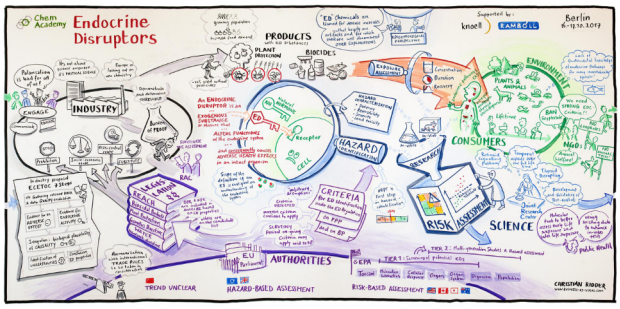
**300€**
Early Bird until
18th July 2022

7th International Conference

# Endocrine Disruptors



Graphic Recording Endocrine Disruptors Conference 2017

## Key Topics

- ED in the context of the EU's Green Deal
- OECD Testing Guidelines
- Risk perception and regulation
- Risk Assessment for Biocidal Active Substances
- The EURION projects

## Presenting Institutions and Companies

- Anne Gourmelon, OECD
- Dr Maristella Rubbiani, European Commission
- James Wheeler, PhD, Corteva Agriscience, The Netherlands
- Prof Dr Lennart Weltje, BASF SE, Germany
- Dr Daniela Fruth, knoell Germany GmbH, Germany
- Dr Volker J. Soballa, Evonik Industries AG, Germany
- Prof Taisen Iguchi, Japan
- Dr Sylvia Jacobi, Albermarle, Belgium
- Gregory Lemkine, Watchfrog, France
- Dr Thomas Sendor, Ramboll Germany GmbH, Germany
- Helen Tinwell, Bayer SAS, France
- Dr Christian Unkelbach, Federal Institute for Occupational Safety and Health (BAuA), Germany
- Stine Jensen, Ministry of Environment, Environmental Protection Agency, Denmark
- Dr Chris J. Borgert, Applied Pharmacology and Toxicology, Inc., USA

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19th and 20th September 2022
Frankfurt, Germany, and online

Presented by
Chem Academy

www.chem-academy.com/endocrine-disruptors

# Monday, 19th September 2022

8.30 Registration and Coffee

9.00

**Opening Remarks**

Dr Bjoern Nehls, Director, Chem-Academy, and
Dr Volker J. Soballa, Vice President, Head of Product Stewardship, Corporate ESHQ, Evonik Industries AG

9.10

**The EU's New Green Deal:**
**The Future of Chemicals Regulation from the Industry's Perspective**

- Relevant trends in global product stewardship
- Chemicals regulation: the EU and country specific requirements
- Key elements of the New Green Deal
- How to encourage sustainability

Dr Volker J. Soballa, Vice President, Head of Product Stewardship, Corporate ESHQ, Evonik Industries AG, Germany

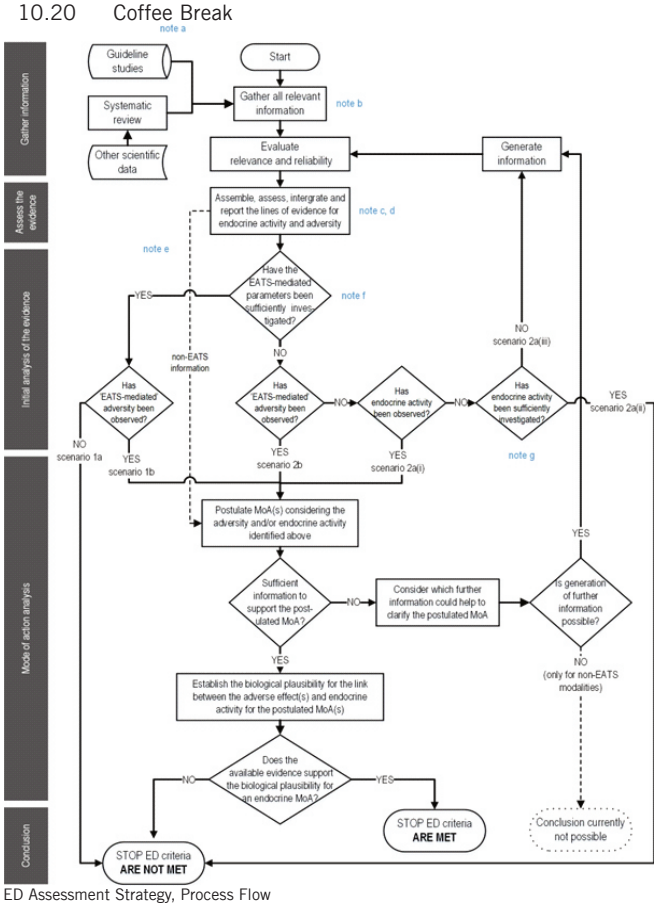
9.30

**Evaluating Endocrine Disruptors**

- BPR and PPP legislation for identification of the ED properties
- Key elements of the EFSA/ECHA Guidance document
- Data requirements update
- Evaluation of ED/non-ED substances so far
- Risk assessment for substances identified as having ED properties
- Work in progress on CLP regulation for definition of new ED hazard classes

