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# Conference
# Endocrine Disruptors

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## Presenting Institutions and Companies

- European Commission
- OECD
- Bayer CropScience, ecetoc
- Karolinska Institutet
- KEMI – Swedish National Chemicals Inspectorate
- Bayer AG
- CEFIC – European Chemical Industry Council
- Dr. Knoell Consult GmbH
- ISS – Italian National Institute of Health
- ECHA – European Chemicals Agency
- Public Health England
- RIVM – National Institute for Public Health and the Environment
- CRD – Chemicals Regulation Directorate
- University of Surrey
- Evonik Industries AG
- ZEG – Berlin Center for Epidemiology and Health Research
- BASF SE
- ExxonMobil Biomedical Sciences, Inc.

- Get an Overview of the Current Situation in Preparing Legislation
- State of the Science on Endocrine Disruption
- Learn about Endocrine Disruption in Ecotoxicology
- Gain Valuable Insight into OECD Activities on Endocrine Disruptors
- Receive News on ECHA's Work on Endocrine Disruptors

## Workshop

**Endocrine Disruptors (ED) and the Interaction of Different Pieces of Regulation**

Dr. Peter Douben, ReachWise

12th and 13th October 2015, Conference
14th October 2015, Workshop
Berlin, Germany

Presented by
Chem Academy

www.chem-academy.com/endocrine-disruptors

## Monday, 12th October 2015

8.00 Registration and Coffee

8.20

**Chairman's Opening Remarks**

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

8.30

**Regulatory Update 2016**

- Status Quo of the proposal for science-based criteria for endocrine disruptors
- Roadmap for defining criteria for identifying endocrine disruptors
- Establishing horizontal criteria
- First results of the public consultation on defining criteria

**Ellen Dhein, Corporate Environmental Affairs, Bayer AG, Germany**

9.10

**Report from the Competent Authorities**

- Sweden's approach in dealing with EDs – medium and long term actions regarding endocrine disruptors
- Challenges in international exchange and coordination
- Development and validation of tests and test strategies – biocides, crop protection products, pharmaceuticals and chemicals

**Dr. Gregory Moore, National Chemicals Inspectorate (KEMI), Sweden**

9.50

**The Impact Assessment for Defining Criteria on Endocrine Disruptors**

- The EU Comissions's Roadmap
- Policy design using Impact Assessment
- Key analytical questions

**Laura Fabrizi, Policy Officer, Unit E3 Sector Pesticides and Biocides, DG Health and Food Safety, European Commission, Belgium**

10.30 **Q&A with Speakers**

11.00 Networking and Coffee

11.30

**Cefic: Overview of Current Situation in Preparing Legislation**

- Industry's engagement on ED
- Industry's views on the criteria
- Commission's impact assessment – industry expectations
- Biocidal Product Regulation

**Peter Smith, Executive Director of the Product Stewardship Programme, European Chemical Industry Council (Cefic), Belgium**

12.10

**Recent Global Regulatory Developments and Data Requirements for Endocrine Disruptor Testing and Assessment**

- Overview on current regulatory developments worldwide: Europe, North and South America, Asia, Australia
- Data requirements within different pieces of legislation and regulations
- Implications for global registrations and recommendations

**Dr. Martina Duft, Ecotoxicology, Industrial Chemicals & Biocides, Dr. Knoell Consult GmbH, Germany**

12.50 Networking Lunch

14.10

**Current State of the Science on Endocrine Disruption**

- Endocrine Disruption as a subject of diverse scientific perspectives
- Endocrine modulation in human biology and medical science
- Endocrine modulation in general and regulatory toxicology
- Is there a role for social sciences in the context of ED?

**Dr. Alfred Pauls, Institute of Sexology and Sexual Medicine, Charité University Medicine Berlin and ZEG - Berlin Centre for Epidemiology and Health Research, Germany**

14.50

**Overview of Industry's Scientific Initiatives on Endocrine Disruptors**

- ECETOC's task forces and criteria for EDs
- ECETOC's work on ED – low dose initiative
- Taking the initiative one step further – Royal Society of Chemistry's initiatives for EDs

**Dr. Rémi Bars, Member of the ECETOC Scientific Committee and Group Leader, Bayer CropScience, France**

15.30 Networking and Coffee

16.00

**OECD Activities on Endocrine Disruptors**

- The process of test guideline development
- Associated OECD documents regarding endocrine disruptors
- Developing AOPs for endocrine disruptors

**Dr. Nathalie Delrue, Toxicologist, Environment Directorate, Environment, Health and Safety Division, OECD, France**

16.40

**Taking forward Endocrine Disruptor Testing Needs for the Protection of Public Health – Under the Auspices of the OECD**

- Test guideline development priorities
- The incorporation of metabolism into in vitro endocrine test guidelines
- Critical windows of exposure and later life onset of endocrine related disease

