



## EU-ToxRisk Open Symposium & General Assembly

10-13 February 2020  
Hotel Zuiderduin, Egmond aan Zee, Netherlands

### Day 1 – Mon. 10 Feb. 2020 – EU-ToxRisk internal CS meetings

#### Objective:

- For all CS meetings, to further discuss and plan the CS activities and clarify open questions or issues.

#### Agenda:

Time	Topic	Speakers/Chairs	Room
14:30-15:00	<b>Welcome coffee (30')</b>		Lobby
<b>15:00</b>	<b>Parallel sessions – EU-ToxRisk-only</b>		
15:00-17:00	CS10 meeting – Multi Target Organ (120')	Sylvia Escher (ITEM)	530
15:00-17:00	CS11/CS12 meeting – Low Tox (120')	Tom Cull (UNILEVER) Bob van de Water (UL)	531
15:00-18:00	CS14 meeting – DNT/neonicotinoids (180')	Susanne Hougaard Bennekou (DTU)	534
15:00-17:00	Cross-Liver System Testing CS meeting (120')	Wolfgang Moritz (IS)	535
<b>18:00</b>	<b>End of the internal meetings</b>		

<b>Dinner</b>	<b><i>Participants arriving on Monday are kindly asked to organise themselves for dinner. We thank you very much for your understanding.</i></b>
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## Day 2 – Tue. 11 Feb. 2020: EU-ToxRisk Open Symposium & General Assembly, EU-ToxRisk internal WP/CS meetings

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

- For the CS2 meeting, to discuss progress and finalization of TK and TX.
- For the CS3/CS1 meeting, to discuss remaining activities and clarify open questions or issues.
- For the WP9 meeting, to discuss and plan remaining activities and clarify open questions or issues.
- For the WP12/WP13 meeting, to discuss and plan remaining activities, in particular the activities around commercialization, and clarify open questions or issues.
- For the Open Symposium, to (1) delineate the regulatory and scientific foundation of the EU-ToxRisk Advisory Document on new approach method (NAM)-enhanced read-across (RAx), (2) host a platform for industry, regulatory and academic stakeholders on practical issues related to the submission of RAx justifications in risk assessment, (3) provide insight in the second set of EU-ToxRisk case studies running through end 2020. For the WP9 meeting, to discuss remaining activities and clarify open questions or issues.

### Agenda:

Time	Topic	Speakers/Chairs	Room
<b>9:00</b>	<b>Parallel sessions – EU-ToxRisk-only</b>		
9:00-10:30	WP9 meeting (60')	Karin Cederbrant (RISE)	530
	WP12/13 meeting (90')	Bart van der Burg (BDS) Giorgia Pallocca (CAATEU)	531
	CS2 meeting (90')	Dinant Kroese (TNO)	534
	CS3 meeting (45') – 9:00-9:45 CS1 meeting (40') – 9:50-10:30	Sylvia Escher (ITEM)	535
<b>11:00</b>	<b>Opening of the Open Symposium</b>		
11:00-11:10	Welcome & Agenda (10')	Bob van de Water (UL)	Lamoraalzaal
<b>11:10</b>	<b>New approach method (NAM)-enhanced read-across (RAx) regulatory application: the EU-ToxRisk Advisory Document [Part 1] – Chair: Bob van de Water (UL)</b>		
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	<b>Regulatory issues in RAx justifications: experience from industry stakeholders (40'):</b>		
	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	

Time	Topic	Speakers/Chairs	Room
<b>12:20-13:20</b>	<b>Lunch break (60')</b>		Lobby
<b>13:20</b>	<b>New approach method (NAM)-enhanced read-across (RAx) regulatory application: the EU-ToxRisk Advisory Document [Part 2] – Chair: Hennicke Kamp (BASF)</b>		
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	
<b>14:15</b>	<b>Incorporation of High Throughput Transcriptomics (HTTr) data in RAx justification for regulatory application: exemplary case studies – Chair: Marcel Leist (UKN)</b>		
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)	
<b>15:15-15:45</b>	<b>Coffee break (30')</b>		Lobby
<b>15:45</b>	<b>EU-ToxRisk Phase-2 Case Studies – Chair: Dinant Kroese (TNO)</b>		
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)	
<b>17:00</b>	<b>Panel Discussion between Stakeholders, RAB, SAB, EU-ToxRisk Steering Team &amp; Case Study Leaders – Chair: Bob van de Water (UL)</b>		
17:00-18:00	Open discussion among EU-ToxRisk partners and stakeholders (60')	Bob van de Water (UL)	Lamoraalzaal
<b>18:00</b>	<b>End of Meeting Day 1</b>		
<b>19:00</b>	<b>Joint work dinner – Restaurant EAZEE, boulevard 7, 1931 CJ Egmond aan Zee</b>		

