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5th July 2019

5th International Conference

Endocrine Disruptors



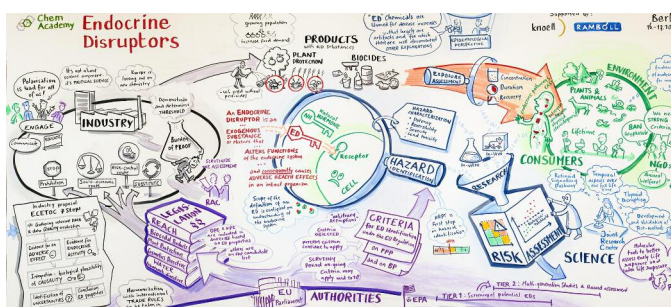
Hot Topics

- Criteria and Guidance Document
- Experiences in the Biocides Sector
- ED Regulation in the US and Japan
- Endocrine Disrupting Substances in Articles
- Horizon 2020 – the EU Commission's Schedule

Workshop

Understanding the Guidance for Identifying Endocrine Disrupting Chemicals

Dr Martina Duft, Dr Daniela Fruth,
knoell Germany GmbH, Germany



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Presenting Institutions and Companies

- Dr Christian Desaintes, European Commission
- Dr Roland Solecki, Federal Institute for Risk Assessment (BfR), Germany
- Ellen Mihaich, Ph.D., Environmental and Regulatory Resources, LLC, USA
- Prof Dr Lennart Weltje, BASF SE, Germany
- Dr Gregory Moore, Swedish Chemicals Agency (KEMI), Sweden
- Dr Andy Adams, Bayer S.A.S., France
- Dr Volker J. Soballa, Evonik Industries AG, Germany
- Ellen Dhein, Bayer AG, Germany
- Dr Christian Kirchnawy, OFI, Austria
- Dr Martina Duft, knoell Germany GmbH, Germany
- Annegaike Leopold, Caldiris Environment, the Netherlands
- Dr Sylvia Jacobi, Albemarle, Belgium
- Prof Taisen Iguchi, National Institute for Basic Biology, Japan
- Stine Jensen, Environmental Protection Agency (EPA), Denmark
- Dr Thomas Sendor, Ramboll Environment & Health GmbH, Germany
- Dr Gerard Swaen, Maastricht University, the Netherlands
- Martinus Nagtzaam, European Commission
- Dr Padmaja Jonnalagadda, Ph.D., National Institute of Nutrition, India

23rd and 24th September 2019, Conference
25th September 2019, Workshop
Berlin, Germany

Presented by



Monday, 23rd September 2019

8.30 Registration and Coffee

8.50

Chairman's Opening Remarks

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

9.00

Regulatory Status Quo – Challenges for the Industry

- State of the political and societal discussion on Endocrine Disruptors
- Criteria and Guidance and their impact on the industry
- Key questions on risk vs hazard and the role of potency
- Chemicals, plant protection products and biocides: the struggle with regulatory inconsistencies
- Upcoming initiatives within ED related sectors

Ellen Dhein, Manager Regulatory and Environmental Affairs, Bayer AG, Germany

9.40

Endocrine Disruptors and Key Aspects of a Science Based Risk Assessment

- Challenges for European risk assessors
- The impact of the ED criteria and the Guidance from an authority's point of view
- Why will there always be room for different interpretations?
- Maximising the use of available data
- Regulation of chemical safety in various sectors: what will the future bring?

Dr Roland Solecki, Head of Department Pesticide Safety, Federal Institute for Risk Assessment (BfR), Germany

10.20 Networking and Coffee Break

10.50

Challenges with Endocrine Disruptors from a Competent Authority's Point of View

- Implementation of ED-criteria
- The path from research to regulation
- Improving our understanding of chemical cocktails
- Differences between national lists of chemicals and the ECHA ED-list
- European harmonisation vs domestic initiatives
- The OECD guidelines as a point of reference
- The challenge with the communication of ED related activities

Dr Gregory Moore, Swedish Chemicals Agency (KEMI), Sweden

11.30

EDCs in the Environment: Evaluating Effects and Pushing the Limits of Analytical Detection

- Alkylphenol ethoxylates as sources of EDCs
- Closing data gaps in the effects assessment: Pitfalls with non-standard test organisms
- How to detect and quantify multiple degradation products?
- Lowering the LoQ to ranges below a possible (disputed?) threshold

Dr Thomas Sendor, Senior Managing Consultant, Ramboll Environment & Health GmbH, Germany

