



EU-ToxRisk Open Symposium

11-12 February 2020
Hotel Zuiderduin, Egmond aan Zee, Netherlands

Day 1 – Tue. 11 Feb. 2020: EU-ToxRisk Open Symposium

9:00 – 11:00	Registration	Welcome desk
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Objectives:

- Delineate the regulatory and scientific foundation of the EU-ToxRisk Advisory Document on new approach method (NAM)-enhanced read-across (RAx).
- Host a platform for industry, regulatory and academic stakeholders on practical issues related to the submission of RAx justifications in risk assessment.
- Provide insight in the second set of EU-ToxRisk case studies running through end 2020.

Agenda:

Time	Topic	Speakers	Room
11:00	Opening of the Open Symposium		
11:00-11:10	Welcome & Agenda (10')	Bob van de Water (UL)	Lamoraalzaal
11:10	New approach method (NAM)-enhanced read-across (RAx) regulatory application: the EU-ToxRisk Advisory Document [Part 1] – Chair: Bob van de Water (UL)		
11:10-11:25	Introduction to the project's NAM-enhanced RAx approaches (15')	Hennicke Kamp (BASF)	Lamoraalzaal
11:25-11:40	Overall EU-ToxRisk learnings for application of NAMs in RAx (15')	Susanne Hougaard Bennekou (DTU)	
11:40-12:20	<u>Regulatory issues in RAx justifications: experience from industry stakeholders (40')</u>		
	Fragrance industry experience and challenges in regulatory acceptance of read-across strategies (10')	Amaia Irizar (IFRA)	
	Nouryon's experience with the application of RAx (10')	Erik Houthoff (Nouryon)	
	Read across; past, present, future (10')	Nicholas Ball (Dow)	
	Q&A (10')	All speakers	
12:20-13:20	Lunch break (60')		Lobby

Time	Topic	Speakers	Room
13:20	New approach method (NAM)-enhanced read-across (RAx) regulatory application: the EU-ToxRisk Advisory Document [Part 2] – Chair: Hennicke Kamp (BASF)		
13:20-13:30	EU-ToxRisk RAx Advisory Document: main principles (10')	Sylvia Escher (ITEM)	Lamoraalzaal
13:30-13:40	EU-ToxRisk RAx Advisory Document: developed NAMs (10')	Marcel Leist (UKN)	
13:40-13:50	EU-ToxRisk RAx Advisory Document: dealing with uncertainty (10')	Andy White (Unilever)	
13:50-14:00	EU-ToxRisk in silico RAx toolbox (10')	Manuel Pastor (UPF)	
14:00-14:15	Q&A RAx Advisory document + session wrap-up (15')	All speakers	
14:15	Incorporation of High Throughput Transcriptomics (HTTr) data in RAx justification for regulatory application: exemplary case studies – Chair: Marcel Leist (UKN)		
14:15-14:30	Introduction of HTTr technology and overall application (15')	Bob van de Water (UL)	Lamoraalzaal
14:30-14:45	HTTr applications in RAx of branched carboxylic acids (10' + 5' Q&A)	Nanette Vrijenhoek (UL)	
14:45-15:00	HTTr applications in RAx of diketones (10' + 5' Q&A)	Matthias Wehr (ITEM)	
15:00-15:15	HTTr applications in RAx of pesticidal mitochondrial complex inhibitors (10' + 5' Q&A)	Wanda van der Stel (UL)	
15:15-15:45	Coffee break (30')		Lobby
15:45	EU-ToxRisk Phase-2 Case Studies – Chair: Dinant Kroese (TNO)		
15:45-15:55	Introduction: overall concepts of new case studies (10')	Dinant Kroese (TNO)	Lamoraalzaal
15:55-16:10	NGRA of developmental neurotoxicity liabilities of neonicotinoids insecticides (10' + 5' Q&A)	Susanne Hougaard Bennekou (DTU)	
16:10-16:25	Multi-organ metabolism for NGRA (10' + 5' Q&A)	Paul Jennings (VU)	
16:25-16:40	Multi-organ test systems to determine LOEL (10' + 5' Q&A)	Sylvia Escher (ITEM)	
16:40-16:55	NGRA to determine non or low toxicity liabilities (10' + 5' Q&A)	Tom Cull (Unilever)	
16:55-17:00	Session wrap-up (5')	Dinant Kroese (TNO)	
17:00	Panel Discussion between Stakeholders, RAB, SAB, EU-ToxRisk Steering Team & Case Study Leaders – Chair: Bob van de Water (UL)		
17:00-18:00	Open discussion among EU-ToxRisk partners and stakeholders (60')	Bob van de Water (UL)	Lamoraalzaal
18:00	End of Meeting Day 1		
19:00	Joint work dinner – Restaurant EAZEE, boulevard 7, 1931 CJ Egmond aan Zee		