## Day 3 – Wed. 12 Feb. 2020: EU-ToxRisk Open Symposium & General Assembly, internal WP/CS meetings

### Objectives:

- For the Open Symposium, to (1) highlight the scientific progress of EU-ToxRisk towards the establishment and validation of next-generation risk assessment (NGRA), (2) spotlight the international perspectives on the application of NGRA frameworks, (3) stimulate interaction and involvement with the EU-ToxRisk NAM-based Testing Commercialization Platform.
- For the 4-Organ-Chip-Meeting, to discuss and plan upcoming activities and clarify open questions or issues.
- For the CS15 meeting, to discuss and plan upcoming activities and clarify open questions or issues.
- For the WP6 meeting, to discuss and plan the remaining activities related to HEPG2 engineering and iPSC engineering and clarify open questions or issues (requested participants: LACDR, BIOT, VU, KUL).
- For the SAB/RAB debrief meetings, to prepare feedback and recommendations to the project.

### Agenda:

Time	Topic	Speakers/Chairs	Room
<b>8:00</b>	<b>EU-ToxRisk-only CS session</b>		
8:00-9:00	<u>4-Organ-Chip meeting (90')</u> – Upcoming activities and open questions or issues	Wolfgang Moritz (IS) Beren Atac Wagegg (TissUse)	530
<b>9:00</b>	<b>Opening of Day 2 of the Open Symposium</b>		
9:00-9:05	Introduction and agenda (5')	Bob van de Water (UL)	Lamoraalzaal
<b>9:05</b>	<b>Scientific highlights from EU-ToxRisk towards Next-Generation Risk Assessment (NGRA) – Chair: Paul Jennings (VU)</b>		
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	
<b>11:00-11:30</b>	<b>Coffee break (30')</b>		Lobby
<b>11:30</b>	<b>Poster session</b>		
11:30-12:30	Project CSs and scientific achievements are presented on posters (60')		Lobby
12:30-13:30	<b>Lunch break + posters (60')</b>		
<b>13:30</b>	<b>NAM-based Testing Commercialization Platform – Solving Industrial Problems in Safety Assessment – Chair: Barry Hardy (EwC)</b>		
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)	

Time	Topic	Speakers/Chairs	Room
13:55-14:30	<u>From screening to complex modelling required for risk assessment (35')</u> – Speed talks on the following topics: 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)	Lamoraalzaal
<b>14:30</b>	<b>International perspectives on NGRA – Chair: Bob van de Water (UL)</b>		
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)	
15:00-15:15	EFSA perspective (10' + 5' Q&A)	Georges Kass (EFSA)	
15:15-15:30	Wrap-up of the session; output and closing of the Open Symposium (15')	Bob van de Water (UL)	
<b>15:30</b>	<b>End of the Open Symposium</b> ⇒ <b>Interested stakeholders</b> have the possibility to stay on for the discussion session with the EU-ToxRisk commercialization partners (room 530). ⇒ <b>A shuttle is scheduled for 17:00</b> to allow external stakeholders to benefit from organised transfer to Schiphol airport / Amsterdam Centraal.		
<b>15:30-16:00</b>	<b>Coffee break (30')</b>		Lobby
<b>15:30</b>	<b>NAM-based Testing Commercialization Platform – Interactive discussion between EU-ToxRisk partners and interested external stakeholders – Chair: Barry Hardy (EwC)</b>		
15:30-17:00	Solving Industrial Problems in Safety Assessment: Discussing Needs (90')	Barry Hardy (EwC)	530
<b>16:00</b>	<b>Parallel Sessions – EU-ToxRisk-only</b>		
16:00-17:00	<u>SAB meeting (60')</u> - Debrief and preparation of the feedback to the project	Thomas Steger-Hartmann (BAYER)	531
16:00-17:30	<u>WP6 meeting (90')</u> – HEPG2 engineering and iPSC engineering	Catherine Verfaillie (KUL)	534
16:00-18:00	<u>Core team meeting with Japanese delegation</u> – Invited participants only (120')	Bob van de Water (UL)	535
<b>17:30</b>	<b>Parallel Sessions – EU-ToxRisk-only</b>		
17:30-18:30	<u>RAB meeting (60')</u> - Debrief and preparation of the feedback to the project	Matthias Herzler (BfR)	530
17:30-19:00	<u>CS15 meeting (90')</u> - Multi-organ metabolism	Paul Jennings (VU)	534
<b>19:00</b>	<b>End of Meeting Day 2</b>		
<b>19:30</b>	<b>Joint work dinner – Tapas buffet at the Zuiderduin hotel (Van Speykzaal in the restaurant area on floor 0)</b>		