12.10 Lunch Break

13.30

Applying the ED Guidance to Crop Protection Products

- Views of the crop protection industry on the criteria and the guidance
- First experiences with application of the Guidance
- Assessing the weight of evidence
- Potential impact on additional vertebrate testing
- The burden of decision-making

- Broader implications for policy and future regulation of ED in EU?
- Dr Andy Adams, Global Agricultural Policy and Stakeholder Affairs, Bayer S.A.S., France**

14.10

Endocrine Disruptors in the Biocide Sector: Regulatory Developments from the Commission's Point of View

- Regulatory state of affairs: the Biocidal Products Regulation
- Key elements for identifying endocrine disrupting properties in biocidal products
- How the criteria and the guidelines are related to each other
- Implementation challenges for biocides and plant products
- Outlook: upcoming regulatory challenges

Martinus Nagtzaam, Policy Officer, Unit E4 – Pesticides and Biocides, DG Health and Food Safety, European Commission

14.50

The Causes of the Increases of Endocrine Related Diseases

- Changing trends in endocrine related diseases
- Impact of changes in human reproduction on the incidence of testicular cancer, hypospadias, and childhood obesity
- Impact of smaller family size on children born from subfertile couples
- Identifying factors at play in the etiology of ED diseases

Dr Gerard Swaen, Senior Epidemiologist, Department of Complex Genetics, Maastricht University, Netherlands

15.30 Networking and Coffee Break

16.00

Endocrine Disruption Regulation of Biocidal Products Industry – Learnings from Assessments so far

- The importance of ED assessment
- Regulating science and the challenges at the different stages
- Harmonisation between the member states on BP regulation
- Overview of the different implementation strategies that have been enforced so far for both active substances and biocidal products
- Harmonisation and cooperation across legislations (PPP and REACH) at this point

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

16.40

ED Criteria and their Impact on Biocidal Products

- Challenges for the Biocides Product sector
- Criteria and how they apply to Biocidal Products
- Interaction with European and domestic competent authorities
- What does the burden of proof mean in terms of time to market?
- Regulation of endocrine Disruptors: how to deal with overlaps and differences between Biocidal Products and REACH

Dr Sylvia Jacobi, Corporate Toxicology Director, Albemarle, Belgium

17.20 Chairman's Closing Remarks

17.30 End of Day 1

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. Benefit from the informal surrounding to intensify business contacts and extend your network.



Tuesday, 24th September 2019

8.45

Chairman's Opening Remarks

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

8.50

Horizon 2020: Research on Chemicals Safety

- H2020: vision and aims of the EU's funding program
- Research and activities related to chemical safety assessment
- Research on endocrine disrupting substances
- Human biomonitoring and exposome research activities
- The role of industry stakeholders and regulators in EU-supported research on chemical safety Horizon Europe
- Environment & Health research: challenges and opportunities

Dr Christian Desaintes, Scientific Officer, DG Research & Innovation, European Commission

9.30

A Global View on the New EU ED Guidance: Requirements, Experiences and Challenges

- The new EU ED Guidance - requirements and first experiences
- Testing vs non-testing - "sufficient data"?
- Recent regulatory developments worldwide: Europe vs the Americas and Asia
- Practical implications, regulatory consequences
- Recommendations for managing potential EDs on a global scale

Dr Martina Duft, Ecotoxicology/Regulatory Affairs, Industrial Chemicals & Biocides, knoell Germany GmbH, Germany

10.10 Networking and Coffee Break

10.40

The US Regulatory Framework on Endocrine Disruptors

- The US EPA's ED Screening Program: lessons learned and developments
- Hazard vs risk – methodological principles in approaching ED issues
- Screening, testing and assessing: what has to be done by the industry and how?
- New assessment methodologies and their challenges

Ellen Mihaich, Ph.D., DABT, President, Environmental and Regulatory Resources, LLC, Adjunct Professor, Duke University, USA

11.20

Endocrine Disruptor: Regulatory Requirements and Challenges in Japan

- Conclusions from Japan's program on endocrine disrupting chemicals EXTEND 2016
- The program's contribution to international cooperation and information sharing
- Concepts of assessment framework
- Criteria for selecting candidate chemicals
- A multi-tier framework for testing and assessing of ED effects
- Environmental risk assessment

Prof Taisen Iguchi, National Institute for Basic Biology, Yokohama City University, Japan

12.00 Lunch Break

13.20

Regulation of Endocrine Disruptors in India

- Regulatory requirements
- The authorities' roles in regulating EDs in India
- Interaction NGOs, industry and authorities
- Current activities and methods in detecting EDs
- Cooperation of Indian authorities with EU institutions

Dr Padmaja Jonnalagadda, Ph.D., Scientist F-Sr.Gr Dy. Director, National Institute of Nutrition, Indian Council of Medical Research, India

14.00

Challenges with Environmental Hazard and Risk Assessment for Chemicals

- Hazard vs risk in environment
- Endocrine active vs endocrine disruptive: how to detect the fine line
- Results from this year's SETAC meeting
- Issues of concern in the need for improved methods of assessment
- How can we find a broader consensus on key scientific questions?

