

NAM-supported read-across: from case studies to regulatory guidance in safety assessment

21-22 May 2019, Hotel Korpilampi, Espoo, Finland

It is a great pleasure for the EU-ToxRisk consortium and meeting organising committee members ECHA, EFSA, NTP, EPA, and OECD, to invite you to the upcoming EU-ToxRisk workshop on ***New Approach Methodologies (NAM)-supported read-across (RAX): from case studies to regulatory guidance in safety assessment***.

EU-ToxRisk project: The project aims to develop and implement new approach methodologies (NAMs) as an alternative approach for the safety testing of chemicals. EU-ToxRisk assembled wide panel of the state-of-the-art *in silico* and *in vitro* test methods, which allow for the testing of systemic repeated dose target organ toxicity (RDT), covering liver, kidney, lung and neuronal system as target organs, as well as experimental systems that cover developmental and reproductive toxicity (DART). The objective is to assess the application of NAMs as a tool to improve read-across, as well as in the context of *ab initio* chemical safety assessment.

Focus & main objective: The workshop focuses on several scientifically advanced project case studies developed within the EU-ToxRisk project, the OECD/IATA program, and NIHS Japan. Case studies are discussed with regard to their applicability to different regulatory requirements e.g. in Europe (e.g. REACH, EU Pesticides) and global (Canada Chemicals Management Plan and Japanese Chemical Substances of Control Law). Stakeholders from academia, industry, and authorities will work together to improve their understanding of each other needs and come to a mutual agreement on the principles of NAM informed risk assessment.

The overall aim is to include the outcome of the event discussions in an improved regulatory guidance document for NAM-supported RAX. Furthermore, the EU-ToxRisk team plans to disseminate a refined read-across template for the toxicological community. This will improve the quality of the submission of read-across cases by registrants, and by this it will increase the success rate of non-animal safety approaches.

Target group & Event format: The workshop is open to experts of the field coming from regulatory agencies, industry, and academia, thus providing an exceptional forum for knowledge exchange.

After a short introduction, break out groups will thoroughly discuss the individual case studies under the direction of the chairs. The case studies are seen as examples and the workshop aims to identify and extract those general approaches and learnings that will help in future NAM guided read-across approaches.

Please, take a look at the below preliminary agenda to get a clearer picture of how the described format will be put into practice and around which case studies.

Registration & Linked costs: The event is open to a limited number of participants to allow an efficient and fruitful discussion. Registration is thus mandatory.

The registration website is currently being prepared and registration will be launched in the first week of March. You will receive an e-mail notification with appropriate instructions, once the website is up and running.

There will be no registration fee. However, a special meeting package covering lunch and coffee breaks on both days will be automatically added to your hotel bill (~57 Euro/day).

Reimbursement: As EU-ToxRisk benefits from public funds, the budget for organising the workshop is limited. Reimbursement of travel costs and lodging can thus not be guaranteed, and the organisers thank you for your understanding.

The whole organization committee, represented by its chair Susanne Hougaard Bennekou (DTU; EU-ToxRisk partner) and co-chair Bob van de Water (UL, EU-ToxRisk coordinator), look forward to welcoming you to this pivotal event.

Workshop Organising Committee:

Chair:

Susanne Hougaard Bennekou (DTU, EU-ToxRisk)

Co-Chair:

Bob van de Water (UL, EU-ToxRisk coordinator)

External committee members:

Georges Kass (EFSA)

Derek Knight (ECHA)

Eeva Leinala (OECD)

Grace Patlewicz (US EPA)

Rositsa Serafimova (EFSA)

Nisha Sipes (US NIH-NTP)

Draft Workshop Agenda

Day 1 – Tue. 21 May

Time	Topic	Speakers
9:00	Opening of the workshop	Susanne H. Bennekou (DTU) Bob van de Water (UL)
Introductory talks (Plenary session)		
9:10	Regulatory / cross-regulatory perspective I	Derek Knight (ECHA)
9:25	Regulatory / cross-regulatory perspective II	Georges Kass (EFSA)
9:40	NTP case study - Bisphenol A	Nisha Sipes (US NIH-NTP)
9:55	Introduction to the EU-ToxRisk RAX concept	
Introductory talks on CS (Plenary session)		
10:00	EU-ToxRisk CS1 – Branched carboxylic acids - Reg. context: REACH - Prediction: no tox, tox - NAMs: TK&TD, battery of tests - Endpoint: steatosis	Sylvia Escher (ITEM)
10:20	EU-ToxRisk CS2 – Branched carboxylic acids	Dinant Kroese (TNO)

Time	Topic	Speakers
	<ul style="list-style-type: none"> - Reg. context: REACH. - Prediction: no tox - NAMs: TK&TD, battery of tests - Endpoint: DART 	
10:40	EU-ToxRisk CS4 – Strobilurins <ul style="list-style-type: none"> - Reg. context: EU Pesticides. - Prediction: no tox - NAMs: TK&TD, battery of tests - Endpoint: neurotox 	Bob van de Water (UL)
11:00	<i>Coffee break</i>	
11:30	OECD/IATA case US-EPA/Health Canada – Phenols: <ul style="list-style-type: none"> - Reg. context: Canada Chemicals Management Plan - Prediction: PoD - NAMs: TK&TD, QSAR/in vitro - Endpoint: estrogenicity 	Grace Patlewicz (US EPA) /Tara Barton-Maclaren (Health Canada)
12:50	OECD/IATA case Japan – Ethylene glycol methyl ether: <ul style="list-style-type: none"> - Reg. context: Japanese Chemical Substances of Control Law - Prediction: PoD and harmonised classification - NAMs: metabolism simulation - Endpoint: testicular tox 	Takashi Yamada (NIHS Japan)
12:10	Instructions to breakout sessions and reporting	
12:45	<i>Lunch</i>	
	Parallel breakout group sessions	
14:00	EU-ToxRisk CS 1 – Branched carboxylic acids	
	EU-ToxRisk CS 2 – Branched carboxylic acids	
	EU-ToxRisk CS 4 – Strobilurins	
	OECD/IATA case US-EPA/Health Canada – Phenols	
	OECD/IATA case Japan – Ethylene glycol methyl ether	
18:15	<i>End of Meeting Day 1</i>	

Day 2 – Wed. 22 May

Time	Topic	Speakers
9:00	Opening of Day 2	Susanne H. Bennekou (DTU)
	Reporting on breakout session from Day 1 (Plenary session)	
9:15	EU-ToxRisk CS 1 – Branched carboxylic acids (steatosis)	Rapporteur tbc
9:35	EU-ToxRisk CS 2 – Branched carboxylic acids (DART)	Rapporteur tbc
9:55	EU-ToxRisk CS 4 – Strobilurins	Rapporteur tbc
10:15	OECD/IATA case US-EPA/Health Canada – Phenols	Rapporteur tbc

Time	Topic	Speakers
10:35	OECD/IATA case Japan	Rapporteur tbc
11:00	<i>Coffee break</i>	
	Presentations & Discussion (Plenary session)	
11:30	Internationalisation of Read Across – 2018 Ranco workshop outcomes	Thomas Hartung (JHSPH)
11:50	Elk River chemical spill	Speaker tbc
12:10	RAX tools: GenRA & EU-ToxRisk RAX tool – back-to-back	Grace Patlewicz Barbara Zdrzil (UNIVIE) or Manuel Pastor (UPF)
12:30	<i>Lunch</i>	
	Closing (Plenary session)	
13:30	Discussion RAX workshop report	
15:00	Wrap-up & Closing	
15:30	<i>End of the Read Across Workshop</i>	