Meeting

Tuesday 19th of November 2019: SETE meeting

First meeting of the COT and COC SETE subgroup

COT/COC subgroup on the synthesis and integration of epidemiological and toxicological evidence in risk assessments

Agenda

TC/Skype Meeting at 13:30-15:30 pm on Tuesday 19th of November 2019.

1. Welcome and introductions
2. Quick overview/reminder of the paper presented to COT/COC (BD)
3. Discussion of TOR
   a) Agree TOR, aims and objectives (problem definition, knowledge gap to be addressed
   b) Agree the form of the output Members would wish to see
   c) Reassess Membership for subgroup, any additional expertise needed
4. Plan next meeting(s)
   a) Time line(s)
   b) Information WG requires from the Secretariat for the next meeting, such as potential literature searches
   c) Identify any existing schemes (that Members are aware off) for the next meeting

Minutes

Present:

Chair: Alan Boobis

Committee Members:

- Gill Clare
- Gunter Kuhnle
- David Lovell
- Heather Wallace
- Alison Gowers, PHE
- Valentina Guercio, PHE

Secretariat:

- Barbara Doerr, FSA
- Frances Hill, FSA
- Cath Mulholland, FSA
- Britta Gadeberg, PHE

The Chair welcomed the Members and other attendees.

The Chair provided a brief overview of the scoping paper presented to both Committees, the COT and COC, earlier this year and concluded that the meeting today was foremost to discuss the problem definition and knowledge gaps the working group would be addressing.

The WG agreed, while data integration is already applied in the work of the Committees, there is a general feeling that there is no explicit explanation of the procedure used and that also there was scope for improvement in the Committees' approaches. Therefore, the output of the WG will be a combination of current practice and a guidance document. Members stressed that the output would need to be applicable and realistic and that it would be useful to test the output/guidance on case studies, such as previously published assessments by COT and COC and if possible, by COM.

Members agreed that the output should be approved by both Committees and published on the respective websites. Members also agreed that, if appropriate, it would be useful to publish the outcome in a scientific journal.

The scoping paper presented to the Committees included a section on dose response modelling, which was included on behalf of the FSA. Members discussed the feasibility of including this in their work and noted that this would not be a trivial exercise, particularly when considering epidemiological data, and that additional expertise would be needed. Members raised concern that including quantitative dose response modelling in the discussions would take the WG beyond their remit and the output anticipated by the Committees. Members agreed that, overall, it would be important to consider dose response

relationships and that they would do so, however without addressing quantitative dose-response modelling in detail.

Members discussed the application of scoring systems, such as the Klimisch Score for animal data and the questions of suitability around scoring systems. Concern was raised by Members that studies might be dismissed without consideration, based on low scores alone. Previous work such as the SEES report applied quality criteria, but no formal quality scores and it was agreed by Members that this would be an approach they would consider in the work of the WG. Quality scoring can be of particular use in sensitivity analysis. It was also pointed out that EFSA does excludes studies of low quality, however they are required to report basis of exclusion in detail, hence considering/examining all studies.

Members of PHE (Secretariat to COMEAP) noted that it would be useful to include an explanation of what is meant by integration as different groups/work use different definitions. It was agreed by the WG Members that the guidance/output would therefor need to capture how studies are used and conclusions are reached, without mathematical integration.

Members discussed the need for additional expertise and concluded that additional expertise on epidemiology would be helpful. It was suggested to contact Lesley Rushton, who had also previously worked on evidence integration, in addition to having epidemiological expertise. Additional expertise on adverse outcome pathways and PBPK modelling/kinetics was considered helpful and Members agreed to think about potential experts who would be suitable. It was suggested to ask George Loizou to become an ad hoc expert as time restrains might prevent him from joining the WG permanently. Members agreed that the WG could always be expanded at a later stage, should the work require. One such area could be dose response modelling, should the WG agree to include it in their output in more detail than currently set out. For the moment, David Lovell agreed that he could cover expertise in biostatistics.

Members noted that the Committees have a Scientific Council liaison and that it would be useful to obtain his input at an early stage of the process. Members also agreed that it would be useful to obtain input from the Members of COMEAP, when their expertise and experience is needed. In the meantime, the Secretariat to COMEAP agreed to participate in the WG meetings and provide their expertise/experience/feedback from previous work.

Going forward it was agreed that the next meeting should be face to face and that subsequent meetings could be held (mostly) by Skype/TC. The next meeting

will be scheduled for February 2020, due to availability of Members and Committee meetings.

For the next meeting the Secretariat was asked to provide a tabled overview of the current/different approaches presented in the scoping paper. It was agreed that the Secretariat would provide column headings covering areas such as inclusion of animal/human data, scoring systems, etc and extract the information once the headings have been circulated and agreed by Members of the WG.