## Day 4 – Thu. 13 Feb. 2020: EU-ToxRisk General Assembly, internal WP/CS meetings, ST meeting

### Objectives:

- For the CS14 meeting, to further discuss and plan the CS activities.
- For the CS8 meeting, to discuss remaining activities and clarify open questions or issues.
- For the WP4/WP10 meeting, to discuss remaining activities and clarify open questions or issues.
- For the CS10 meeting, discuss mass spectrometry issues.
- For the General Assembly session, to (1) receive feedback from the external advisory boards (SAB, RAB), (2) announce the results from the poster session and distribute the awards, (3) get inspiration and learn from the UNILEVER ab initio case study, and (4) discuss strategic project topics.
- For the WP2/WP3 meeting, to discuss and plan remaining activities and involvement in the new CSs, and clarify open questions or issues.
- For the WP5/WP7 meeting, to discuss and plan remaining activities and clarify open questions or issues.
- For the WP11 meeting, to discuss and plan remaining activities and clarify open questions or issues.
- For the CS11/CS12 meeting, align the earlier discussed CS activities with the outcome and new insights from the discussions from the Open Symposium and General Assembly.
- For the Steering Team meeting, to debrief on the Open Symposium & General Assembly and discuss any identified issues.

### Agenda:

Time	Topic	Speakers/Chairs	Room
<b>8:00 / 8:30</b>	<b>WP/CS parallel sessions</b>		
8:00-9:30	CS14 meeting – DNT/neonicotinoids (90')	Susanne Hougaard Bennekou (DTU)	530
8:30-9:30	CS8 meeting – Popcorn lung (60')	Tanja Hansen (ITEM)	531
8:30-9:30	WP4/WP10 meeting (60')	Iain Gardner (Certara) Frédéric Bois (INERIS)	535
<b>9:30</b>	<b>General Assembly (Plenary) – Chair: Bob van de Water (UL)</b>		
9:30-10:30	NGRA of Coumarin in a Hypothetical Face Cream Product (50' + 10' Q&A)	Tom Cull (Unilever)	Lamoraalzaal
10:30-11:15	Feedback from the SAB (20') Feedback from the RAB (20')	Thomas Steger-Hartmann (BAYER) Matthias Herzler (BfR)	
<b>11:15-11:45</b>	<b>Coffee break (30')</b>		Lobby
11:15-12:00	CS10 meeting – Multi Target Organ (45')	Sylvia Escher (ITEM)	530
11:45-12:25	Project Management: Achievements & Roadmap for the coming period (40')	Bob van de Water (UL) Martijn Moné (UL) Elisabeth Graf (ARTTIC) Giorgia Pallocca (CAATEU)	Lamoraalzaal
12:25-12:35	Poster award (10')	Bob van de Water (UL)	
12:35-12:45	Wrap-up & Closing of the General Assembly (10')	Bob van de Water (UL)	
<b>12:45-13:45</b>	<b>Lunch break (60')</b>		Lobby
<b>13:45</b>	<b>Shuttle to Schiphol Airport / Amsterdam Centraal</b>		

Time	Topic	Speakers/Chairs	Room
<b>13:45</b>	<b>WP/CS parallel sessions</b>		
13:45-14:45	WP2/WP3 joint meeting (60')	Ugis Sarkans (EBML- EBI) Manuel Pastor (UPF)	530
13:45-15:45	WP5/WP7 joint meeting (120')	Jan Hengstler (IFADO) Marcel Leist (UKN)	531
13:45-15:45	WP11 meeting (120')	Hennicke Kamp (BASF)	535
<b>14:45</b>	<b>WP/CS Parallel sessions</b>		
14:45-15:45	CS11/CS12 debrief meeting – Low Tox (60')	Tom Cull (UNILEVER) Bob van de Water (UL)	530
<b>15:45-16:00</b>	<b>Good-bye coffee before departure (15')</b>		Lobby
<b>16:00</b>	<b>Shuttle to Schiphol Airport / Amsterdam Centraal</b>		
<b>16:00</b>	<b>Steering Team meeting</b>		
16:00-17:30	Debrief from the Open Symposium and General Assembly (90')	Bob van de Water (UL)	530
<b>17:30</b>	<b>End of the meeting</b>		
<b>17:45</b>	<b>Shuttle to Schiphol Airport</b>		