**Dr. Miriam Jacobs, Principal Toxicologist, Public Health England, United Kingdom**

17.20 **Chairman's Closing Remarks**

17.30 **End of Conference Day 1**

18.00 **Evening Reception**

## Tuesday, 13th October 2015

8.20

**Chairman's Opening Remarks**

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

8.30

**ECHA's Work on Endocrine Disruptors under REACH**

- Current work of ECHA's Endocrine Disruptor Expert Group: mandates and tasks of the group
- Types of assessement
- Potential consequences for risk management
- PACT – a tool for communication activities and increasing transparency

Dr. Conor Clenaghan, Unit D 2 – Classification and Prioritisation, European Chemicals Agency, Finland

9.10

**Endocrine Disruptors in the Context of REACH**

- Endocrine disruptors and SVHC
- Lessons learnt on SVHCs and authorisation
- Endocrine active substances vs. endocrine disruptors

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

9.50 Networking and Coffee

10.20

**Potential Impact of Identifying Endocrine Disruptors Across Different Legislations**

- Legislative provisions
- Regulatory consequences
- Possible impact of different criteria

Dr Susy Brescia, Senior Scientist, Chemicals Regulation Directorate, Health & Safety Executive, United Kingdom

11.00

**Low Dose in Endocrine Disruption**

- Challenges regarding thresholds in toxicological hazard assessment
- Redefining adaptive changes versus adverse effect
- Study design and statistics for low dose studies: current and alternative hazard assessment tools

Professor Aldert Piersma, Professor of Reproductive and Developmental Toxicology Center for Health Protection, National Institute for Public Health and the Environment (RIVM), The Netherlands

11.40

**Risk assessment for EDs**

- Extrapolating laboratory data to terrestrial ecosystems
- Endocrine active vs. endocrine disrupting substances
- Levels of concern

Dr. Christopher M. Prosser, Senior Environmental Scientist, ExxonMobil Biomedical Sciences, Inc., USA

12.20 Networking Lunch

13.40

**Use of Weight of Evidence (WoE) for Decision Making**

- The methodology of WoE: What constitutes a sufficient WoE?
- Implementing a consistent approach to WoE assessment and applying this on all regulatory areas
- How to deal with poor data and lack of data quality

Professor Jim Bridges, Toxicology and Environmental Health, University of Surrey, United Kingdom

14.20

**Ecotoxicology: Identifying Endocrine Disrupting Properties**

- Risk based approaches vs. hazard assessment
- Result driven testing: strategies, risks and benefits
- Consequences for the industry: relevant input for risk assessments

Dr. Lennart Weltje, Senior Regulatory Ecotoxicologist, BASF SE, Germany

15.00 Networking and Coffee

15.30

**Case Study: Detailed Review Paper on the Retinoid System**

- Gaining state of the art knowledge about the retinoid system in the toxicology endocrine disruption
- Approaches for testing retinoid system toxicity
- Establishing a retinoid system toxicity testing method
- Contributing to further international harmonisation of hazard and risk assessment for EDs

Professor Helen Håkansson, Institute of Environmental Medicine (IMM), Karolinska Institutet, Sweden

16.10

**Endocrine Disruptors in the Context of the Water Framework Directive (WFD)**

- Priority endocrine disruptors in the Water Framework Directive
- Developing harmonised methods and screening tools for effect-based and chemical analytical monitoring in surface and wastewaters
- Linking reliable effect-based tools with regulatory needs

Dr. Mario Carere, Department Environment and Primary Prevention, National Institute of Health, Italy

(Co-author: Robert Kase, Swiss Centre for Applied Ecotoxicology, EAWAG-EPFL, Switzerland)

16.50 **Chairman's Closing Remarks**

17.00 **End of Conference**

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## Wednesday, 14th October 2015

| | |
|---|---|
| 8.00 | Reception and Coffee |
| 8.30 to 16.30 | **Endocrine Disruptors (ED) and the Interaction of Different Pieces of Regulation** |
| | Breaks will be arranged flexibly. |

## Your Course Facilitator

**Dr. Peter Douben, Director, REACHwise**

Peter is founder and Director of REACHWise, a London based consultancy aimed at assisting companies with their implementation of REACH, CLP and associated legal duties.
Before REACHWise, Peter was Head of Environmental Protection in Unilever and served on many industry bodies in Europe and North America. Then he was Director REACH/Chemicals Policy in Cefic, the European Chemical Industry Council, during which he was responsible for the implementation of REACH, and as such he was involved in several RIPs. He led the Project Management Groups on the guidance for information requirements on intrinsic properties of substances, and the one on carrying out the chemical safety assessment.
He has a University degree from the University of Wageningen, The Netherlands, and a PhD in ecotoxicology, based on a collaboration between Wageningen University and the Natural Environment Research Council, funded by the EEC, the forerunner of the EU, with additional financial support from the British Council.

## Content of Workshop

**The Endocrine System in a Nutshell**

- How does it work
- Why is it important

This introductory part summarises key parts of the endocrine system to provide a common understanding and scene setting of the workshop. It also serves as a lead in to the next part: why regulators are concerned about it.