Dr Maristella Rubbiani, Policy Officier, European Commission, Directorate-General for Health and Food Safety, Unit E4 – Pesticides and Biocides

10.20 Coffee Break




ED Assessment Strategy, Process Flow
Source: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5311, 05/23/2022

10.50

**The Impact of Updated ED Data Requirements on Biocide Applications**

- Regulatory framework for assessing ED properties of biocides
- Interdependence of legislation (BPR) and guidance
- Interactions between ED assessment for mammalian and environmental toxicology
- Challenges for applicants in a changing regulatory framework – practical examples

Dr Thomas Sendor, Senior Managing Consultant, Ramboll Deutschland GmbH

11.40

**The Regulatory Framework for EDs: Requirements, Experiences and Challenges from a Global Point of View**

- Key elements of the EU ED Guidance and how they relate to global regulatory concepts
- Assessments under Crop protection vs. Biocides vs. Chemicals Regulations
  - Five stages towards the assessment of potential ED properties
- One substance, one assessment: challenges how might that work?
  - Issues with data ownership
- State of regulation as well as management and anticipation in major global markets
  - Europe
  - The Americas
  - Asia

Dr Daniela Fruth, Regulatory Toxicologist, Environmental and Human Toxicology, knoell Germany GmbH, Germany

12.30 Lunch Break

13.50

**Involving Stakeholders: the EURION Projects from the Industry's Point of View**

- The process to assess Endocrine Disruption
- Current gaps and how they can be closed
- Increasing transparency in research projects
- Criteria for research methods
- Challenges with multi stakeholder projects in times of the Corona crisis
- How to deal with upcoming bottlenecks on GLP studies

Helen Tinwell, Distinguished Bayer Science Fellow and Regulatory Toxicology Group Leader, Bayer SAS

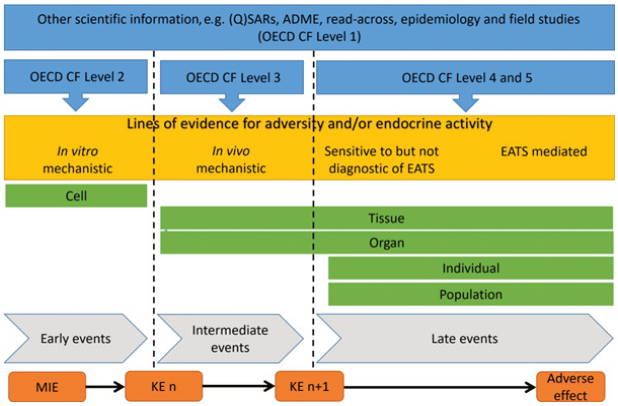
14.40

**The Scientific Approach for Endocrine Testing**

- How to assess endocrine activity vs adverse outcome
- Key elements of EFSA's and ECHA's ED testing strategy
- How methods contribute to elucidate endocrine MOA
- Recent developments on the endocrine axes: estrogenic, androgenic, thyroid
- Drawing conclusions from in vitro: how far can we go?

Dr Gregory Lemkine, CEO, Laboratoire Watchfrog S.A., France

15.30 Coffee Break




Lines of Evidence for Adversity and/or Endocrine Activity
Source: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5311, 05/23/2022

16.00

**The OECD Test Guidelines Programme: Activities and Insights**

- OECD Activities on Endocrine testing
- How methods are validated and improved continuously
- Recent innovations in ED testing
- Examples from current research projects
- How to engage in developing testing methods, standards and guidelines
- JRC in vitro methods for thyroid disruption

Anne Gourmelon, Principal Administrator - Test Guidelines Programme, Environment Health and Safety Division, Environment Directorate, OECD

16.50 Chairman's Closing Remarks

17.00 End of Day One

18.00 Evening Reception

Following the official part of the conference, Chem-Academy invites you to a social evening reception at an atmospheric local restaurant (with fresh air 😊). Benefit from the informal surrounding to intensify business contacts and extend your network. Enjoy meeting people again, though with social distance.

