

Topical Scientific Workshop on New Approach Methodologies in Regulatory Science

Helsinki, 19 – 20 April, 2016

Programme

Day 1, 19 April 2016

08:15—08:45	<i>Registration of participants presenting posters</i> <i>Poster exhibition set-up</i>
08:45—09:15	<i>Registration of participants</i>
09:15—09:30	Welcome Mr Jukka Malm, Deputy Executive Director, ECHA, Finland
09:30—09:40	Introduction to the workshop Dr Tomasz Sobański, Scientific Committee Chair, ECHA, Finland
09:40—09:55	EU Research and innovation in support to chemical safety Dr Christian Desaintes, Scientific Officer, European Commission, DG Research & Innovation, Belgium

Theme 1: Definitive hazard assessment: improvement of read-across

Chairs:

[Dr Matthias Herzler, Federal Institute for Risk Assessment, Germany](#)
[Mr Mike Rasenberg, Head of Unit, Computational Assessment and Dissemination, ECHA, Finland](#)

10:00—10:40	Setting the scene Critical aspects in the assessment of read-across adaptations: the role of supporting evidence Dr Norbert Fedtke, ECHA, Finland
10:40—11:20	Case study from SEURAT-1 Read-Across for 90-Day Rat Oral Repeated-Dose Toxicity for Selected Perfluoroalkyl Acids: A Case Study Professor Terry Schultz, University of Tennessee, USA
11:20—11:50	<i>Coffee break in the poster exhibition area</i>
11:50—12:30	Case study from SEURAT-1 Read-Across for 90-Day Rat Oral Repeated-Dose Toxicity for Selected β -Olefinic Alcohols: A Case Study Professor Mark Cronin, Liverpool John Moores University, United Kingdom
12:30—13:10	Case study from BASF Metabolomics as read-across tool: a case study with phenoxy herbicides Dr Bennard van Ravenzwaay, BASF, Germany

Day 1, 19 April 2016 (cont.)

- 13:10—14:00 *Lunch, followed by coffee in the poster exhibition area*
- 14:00—14:30 *Discussion with poster presenters, poster exhibition area*
SEURAT-1 film, Marie Skłodowska Curie room (14:00–14:30)
- Chairs:
 Dr Matthias Herzler, Federal Institute for Risk Assessment, Germany
 Mr Mike Rasenberg, Head of Unit, Computational Assessment and
 Dissemination, ECHA, Finland
- 14:30—15:20 Panel discussion
Role of NAM in definitive hazard assessment (read-across)
- Moderator: Mr Mike Rasenberg, Head of Unit, Computational
 Assessment and Dissemination, ECHA, Finland
- Panelists:
- Dr Elisabet Berggren, European Commission, Joint Research Centre, Italy
 Professor Ian Cotgreave, Swetox, Sweden
 Dr Karel de Raat, advisor to ECHA, The Netherlands
 Dr Norbert Fedtke, ECHA, Finland
 Dr Matthias Herzler, Federal Institute for Risk Assessment, Germany
 Dr Derek Knight, ECHA, Finland
 Dr Catherine Mahony, Procter & Gamble, United Kingdom
 Dr Magdalini Sachana, OECD, France
- 15:20—15:30 Introduction to the break-out sessions
 Dr Kaihsu Tai, Local Organising Committee Chair, ECHA, Finland

Day 1, 19 April 2016 (cont.)

15:30—17:30

Break-out sessions: case studies
(Coffee break at any time between 16:00-17:30)

1. Case study from SEURAT-1

Perfluorinated alkyl acids: direct acting toxicant category supported by ToxCast evidence

Chair: [Dr Watze de Wolf](#), Chairman of the Member State Committee, ECHA, Finland

Presenter: [Ms Sharon Stuard](#), Procter & Gamble, United States of America

Rapporteur: [Dr Norbert Fedtke](#), ECHA, Finland

2. Case study from SEURAT-1

β -Unsaturated alcohols: indirect acting toxicant category supported by SEURAT-1 data

Chair: [Dr Derek Knight](#), Senior Scientific Advisor, ECHA, Finland

Presenter: [Dr Andrea Richarz](#), European Commission, Joint Research Centre, Italy

Rapporteur: [Dr Elisabet Berggren](#), European Commission, Joint Research Centre, Italy

