

Meeting

Thursday 11th of February 2021

SETE meeting

Eighth 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

Agenda of the eighth Meeting, Thursday 11 February 2021, 14:00 am to 17:00 pm, via teleconference

1. Welcome and goals of meeting
2. Guidance document (AB)
3. Discussion of the section on data integration (section 5)
4. Discussion of the full document
5. AOB:
 - Finalise documents
 - Presentation of report/guidance to COC (11/03/2021) and COT (23/03/2021)
 - Plan next meeting(s) to address comments from Committee

Discussion of the section on data integration:

- Exposure
- Revised draft text on PBPK modelling (GL)
- General exposure text (DG)
- Introductory/general text on data integration
- Examples for data integration
- Lines of evidence (Annex 2)
- Visualisation (display of uncertainty in the graphical synthesis of the evidence)

Minutes

Present:

Chair: Alan Boobis

Committee Members:

- Phil Botham
- Valentina Guercio
- Gunter Kuhnle
- George Loizou
- Lesley Rushton
- Mireille Toledano
- Heather Wallace

Secretariat:

- Barbara Doerr, FSA
- David Gott, FSA
- Britta Gadeberg, PHE

Officials:

- Catriona McCallion, FSA

Apologies were received by Gill Clare, Alison Gowers, David Lovell, Neil Pearce.

The Chair welcomed Members and other attendees.

The aim of this meeting was to finalise the draft report and guidance for discussion at COC and COT on March 11th and March 23rd, 2021, respectively.

Members reflected on the aim of the SETE report and guidance, to formalise the way Committees integrate different evidence streams in a transparent approach and to reflect on best practice.

Both, the report and guidance were discussed in full and any comments by Members, at the meeting and/or circulated prior to the meeting, were addressed. Members felt that the current text on PBPK modelling may be too detailed for the aim of the SETE report. However, given that this report was the first opportunity for Committees to capture PBPK modelling, it was proposed to leave the draft text

as is and amend it subject to comments/discussions at the Committee meetings.

Members confirmed their view that providing practical examples of the integrated approach would be beneficial to the report, however due to the tight deadline for circulation to the Committees, the discussions of the examples could not be finalised at this meeting. A note has been added to the report/guidance to inform Committee Members that work on the practical examples is still ongoing and will be finalised at the next SETE meeting in April 2021.

Catriona McCallion from the FSA attended the meeting to update Members on the report on third party evidence by the FSA.

The next meeting will be held on 19th April 2021, via TC.