



12<sup>th</sup> International Akademie Fresenius Conference

# Endocrine Disruptors

+++ ONLINE CONFERENCE +++

23 and 24 November 2021

## Highlights

- Regulatory developments
- Update from the EU Commission
- Industry perspective: EDs under REACH and CLP – current challenges
- Member State perspective: Implementation of the EU ED criteria in the risk assessment of Plant Protection Products and Biocides
- The Chemicals Strategy for Sustainability: Potential impact on ED-related information requirements
- Scientific developments in the area of the thyroid, e.g. progress on assessing thyroid endpoints in fish studies
- ED testing methods
- The OECD steroidogenesis assay



## The Experts

**Andy Adams** Bayer | **Lisa Baumann** University of Heidelberg | **Sofie Christiansen** The Danish National Food Institute (DTU) | **Anne-Laure Demierre** Federal Office of Public Health of the Swiss Confederation (BAG) | **Daniela Fruth** knoell Germany | **Mary Gilbert** US Environmental Protection Agency (US EPA) | **Anne Gourmelon** Organisation for Economic Co-operation and Development (OECD) | **Agnes Karmaus** Integrated Laboratory Systems | **Martin Klatt** BASF | **Gregory Lemkine** Laboratoire Watchfrog | **Emily McVey** Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) | **Aldert Piersma** Dutch National Institute for Public Health and the Environment (RIVM) | **Apolline Roger** Client Earth | **Marize Solano** German Federal Institute for Risk Assessment (BfR) | **Lennart Weltje** BASF | **Jordane Wodli** European Commission

Tuesday, 23 November 2021

Timings are in  
Central European Time [CET](#).

## Morning Session 10:45 – 12:30 CET

10:45 **Welcome address by the organisers and the chairs**

**Lennart Weltje**, BASF, Germany

**Emily McVey**, Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), The Netherlands

## Regulatory Developments

11:00 **Update from the European Commission**

**Jordane Wodli**, European Commission, Belgium

11:30 **The Chemicals Strategy for Sustainability: Potential impact on ED-related information requirements**

- Update of BPR data requirements
- Expected updates to REACH data requirement
- Implications for testing and timelines

**Daniela Fruth**, knoell Germany, Germany

12:00 **The identification and regulation of endocrine disruptors as part of the CSS**

- Why is it a necessary part of the Strategy for Sustainability
- How would it ideally play out?

**Apolline Roger**, Client Earth, Belgium

12:30 **Lunch break**

## Afternoon Session 13:30 – 16:20 CET

13:30 **An industry perspective on EDs under REACH and CLP**

- GHS first
- Are separate Hazard phrases necessary?
- Information requirements for ED assessment
- How can we avoid animal tests by alternative testing?
- Industry's position and recommendation

**Martin Klatt**, BASF, Germany

14:00 **A Swiss position on ED regulation in the EU**

- Chemicals
- Biocides
- The example of BPA ban in thermal papers

**Anne-Laure Demierre**, Federal Office of Public Health of the Swiss Confederation (BAG), Switzerland

14:30 **Short break**

14:45 **Member State perspective: Implementation of the EU ED criteria in the risk assessment of Plant Protection Products (PPP) and Biocides (BP)**

- Current ED in Human Health PPPR and BPR risk assessment
- Changes at GHS / CLP for Human Health in PPP and BP

**Marize Solano**, Federal Institute for Risk Assessment (BfR), Germany

15:15 **Regulation of Endocrine Disruptors: Current challenges for the Agro-Industry**

**Andy Adams**, Bayer, France

## ED Testing Methods

15:45 **Performance of the OECD steroidogenesis assay: Insight into predictivity and statistical performance**

**Agnes Karmaus**, Integrated Laboratory Systems, United States

16:20 **End of the first day**

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## Morning Session 10:45 – 12:30 CET

### 10:45 Brief welcome by the Chairs

**Emily McVey**, Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), The Netherlands

**Lennart Weltje**, BASF, Germany

## Continuation: ED Testing Methods

### 11:00 OECD Test methods for Endocrine Disruptors: Latest developments

**Anne Gourmelon**, Organisation for Economic Co-operation and Development (OECD), France

### 11:30 Inclusion of sensitive endpoints in reproductive toxicity studies to detect endocrine disruptors

- The OECD Test Guidelines – overview
- ED endpoints with focus on: Anogenital distance (AGD) and nipple/areola retention (NR) and abnormalities of external genital organs
- Feasibility studies performed to support proposed enhancements with ED relevant endpoints in
  - The repro screening studies (OECD TG 421/TG 422)
  - TG 414 (Prenatal Developmental Toxicity Study)
  - Ongoing work on female reproduction (mammary gland whole mount inclusion)

**Sofie Christiansen**, The National Food Institute (DTU), Denmark

## Developments in Thyroid Assessment

### 12:00 Assessment of thyroid-related endpoints in fish studies: gaps and novel developments

- Update from ongoing EU research activities: ERGO and iFEDT project
- The challenge to identify thyroid-specific adverse effects in fish
- Implementation of thyroid-related endpoints in existing regulatory guidelines with fish

**Lisa Baumann**, University of Heidelberg, Germany

### 12:30 Lunch break

## Afternoon Session 13:30 – 15:30 CET

### 13:30 Place of the XETA (OECD TG 248) within the Endocrine Disruptors Testing Strategy defined by EFSA and ECHA

- Building the weight of evidence combining mammalian and eleutheroembryos data
- Consolidation of the interpretation of the XETA with specific modes of action

**Gregory Lemkine**, Laboratoire Watchfrog, France

### 14:00 Short break

### 14:15 A quantitative AOP for liver-mediated thyroid modulation after prenatal exposure in the rat

**Aldert Piersma**, National Institute for Public Health and the Environment (RIVM), The Netherlands

### 14:45 The adverse outcome pathway framework: The thyroid and brain development

- The adverse outcome pathway framework: The thyroid and brain development
- Thyroid system disrupting chemicals – multiple sites of action
- Role of thyroid hormone in brain development
- Establishing critical key events in AOPs for thyroid and brain
- Intra and extrathyroidal sites of chemical action

**Mary Gilbert**, Environmental Protection Agency, United States

### 15:15 Final discussion, concluding remarks

### 15:30 End of the conference

## How will this online conference work?

Our online conference will be live – with interactive participation – and will be held in the English language. Prior to the conference, we will provide you with your login details, which will allow you to participate and ask questions from your preferred location. All you need is a stable internet connection and an audio hardware system – and away you go!

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By email [registration@akademie-fresenius.com](mailto:registration@akademie-fresenius.com)  
By fax +49 231 75896-53

## Participation Fee: € 895.00 plus VAT

Representatives of an authority or a public university are eligible for a reduced fee of € 495.00 plus VAT per person (please provide evidence). The reduced fee cannot be combined with other rebates.

If you are unable to attend the online event, you can order the event documentation for € 295.00 plus VAT. It will be available after the online event through the download area of our website where you will find the latest versions of the presentations as pdf files.

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## Do you have any questions?



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## Who do you meet?

### Professionals working in the fields of:

- ✓ Toxicology and ecotoxicology
- ✓ Chemical risk assessment
- ✓ Research and development
- ✓ Regulatory affairs
- ✓ Registration and authorisation
- ✓ Legal and general counselling

### Sectors taking part:

- ✓ Chemical/biocide/agrochemical/ pharmaceutical/cosmetic industries
- ✓ Research institutes
- ✓ Regulatory authorities
- ✓ Environmental and health risk consultants
- ✓ Testing laboratories and contract research organisations (CROs)
- ✓ NGOs

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