**Regulatory Framework**

- Key areas of regulation: chemicals, biocides, crop sciences
- Regulatory requirements on endocrine disruptors: Where do we stand in the regulatory process?
- Wrap up on the regulatory background

This part of the workshop considers the broad framework which endocrine disruption regulation is part of. Regulatory requirements for chemicals, biocides and crop sciences will be compared. How does especially the REACH regulation affect the way these interact? Which kind of changes can be expected in the future? To what extent will global harmonisation take place? What is the impact e.g. of scientific studies in the US or other areas on European manufacturers?

**Project Management Set Up**

- Under which circumstances do companies have to re-evaluate their dossiers?
- Concrete challenges on ED deriving from the regulatory requirements
- Overall purposes of ED related activities

Having covered the relevant regulatory requirements the course will be directed to more concrete challenges. Upcoming activities will be summarized and prioritized in order to shape a project, involving a number of departments. Delegates will have to work out their key aspects of their projects and keep in mind the purposes of product stewardship.

**Compliance Step by Step**

- Relevant information sources
- Available tests and conclusions
- Substances of Very High Concern (SVHCs): lessons learned

Maintaining compliance is one of the vital aims of the project management outlined above. This part of the workshop focusses on what needs to be taken into consideration for certain substances or products? How do people in charge of assessing endocrine activity aggregate sufficient information? What role do hazard and exposure play? What methodologies for risk assessment are available? And which conclusions can be drawn from SVHCs?

**Outlook on Main Challenges**

- Bottlenecks to be expected when working on ED
- Further developments and upcoming challenges on ED and regulation

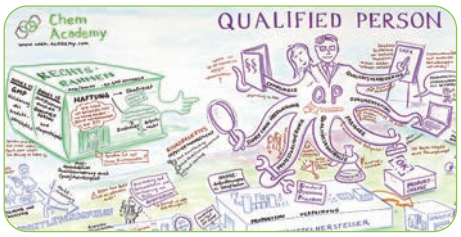
Endocrine disruption has become more and more important for a growing number of companies. The workload will increase for most of the stakeholders from industry, authorities, NGOs, etc. The final part of this work-shop will deal with the bottlenecks that are most likely to occur and measures against it.

Chem Academy

## About Chem-Academy

Chem-Academy is part of Vereon AG and is running both industry specific conferences and courses since 2007. Its main target groups are the chemical and the pharmaceutical industry. Events mainly focus on regulatory topics, e.g. chemical regulation like REACH or the GMP framework for pharmaceutical companies. Representatives of all major companies as well as of the most important public authorities give presentations or facilitate courses.
**www.chem-academy.com**

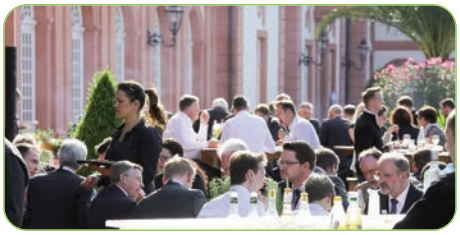
# Impressions




## Q&A Session

## Graphic Recording
## Evening Reception

## Case Studies



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**Your contact:** Dr. Thomas Rücker, Chemical Safety & Regulatory Compliance, Toxicologist, T: +49 89 1392 832 16, truecker@environcorp.com, Ramboll Environ Germany GmbH, Aschauer Strasse 32a, 81549 Munich, Germany

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Conference: **Endocrine Disruptors**

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| ☐ Conference and Workshop* 12th - 14th October 2015 | 2.195 EUR (plus VAT) | 2.395 EUR (plus VAT) |
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## Conference Venue

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Registration is confirmed in writing by the organisers. The registration fee covers attendance at the lectures for the number of days selected, full documentation, entrance to the exhibition area, lunch and refreshments. VAT has to be added. Important note in terms of late payment: As mentioned in the registration form all payments must be received within the due date given in the invoice. If you assume that your company is not able to manage payment in-time by bank transfer, please provide your credit card details in order to guarantee your booking. This helps to avoid any inconvenience upon your arrival at the event. At that time the full amount of the payment must be received in our accounts at latest. Thank you very much for your co-operation.

2. Cancellations

Cancellations of a registration by a delegate has to be received in writing at least 30 days prior to the event and will be subject to a service charge of 200 Euro. Substitutions are acceptable at any time. Where cancellations are received later, the registration fee remains payable in its entirety. In case the event has to be cancelled by the organiser payments already received will be credited for the following year's event.

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The organiser gathers and processes data in accordance with data protection laws. Your data is stored electronically for the purpose of future updates of our services. If you wish your data to be amended, removed or not passed to an external organisation, please write to info@chem-academy.com.

5. Final Clauses

The contract is subject to the Swiss law. Area of jurisdiction is Kreuzlingen (Switzerland).

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