this should be made clear in this statement. In the paragraphs on human observations it needed to be made clear whether there is considered to be clear evidence for causality and make clear what EFSA had concluded overall, as this was not consistent in the EFSA opinion. For the studies considered critical, Members agreed that there were associations, but they are not very robust.

6. The Committee also requested that further information on the link between cholesterol and cardiovascular disease, background information on the interaction between PPARα and ALT and a summary of EFSA's comments for birth weight should be added, prior to the comments on the paper in press, in the "COT comments on suitability of studies and causality" section. A revision of the characterisation of the end points was requested.

7. The Committee agreed with the benchmark dose (BMD) modelling approach and discussed the physiologically based pharmacokinetic (PBPK) modelling. The modelling was quite difficult to follow and the assumption on half-life could influence other parameters. It was requested that more background be included, especially on the parameters and clarification of the data sources. The feasibility of conducting the PBPK modelling again using a shorter half-life, for which there was some evidence from the study by Convertino et al (2018), as a sensitivity analysis should be considered.

8. The exceedance of the TWI from breast milk was discussed and was one of the reasons that a request was made to consider the PBPK modelling. It is likely that further discussion will be required on how to interpret these exceedances and how much of a concern they are. The dose-response modelling was based on single studies, which was an additional source of uncertainty.

9. In addition, a number of editorial changes were requested. A revised draft statement would be brought back to a future meeting.