## Tuesday, 20th September 2022

8.30

**Chairman's Opening Remarks**

Dr Volker J. Soballa, Head of Product Stewardship, Corporate ESHQ, Evonik Industries AG

8.40

**Endocrine Disruption and its Impact on Regulatory Requirement**

- Consequences from ED regulations so far
- REACH data requirements: Upcoming adaption
- Planned new ED hazard classes for CLP
- Further impacts on related chemicals regulation
- Bisphenols restriction proposal: A case study for ED-based regulation

Dr Christian Unkelbach, Federal Office for Chemicals (BfC), Federal Institute for Occupational Safety and Health (BAuA), Germany

9.30

**Japan's Regulation on Endocrine Disrupting Effects**

- EXTEND 2016: key to the current regulation of ED
- How Japanese regulation compares to other regulatory frameworks
- Criteria for candidate chemicals
  - Selection
  - How to understand effect vs disruption
- Challenges with tests and animal welfare
- Japanese Chemical Substances Control Law: Environmental risk assessment

Prof Taisen Iguchi, National Institute for Basic Biology, Japan

10.20 Coffee Break

10.50

**Endocrine Disruptors: State of the Regulation in the US**

- Endocrine hazards – a definition and the meaning of potency
- Case study: Human-Relevant Potency-Threshold (HRPT) for the ERα-Agonist MoA
- The interaction of hormones and Endocrine Disrupting Chemicals
- Chemicals regulation in the US and the broader picture: impact of ToxCast® Tox 21 data, and Key Characteristics Approach
- Pesticides, biocides, industrial chemicals: restrictions to be expected?

Dr Christopher J. Borgert, President & Principal Scientist, Applied Pharmacology and Toxicology, Inc., USA

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11.40

**Endocrine Disruption: Ecotoxicology and its Contribution to ED Assessment**

- Ecotox in context of ED regulation within the EU
- OECD framework and guidance
- Lessons learned on 52 substances from the EDSP Impact Assessment
- Thoughts and numbers on animal welfare
- Adversity vs activity

Prof Dr Lennart Weltje, Senior Regulatory Scientist, BASF SE, Germany

12.30 Lunch Break

13.50

**Pesticides vs Chemicals: Key Issues from an Ecotoxicological Point of View**

- Testing requirements: pesticides vs chemicals
- Case studies: Fish short reproduction tests
- Insights and limitations: conclusions to be drawn
- Why Weight of Evidence matters
- Endocrine vs non-endocrine effects
- Animal use within the assessment
- Non-animal methods

Dr James Wheeler, Global Regulatory Ecotoxicologist, Corteva Agriscience, The Netherlands

14.40

**Development in ED Risk Assessment for Biocidal Active Substances**

- Active substances and biocidal products – the challenges from a Competent Authority's point of view
- How is the industry being involved?
- "Negligible exposure" – how to deal with the lack of a clear definition for biocides
- Learnings from the interaction of authorities and industry
- Key elements of the technical and scientific part
- The framework, the process and potential obstacles: looking back at pioneer work

Stine Jensen, Academic Officer, Doctor of Veterinary Medicine, Pesticides & Biocides, Ministry of Environment and Food of Denmark, Environmental Protection Agency

15.30 Coffee Break

16.00

**Endocrine Disruption and Biocidal Products: Challenges for the Industry**

- Regulatory framework for the Biocides Product sector
- Insights into Ecetoc's Special T4 Task Force
- Considerations on a science-based testing strategy for identification of maternal thyroid hormone imbalance
- Epidemiological data so far
- Potential pathways to thyroid disruption