3. Case study from BASF

Read-across with metabolomics for phenoxy herbicides

Chair: [Dr Tomasz Sobański](#), ECHA, Finland

Presenter: [Dr Bennard van Ravenzwaay](#), BASF, Germany

Rapporteur: [Dr Karel de Raat](#), advisor to ECHA, The Netherlands

17:30—17:55

SEURAT-1 film, Marie Skłodowska Curie room

18:00—19:30

Cocktail reception, canteen

Introductory words

[Dr Derek Knight](#), Senior Scientific Advisor, ECHA and

[Dr Renate Weissenhorn](#), Advisor, European Commission, European Partnership for Alternative Approaches to animal testing

Day 2, 20 April 2016

- 08:15—08:50 *Registration of participants*
Discussion with poster presenters, poster exhibition area
- 08:50—09:00 Introduction to the second day
[Dr Tomasz Sobański, Scientific Committee Chair, ECHA, Finland](#)
- 09:00—10:00 Reports from break-out sessions
[Rapporteurs of the break-out sessions](#)
- 10:00—10:15 Discussion on break-out sessions' reports/outcome
- Moderator: [Mr Mike Rasenberg, Head of Unit, Computational Assessment and Dissemination, ECHA, Finland](#)
- 10:15—10:45 *Coffee break in the poster exhibition area*
- Theme 2: Screening and priority setting
- Chairs:
[Dr Kerry Nugent, National Industrial Chemicals Notification and Assessment Scheme, Australia](#)
[Dr Jack de Bruijn, Director of Risk Management, ECHA, Finland](#)
- 10:45—11:15 The NICNAS IMAP Program
[Dr Kerry Nugent, National Industrial Chemicals Notification and Assessment Scheme, Australia](#)
- 11:15—11:45 Application of computational and high-throughput *in vitro* screening for prioritization
[Dr Richard Judson, Endocrine Disruptor Screening Program, United States Environmental Protection Agency, USA](#)
- 11:45—12:15 Integrating New Approach Methodologies under Canada's Chemicals Management Plan
[Dr Christine Norman, Health Canada, Canada](#)
- 12:15—12:40 A Common Screening Approach for REACH and CLP Processes
[Dr Panagiotis Karamertzanis, ECHA, Finland](#)
- 12:40—13:10 Panel discussion
Role of NAM in screening and priority setting
- Moderator: [Dr Jack de Bruijn, Director of Risk Management, ECHA, Finland](#)
- Panelists:
[Dr Tara Barton-Maclaren, Health Canada, Canada](#)
[Dr Richard Judson, Endocrine Disruptor Screening Program, United States Environmental Protection Agency, USA](#)
[Dr Panagiotis Karamertzanis, ECHA, Finland](#)
[Dr Kerry Nugent, National Industrial Chemicals Notification and Assessment Scheme, Australia](#)

Day 2, 20 April 2016 (cont.)

13:10—14:10 *Lunch, followed by coffee in the poster exhibition area*

Theme 3: Prospects for regulatory science

Chairs:

Dr Rusty Thomas, United States Environmental Protection Agency, USA

Dr Wim De Coen, Head of Unit, Executive Office, ECHA, Finland

14:10—14:35 Moving Towards Version 2.0 of Toxicity Testing in the 21st Century and Application to Regulatory Decision-Making
Dr Rusty Thomas, United States Environmental Protection Agency, USA

14:35—15:00 How to overcome limitations of new approach methodologies in the context of regulatory science
Dr Romualdo Benigni, Istituto Superiore di Sanità, Italy

15:00—15:25 Analysing Data: Towards a framework for transcriptomics and other Big Data analysis for regulatory application
Dr Timothy W Gant, Public Health England, United Kingdom

15:25—15:50 Using new approach methodologies in regulatory science: tools and methods for integration of evidence
Dr George Fotakis, ECHA, Finland

15:50—16:50 Panel discussion
Role of NAM in prospects for regulatory science

Moderator: Dr Wim De Coen, Head of Unit, Executive Office, ECHA, Finland

Panelists:

Dr Jean-Lou Dorne, European Food Safety Authority, Italy

Dr Annette Mehling, European Partnership for Alternative Approaches to Animal Testing, Germany

Professor Michael Schwarz, Tübingen University, Germany

Dr Rusty Thomas, United States Environmental Protection Agency, USA

Dr Bennard van Ravenzwaay, BASF, Germany

Professor Maurice Whelan, European Commission, Joint Research Centre, Italy

16:50—17:00 Summary and conclusions
Dr Tomasz Sobański, Scientific Committee Chair, ECHA

17:00—17:30 *Poster exhibition dismantling*