Day 2 – Wed. 12 Feb. 2020: Open EU-ToxRisk Symposium (cont'd)

Objectives:

- Highlight the scientific progress of EU-ToxRisk towards the establishment and validation of next-generation risk assessment (NGRA).
- Spotlight the international perspectives on the application of NGRA frameworks.
- Stimulate interaction and involvement with the EU-ToxRisk NAM-based Testing Commercialization Platform.

Agenda:

Time	Topic	Speakers	Room
9:00	Opening of Day 2 of the Open Symposium		
9:00-9:05	Introduction and agenda (5')	Bob van de Water (UL)	Lamoraalzaal
9:05	Scientific highlights from EU-ToxRisk towards Next-Generation Risk Assessment (NGRA) – Chair: Paul Jennings (VU)		
9:05-9:50	9 speed presentations of 5' each (45')	(cf. separate list of speed presentations)	Lamoraalzaal
9:50-10:05	Q&A (15')	ALL	
10:05-10:45	8 speed presentations of 5' each (40')	(cf. separate list of speed presentations)	
10:45-11:00	Q&A (15')	ALL	
11:00-11:30	Coffee break (30')		Lobby
11:30	Poster session		
11:30-12:30	Project CSs and scientific achievements are presented on posters (60')		Lobby
12:30-13:30	Lunch break + posters (60')		
13:30	NAM-based Testing Commercialization Platform – Solving Industrial Problems in Safety Assessment – Chair: Barry Hardy (EwC)		
13:30-13:45	Introduction of the EU-ToxRisk commercialization platform (15')	Barry Hardy (EwC)	Lamoraalzaal
13:45-13:55	NAM-based Safety Assessment (10')	Costanza Rovida (CAATEU)	
13:55-14:30	<u>From screening to complex modelling required for risk assessment (35') – Speed talks on the following topics:</u> In silico screening – In vitro HTS – High content screening – Safety Testing using 3D Liver Cell Cultures – Key event-based mitochondrial toxicity assessment – Adverse effect prediction using transporter modelling – Neurotoxicity screening	Selected partners (cf. separate session programme)	
14:30	International perspectives on NGRA – Chair: Bob van de Water (UL)		
14:30-14:45	Current research projects of Japan towards NGRA (10' + 5' Q&A)	Akihiko Hirose (NIHS)	Lamoraalzaal
14:45-15:00	US NIEHS/NTP perspective (10' + 5' Q&A)	Warren Casey (NIEHS-NTP)	

Time	Topic	Speakers/Chairs	Room
15:00-15:15	EFSA perspective (10' + 5' Q&A)	Georges Kass (EFSA)	Lamoraalzaal
15:15-15:30	Wrap-up of the session; output and closing of the Open Symposium (15')	Bob van de Water (UL)	
15:30	<i>End of the Open Symposium</i> ⇒ <i>Interested stakeholders</i> have the possibility to stay on for the discussion session with the EU-ToxRisk commercialization partners (room 530).		
15:30	NAM-based Testing Commercialization Platform – Interactive discussion between EU-ToxRisk partners and interested external stakeholders – Chair: Barry Hardy (EwC)		
15:30-16:30	Solving Industrial Problems in Safety Assessment: Discussing Needs (60')	Barry Hardy (EwC)	530
17:00	Shuttle to Schiphol airport and Amsterdam Centraal train station		