New Approach Methodologies (NAMs) In Regulatory Risk Assessment Workshop Report 2020- Exploring Dose Response

# Mission and Vision: Objectives and outline of workshop - 2020

# In this guide

## In this guide

- 1. Cover Page 2020 Workshop Report
- 2. Abstract 2020 Workshop Report
- 3. About the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) 2020
- 4. About the FSA 2020 Workshop Report
- 5. Executive Summary 2020 Workshop Report
- 6. Introduction and Background 2020 Workshop Report
- 7. Mission and Vision: Objectives and outline of workshop 2020
- 8. Presentations and panel discussions 2020 Workshop Report
- 9. Panel Discussion Sessions Outputs 2020 Workshop Report
- 10. Future Steps 2020 Workshop Report
- 11. Overarching conclusions and recommendations 2020 Workshop Report
- 12. Abbreviations 2020 Workshop Report
- 13. References 2020 Workshop Report
- 14. Technical Terms 2020 Workshop Report
- 15. Workshop Organizing Committee 2020

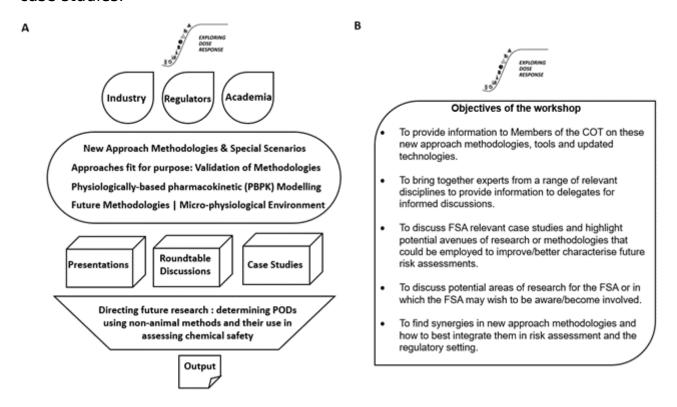
## **Objectives of the workshop**

The application of these alternative strategies to human health risk assessment requires effective collaboration between scientists including chemists, toxicologists, informaticians and risk assessors. As such, this multi-disciplinary workshop drew upon delegates and speakers from industry, academia, and regulatory agencies with a diverse range of experience.

The workshop provided a platform (Figure 2A) from which to address the latest in silico prediction models and PBPK modelling techniques. It provided speakers with the opportunity to share their knowledge and experience through case studies and roundtable discussions on approaches fit for purpose, including consideration of their validation and integration into current health risk assessment practices (Figure 2B).

## **Outline of the workshop**

The workshop was divided into different area sessions; New Approach Methodologies & Special Scenarios, Approaches fit for purpose: Validation of methodologies, PBPK modelling, Future Methodologies (micro-physiological environment) and consisted of presentations accompanied by roundtable discussions of case studies with feedback and a discussion about future research needs. The presentations were delivered by invited experts (Figure 3) and had been designed to provide relevant information to inform the later discussions and case studies.



Diagrams representing outline and objectives of workshop. These diagrams are black and white. It has 2 images, A and B. The diagrams are made up of text, 2 D and 3D shapes. Image B has a text box with bullet points.

**Figure 2**. Diagrams representing outline and objectives of workshop. Overview and outline (A) and objectives (B) of the Exploring Dose Response Workshop.



#### New Approach Methodologies & Special Scenarios

Dr Mark Cronin (Liverpool John Moores University) - Next Approach Methodologies (NAMs): Application in Risk Assessment

Dr Camilla Alexander-White (Royal Society of Chemistry) - NAMS: case studies of regulatory use (or not) for risk assessment

Dr Fiona Sewell (NC3Rs) - Using in silico approaches to support the 3Rs in safety assessment

Dr Carl Westmoreland (Unilever) - Next Generation Risk Assessment (NGRA). A case study approach

#### Approach that is fit for purpose : Validation of methodologies

Prof Gary Hutchison (Edinburgh Napier University)- Approach that is fit for purpose: Validation of methodologies for nanomaterials

Dr Judith Madden (Liverpool John Moores University) - Establishing the Credibility of Models

#### Physiologically-based pharmacokinetic (PBPK) modelling

Dr George Loizou (Health and Safety Executive) - RVis: A Tool for Quantitative In Vitro Concentration Response to In Vivo Dose Response Extrapolation

Dr Sheila Annie Peters (Merck) - Establishing confidence in PBPK models without human toxicokinetic data

#### Future Methodologies | Micro-physiological environment

Dr lan Wilson (Imperial College London) - Organ-on-a chip/ in silico modelling/ gut microbiome

Dr Tim Allen (University of Cambridge) - Al, Machine Learning and Big Data

Figure 3 is made up of 4 black and white outlined text boxes. Text is centred in each box. At the top left of the figure is a pictogram of a person pointing to a board. Each text box has a tapered angle to the right.

**Figure 3**. Diagram overview of sessions and presentations of the Exploring Dose Response Workshop.

### **Brief overview of case studies**

The case studies (Figure 4) were based on a range of chemical areas (man-made and environmental) relevant to the FSA, where limited information was available for the purposes of risk assessment: contaminants (tropane alkaloids (TAs), food supplements (selective androgen receptor modulators (SARMs), food contact materials (vinyl acetate monomer (VAM) and polymers (plastic particles). Background on the chemical groups was provided and questions were asked to prompt discussion. Each of the case study discussion groups included invited experts, Members of the COT, COT Secretariat and other attendees to try and ensure consistent expertise across groups.

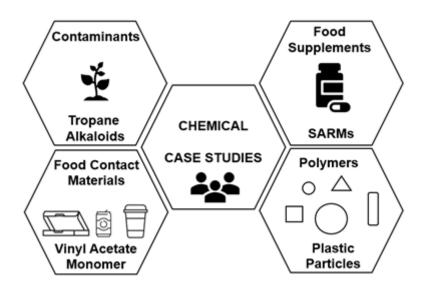


Figure 4 is an image of the case studies overview. The image is 5 hexagons with black and white pictograms and text inside them.

**Figure 4**. Case studies overview. The case studies were based on a range of chemical areas (man-made and environmental) relevant to the FSA, where limited information was available for the purposes of risk assessment: contaminants (tropane alkaloids (TAs), food supplements (selective androgen receptor modulators (SARMs), food contact materials (vinyl acetate monomer (VAM) and polymers (plastic particles).