Dr Sylvia Jacobi, Corporate Toxicology Director, Albemarle, Belgium

16.50 Chairman's Closing Remarks

17.00 End of the Conference

## Advance Notice

**Seminar REACH**

26. and 27. September 2022, Bonn and online
Event language: German

**8. Jahrestagung Regulatorische Toxikologie**

17. and 18. Oktober 2022, Berlin and online
Event language: German

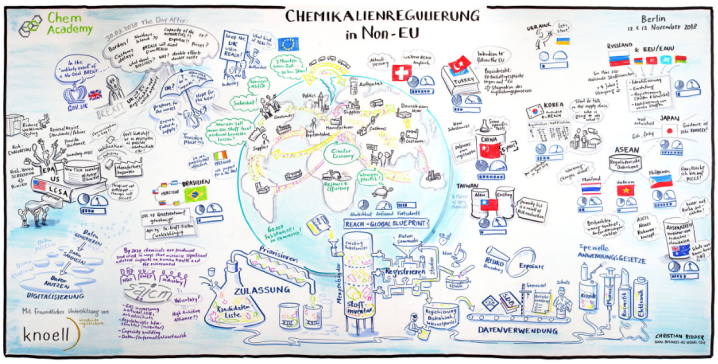
**Chemikalienregulierung in Non EU**

14. and 15. November 2022, Bonn and online
Event language: German

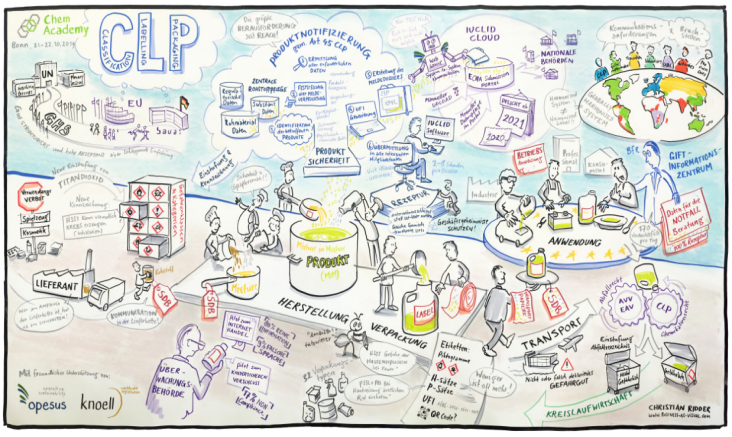
**Neuerungen bei CLP und GHS**

20. and 21. November 2022, Bonn and online
Event language: German

For more Information please visit: **www.chem-academy.com**




**Graphic Recording Chemikalienregulierung in NON-EU 2018**




**Graphic Recording CLP 2019**

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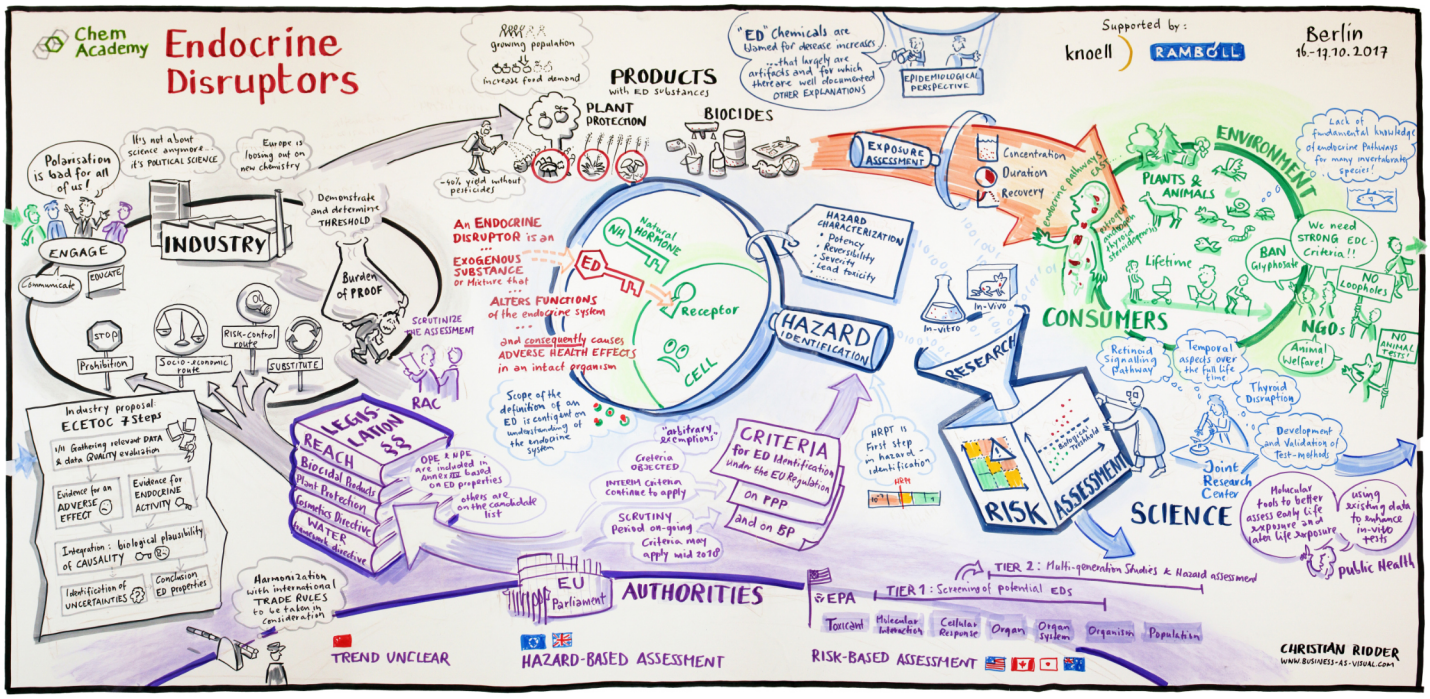
## Graphic Recordings

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**Your Contact:**

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## Conference Venue

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**Endocrine Disruptors**

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