Annegaaike Leopold, Consultant, Calidris Environment B.V., the Netherlands

14.40 Networking and Coffee Break

15.10

Latest Developments on Endocrine Testing and Assessment in Ecotoxicology with a Focus on Europe

- The ED assessment according to EFSA
- Insights from fish and amphibian studies
- Distinguishing endocrine activity from endocrine disruption
- Consequences for the industry and for animal welfare

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

15.50

Endocrine Disrupting Substances in Articles

- Consumer concerns and ED in the media vs the scientific point of view
- Methods for identifying potential endocrine disruptors in plastics
- How do in vitro bioassays work?
- Examples and results
 - Food packaging materials
 - Plastic in toys
- How to detect weaknesses in studies

Dr Christian Kirchnawy, Team Leader, OFI Technologie & Innovation GmbH, Austria

16.30 Chairman's Closing Remarks

16.45 End of the conference

Advance Notice

11th Annual Conference

CLP

21th to 23th October, 2019, Bonn Germany

www.chem-academy.com/ghs

Conference Language German

3rd Annual Conference

Chemikalienregulierung in Non-EU

11th to 13th November, 2019, Berlin, Germany

www.chem-academy.com/chemikalienregulierung

Conference Language German

Group Discount

There are more people in your company interested in our event? Benefit from our attractive offer for group bookings!

If you register 2 or more people at once for a minimum of 2 days you will save €300 respectively starting with the second delegate.

Wednesday, 25th September 2019

8.30 Reception and Coffee

9.00 to 16.30 **Understanding the Guidance for Identifying Endocrine Disrupting Chemicals**

Breaks will be arranged flexibly.

Your Workshop Facilitators

Dr Martina Duft, Biologist, Expert Environmental Safety/Regulatory Affairs, knoell Germany GmbH, Germany

**Dr Daniela Fruth
Food Chemist, Regulatory Toxicology Biocides, knoell Germany GmbH, Germany**

Content of the Workshop

This workshop will provide the target audience (risk assessors and regulatory managers engaged with the assessment of biocidal and crop protection active substances/products) with comprehensive background information and in-depth insight into the new EU Endocrine Disruptor criteria and the recent ECHA/EFSA Guidance.

The main objective of the training course is to equip the participants with the necessary know-how and tools in the challenging landscape of the required endocrine disruptor assessment.

The EU has finally agreed upon the long awaited scientific criteria for the evaluation of substances with a potential for endocrine disruption. The recently issued ECHA/EFSA guidance for the identification of endocrine disruptors, applicable for plant protection products and biocides (June 2018), requires a highly complex and challenging assessment for all substances. Particularly when dealing with such substances on a global scale, you may be facing substantial uncertainty regarding data requirements, testing and assessment strategies as well as impact outside the EU market.

In the field of biocides and plant protection products, the evaluating bodies are now obliged to also consider the ED properties of substances/products in any procedure that is still under the evaluation phase. As a consequence, from 07 June 2018 the evaluating competent authority are assessing the potential ED properties of biocidal products, and since 10 November 2018 for plant protection products.

Additionally for biocides, beside active substances also co-formulants contained in the biocidal products must be assessed. With a view to the ED assessment co-formulants represent a particular challenge in terms of available data package and data access, possibly requiring a revised assessment strategy.

Program:

- Introduction on endocrine disruptors: regulatory background, history, criteria and guidance
- Stepwise approach: overview on the main requirements of the new guidance
- First steps: Gathering and assembly of data – targeted literature search, data bases, QSAR profiling and reporting of data
- Investigation of ED properties with a focus on EATS endpoints: Specific toxicological and ecotoxicological study types
- Identification and assessment of ED properties for human health and : evaluation of all available data
- Assembly of the lines of evidence, evaluation of completeness of data
- Weight of evidence evaluation: bringing together an overall argumentation

Agenda

Introduction on endocrine disruptors: Regulatory background, history, criteria and guidance

- Definition and criteria
- Regulatory history
- New EU ED criteria Biocides and Crop Protection Products
- New ECHA/EFSA ED Guidance

Stepwise approach: Overview on the main requirements of the new ED guidance

- Scope of the ED Guidance
- Assessment strategy for determining potential ED properties
- Overview on information sources and guidance
- Recommendations for applicants and evaluating authorities

