

NAM-Supported Read-Across: From Case Studies to Regulatory Guidance in Safety Assessment

Tue. 21 – Wed. 22/Thu. 23 May 2019, Hotel Korpilampi, Espoo, Finland

Day 1 – Tue. 21 May 2019

| Time | Topic | Speakers/Chairs | Room |
|---|---|--|---------------|
| 8:15-9:00 | Registration at the welcome desk | | Lobby |
| Opening of the workshop | | | |
| 9:00-9:10 | Welcome and introduction (10') | Susanne Hougaard Bennekou (DTU) Bob van de Water (UL) | Auditorium |
| Introductory talks (Plenary session) | | | |
| 9:10-9:25 | Regulatory / cross-regulatory perspective I (15') | Derek Knight (ECHA) | Auditorium |
| 9:25-9:40 | Regulatory / cross-regulatory perspective II (15') | Georges Kass (EFSA) | |
| 9:40-9:55 | NTP case study - Bisphenol A (15') | Nisha Sipes (US NIH-NTP) | |
| 9:55-10:10 | Introduction to the EU-ToxRisk RAX concept (15') | Hennicke Kamp (BASF) | |
| Introductory talks on CS (Plenary session) | | | |
| 10:10-10:30 | <u>EU-ToxRisk CS1 – Branched carboxylic acids (20')</u> : - Reg. context: REACH - Prediction: no tox, tox - NAMs: TK&TD, battery of tests - Endpoint: steatosis | Sylvia Escher (ITEM) | Auditorium |
| 10:30-10:50 | <u>EU-ToxRisk CS2 – Branched carboxylic acids (20')</u> : - Reg. context: REACH - Prediction: no tox - NAMs: TK&TD, battery of tests - Endpoint: DART | Dinant Kroese (TNO) | |
| 10:50-11:20 | Coffee break (30') | | Coffee market |

| Time | Topic | Speakers/Chairs | Room |
|--|---|---|-------------------|
| 11:20-11:40 | <u>EU-ToxRisk CS4 – Strobilurins (20')</u> : - Reg. context: EU Pesticides - Prediction: no tox - NAMs: TK&TD, battery of tests - Endpoint: neurotox | Susanne Hougaard Bennekou (DTU) | Auditorium |
| 11:40-12:00 | <u>OECD/IATA case US-EPA/Health Canada – Phenols (20')</u> : - Reg. context: Canada Chemicals Management Plan - Prediction: PoD - NAMs: TK&TD, QSAR/in vitro - Endpoint: estrogenicity | Francina Webster (Health Canada) | Auditorium |
| 12:00-12:20 | <u>OECD/IATA case Japan – Ethylene glycol methyl ether (20')</u> : - Reg. context: Japanese Chemical Substances of Control Law - Prediction: PoD and harmonised classification - NAMs: metabolism simulation - Endpoint: testicular tox | Takashi Yamada (NIHS Japan) | |
| 12:20-12:30 | Instructions for breakout sessions and reporting (10') | Susanne Hougaard Bennekou (DTU) | |
| 12:30-14:00 | <i>Lunch (90')</i> | | Restaurant |
| 14:00-18:00 <i>(30 min. coffee break inbetween)</i> | Parallel breakout group sessions | | |
| | EU-ToxRisk CS1 – Branched carboxylic acids | Derek Knight (ECHA) Sylvia Escher (ITEM) | Auditorium |
| | EU-ToxRisk CS2 – Branched carboxylic acids | Matthias Herzler (BfR) Dinant Kroese (TNO) | Room n°4 |
| | EU-ToxRisk CS4 – Strobilurins | Georges Kass (EFSA) Susanne Hougaard Bennekou (DTU) | Room n°5 |
| | OECD/IATA case US-EPA/Health Canada – Phenols | Andrea Richarz (ECHA) Francina Webster (Health Canada) | Room n°6 |
| | OECD/IATA case Japan – Ethylene glycol methyl ether | Lidka Maslankiewicz (RIVM) Takashi Yamada (NIHS Japan) | Room n°3 |
| 18:00 | End of Meeting Day 1 | | |
| 19:30 | Joint work dinner in the hotel restaurant | | |

Day 2 – Wed. 22 May 2019

| Time | Topic | Speakers/Rapporteurs | Room |
|---|--|--|----------------------|
| 9:00-9:10 | Opening of Day 2 (10') | Susanne Hougaard Bennekou (DTU) | Auditorium |
| Reporting on breakout session from Day 1 (Plenary session) | | | |
| 9:10-9:30 | EU-ToxRisk CS1 – Branched carboxylic acids (steatosis) (20') | Agnes Kovari (ECHA) | Auditorium |
| 9:30-9:50 | EU-ToxRisk CS2 – Branched carboxylic acids (DART) (20') | Leon van Aerts (RIVM) | |
| 9:50-10:10 | EU-ToxRisk CS4 – Strobilurins (20') | Hennicke Kamp (BASF) | |
| 10:10-10:30 | OECD/IATA case US-EPA/Health Canada – Phenols (20') | Grace Patlewicz (US EPA) | |
| 10:30-10:50 | OECD/IATA case Japan (20') | Nisha Sipes (US NIH-NTP) | |
| 10:50-11:00 | Closing of reporting session (10') | Susanne Hougaard Bennekou (DTU) | |
| 11:00-11:30 | <i>Coffee break (30')</i> | | Coffee market |
| Presentations & Discussion (Plenary session) | | | |
| 11:30-11:50 | Internationalisation of Read Across – 2018 Ranco workshop outcomes (20') | Thomas Hartung (JHSPH) | Auditorium |
| 11:50-12:10 | Elk River chemical spill (20') | Nisha Sipes (US NIH-NTP) | |
| 12:10-12:30 | <u>RAX tools (20')</u> : - GenRA - EU-ToxRisk | Grace Patlewicz (US EPA) Alessandra Roncaglioni (IRFMN) | |
| 12:30-13:30 | <i>Lunch (60')</i> | | Restaurant |
| Closing (Plenary session) | | | |
| 13:30-15:00 | Discussion RAX workshop report (90') | ALL | Auditorium |
| 15:00-15:30 | Wrap-up & Closing (30') | Susanne H. Bennekou (DTU) | |
| 15:30 | End of the public part of the Read Across Workshop ⇒ Shuttle to Vantaa Airport, leaving from the hotel at 15:45 | | |
| 15:30-16:00 | <i>Coffee break for the reporting group (30')</i> | | Coffee market |
| 16:00-18:00 | Reporting: subgroups (per Case Study) + plenary (120') | | Room n°4 |
| 18:00 | End of the reporting session | | |
| 19:30 | Joint work dinner in the hotel restaurant | | |

Day 3 – Thu. 23 May 2019

| Time | Topic | Chair | Room |
|--|--|--|-----------------|
| 9:00-12:00 <i>(coffee served in the meeting room)</i> | Reporting: plenary discussion and integration | Susanne Hougaard Bennekou (DTU) Bob van de Water (UL) | Room n°4 |
| 12:00 | <i>End of the EU-ToxRisk Read Across workshop – Takeaway lunch bags</i> | | |

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)

Qasim Chaudhry (SCCS)

Grace Patlewicz (US EPA)

Rositsa Serafimova (EFSA)

Nisha Sipes (US NIH-NTP)

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