Proposal on the potential structure of COT guidance

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14. Based on the COT's discussions to date it is proposed that the guidance take the form of a main guidance document, which contains the overarching principles, and then separate guidance documents on specific topics which link to this. The starting point for the guidance would be existing guidance. It is suggested that the guidance should:

- Take a tiered approach.
- Be flexible.
- Take into account the 3/6 Rs (replacement, reduction and refinement of animal testing, but also recently extended to include the reproducibility, relevance and regulatory acceptance of alternatives).
- Specify the information needed rather than the specific studies.
- Be futureproof.
- Include NAMs and how they can be used in risk assessment or to support risk assessment.

- Include the integration of evidence.

15. Aspects that have been noted that may need to be taken into account include:

- Regulatory requirements / sector specific risk assessment needs.
- General chemical risk assessment versus assessment of applications for regulated products.
- The roles of COC and COM, how to interlink with or cross-reference their guidance and possible areas of joint working.
- The joint COT/COC reports on synthesising epidemiological evidence (SEES) and synthesising and integrating epidemiological and toxicological evidence (SETE) reports.
- The four nations of the UK and divergence, e.g. between Great Britain and Northern Ireland.

16. Views of the COT are sought, but areas where UK-specific guidance may be helpful may include:

- Risk assessment of mixtures.
- Integrated approaches to testing and assessment (IATA).
- Benchmark dose modelling.
- Exposure assessment.
- Novel forms of, for example, supplements ingredients.
- The use of artificial intelligence (IA).
- Risk-benefit approaches.
- Biological and statistical significance.
- Biomonitoring.
- Systematic reviews and literature techniques.
- Risks to infants <12 weeks of age.

17. Members are asked to consider where UK-specific guidance is required as it would be helpful to not diverge significantly from EFSA guidance where this is not necessary.