

Conference

# Endocrine Disruptors

Save  
200€

Early Bird  
Register by  
17<sup>th</sup> July 2015

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## Presenting Institutions and Companies

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

REACHWise

12<sup>th</sup> and 13<sup>th</sup> October 2015, Conference  
14<sup>th</sup> October 2015, Workshop  
Berlin, Germany

Presented by



**Monday, 12<sup>th</sup> 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, Swedish Chemicals Agency (KEMI), Sweden**

9.50

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

- The EU Commissions'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, 13<sup>th</sup> 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 assessment
- 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

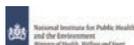


## Potential Impact of Identifying Endocrine Disruptors Across Different Legislations

- 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



## Detailed Review Paper on the Retinoid System

- Case study in the OECD program on Endocrine Disruptors
- Developing disease-relevant AOPs
- Elucidate end-point specific MOAs
- Potential for a new testing paradigm?

**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

**Wednesday, 14<sup>th</sup> 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

REACHWise

**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.





## Conference: Endocrine Disruptors

I would like to register:

	Early Bird until 17 <sup>th</sup> July 2015	from 18 <sup>th</sup> July 2015
<input type="checkbox"/> Conference and Workshop* 12 <sup>th</sup> - 14 <sup>th</sup> October 2015	2.195 EUR (plus VAT)	2.395 EUR (plus VAT)
<input type="checkbox"/> Conference 12 <sup>th</sup> to 13 <sup>th</sup> October 2015	1.795 EUR (plus VAT)	1.995 EUR (plus VAT)
<input type="checkbox"/> Workshop* 14 <sup>th</sup> October 2015	1.595 EUR (plus VAT)	1.595 EUR (plus VAT)

Unfortunately, I am not able to participate at the conference.  
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## Conference Venue

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### 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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