COT workshop: Evolving Our Assessment & Future Guiding Principles

In this guide

In this guide

- 1. Developing COT guidance Introduction
- 2. <u>Developing COT guidance -COT workshop: Evolving Our Assessment &</u>
 Future Guiding Principles
- 3. <u>Developing COT guidance Existing guidance</u>
- 4. <u>Developing COT guidance Proposal on the potential structure of COT guidance</u>
- 5. Developing COT guidance Discussion and Questions
- 6. Developing COT guidance Abbreviations
- 7. <u>Developing COT guidance Annex A</u>
- 8. Developing COT guidance Annex B
- 3. In May 2023, the COT held a workshop to start the work on new COT guidance. The workshop report is at Annex A. It was noted that the starting point for the process should be existing frameworks and guidance, but with the aim of including innovative improvements, where possible. The workshop aimed to identify the key areas that need to be considered in developing the guidance, and these included reviewing fundamental risk assessment principles, current guidance on risk assessment and what can be learned from it, integration of new approach methodologies (NAMs), exploring hazard versus risk, and weight of evidence. The overall objective of the workshop was to discuss how the Committee moves forward in a new era of risk assessment.
- 4. Topics discussed at the workshop included models and tools, assessment methods, data sources and quality, uncertainty, NAMs, training and skills, validation, regulatory interfaces, and the role of scientific advisory

committees.

5. The workshop's recommendations, priorities and proposed improvements to guidance are shown in Table 1.

Table 1. Recommendations, priorities, and proposed improvements to the COT guidance from the "Evolving our assessment and future guiding principles" workshop.

Recommendations	Priorities	Improvement
Transparency	Resourcing and capturing institutional wisdom	Clear distinction between who is responsible for what
Build relationships with other agencies and harmonization internationally	Weight of Evidence	Strengthen links between Scientific Advisory Committees across government agencies
Explore uncertainty and validation	Tiered Testing	Integrated (systematic) reviews in risk assessment
Explore risk benefit and comparative risk	Enhancing public health	Codify what we have

Table 1 sets out the recommendations and priorities for improvement identified in the COT workshop "Evolving our assessment and future guiding principles." The table is shown in black line and text. It has 3 columns and 5 rows.

6. Following the workshop, the COT reviewed the draft workshop report at its October 2023 meeting, and identified the most important "must," "could" and "should" points. These are shown below.

Must: Identify and adapt existing frameworks, guidance, and assessments to enhance public safety.

Should: Integrate new approach methodologies by using the best available science.

Could: Explore risk benefit and comparative risk.

This box follows on from Table 1 separating the recommendations into must, should and could. The image shows a table in black line and text.

7. The Committee noted that assessment of benefits was not within the terms of reference of the COT and thought should be given as to how COT advice could be best aligned for this to be undertaken when needed or appropriate.

- 8. The Committee noted that to take the guidance forward, establishing an initial framework would be important. This could then be expanded and linked to other guidance as necessary. There were considered to be two parts to the work, to codify what the Committee currently do, and then to provide guidance on areas where the approach was not yet codified such as benchmark dose modelling.
- 9. The Committee agreed that it would be important to work with the policy colleagues from the relevant Government departments and not re-invent the risk analysis process. In particular, the required levels of protection needed for consumers should be considered.