First steps: Gathering and assembly of data – targeted literature search, data bases, QSAR profiling and reporting of data

- Process of data gathering: Relevance and reliability of data
- Developing search strategy protocols
- Databases, software tools and literature-derived (Q)SARs
- Reporting the available information relevant for ED assessment

Investigation of ED properties with a focus on EATS endpoints: Specific toxicological study types - Strategy for endocrine disruptor identification

- Human health-related endpoints: OECD Conceptual Framework and OECD GD 150
- Limitations of testing guidelines
- Epidemiology data

Investigation of ED properties with a focus on EATS endpoints: Specific ecotoxicological study types

- Environment/Ecotoxicity-related endpoints: OECD Conceptual Framework and OECD GD 150
- In vitro and in vivo test methods and parameters for non-target organisms
- Epidemiological data, field studies and population models

Assembly of the lines of evidence, evaluation of completeness of data

- Assembly of the lines of evidence: Adversity vs. endocrine activity
- Empirical support vs expert judgement
- Analysis of the evidence and conclusions on potential ED properties
- Sufficiency/completeness of data for assessment and generation of information

Weight of evidence evaluation: Bringing together an overall argumentation – Case studies for human health and non-target organisms

- WoE methodology for adversity and ED activity and mode of action analysis
- Annex E table: revisions and changes
- Practical exercises for human health and non-target organisms

Mode of Action Analysis – Assessing the biological plausible link between observed effects and ED activity

- Identification of the need for MoA analysis
- Interlinkage of molecular initiating event and key events
- Examples for plausible link between adversity - ED activity and need for further information
- Limitations and issues

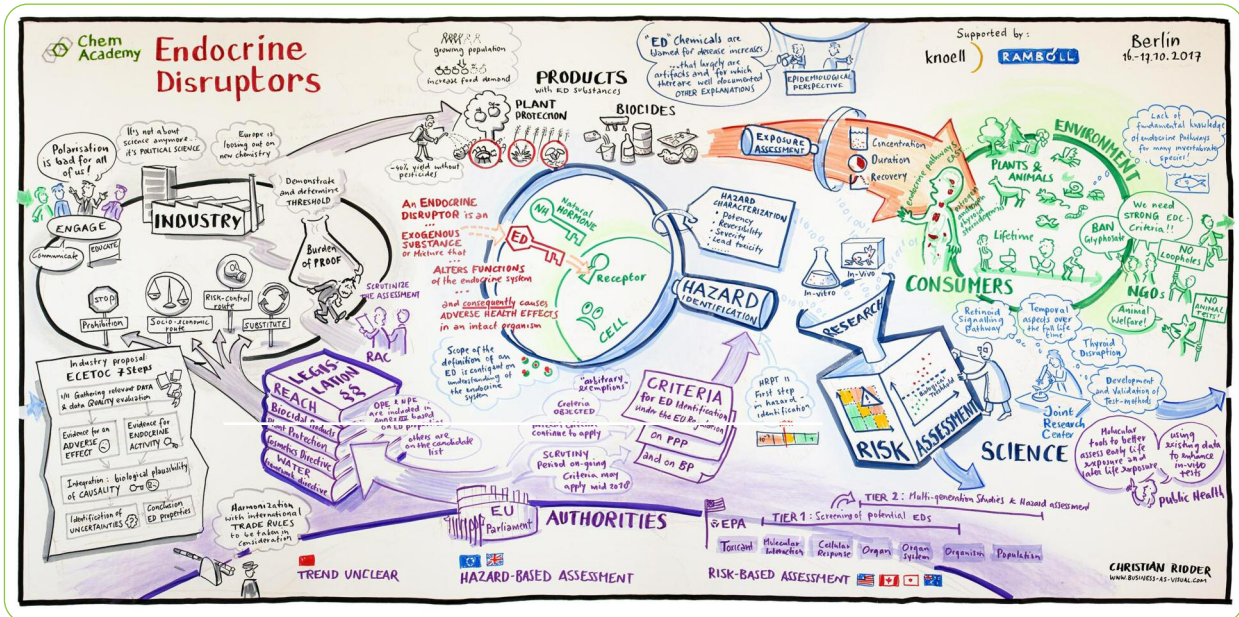
Regulatory consequences for applicants and overall implications on dossier preparation for biocides and crop protection products: Derogations human health/environment

- Outcomes on ED assessment
- Regulatory consequences for humans and non-target organisms in the biocides and crop protection area
- Impact on ongoing evaluations, approvals and renewals

About Chem-Academy

Chem-Academy is a division 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



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5th International Conference Endocrine Disruptors

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