

Where Experts Meet!

14th International Akademie Fresenius Conference

Endocrine Disruptors

+++ HYBRID EDITION +++

30 November and 1 December 2023 in Cologne/Germany and via Live Stream

Highlights

Regulatory Developments

- Update from the EU Commission: ED-related activities
- REACH Revision and impact on requirements for ED substances
- The German BfR on regulatory developments relevant for PPPs and Biocides

Methods: Studies, NAMs & AOPs

- The EU Commission's JRC on better assessment of endocrine disruptors using non-animal approaches
- The US Environmental Protection Agency on thyroid-relevant bioassays in ToxCast: aligning with the Adverse Outcome Pathway Network
- Mechanistic modelling of thyroid hormone disruption as a new approach methodology (NAM) for human risk and hazard assessment: the state of the science: A mathematical model of thyroid homeostasis for multiple mammalian species, including humans
- Update on the OECD's ED-related activities
- Dietary restriction: Amphibian Metamorphosis Assay



The Experts

Alex Charlton Syngenta | Anne Gourmelon Organisation for Economic Co-operation and Development (OECD) | Heli Hollnagel Dow Europe | Effrosyni Katsanou European Commission's Joint Research Centre | Pim Leonards Vrije Universiteit Amsterdam | Iris Mangas European Food Safety Authority (EFSA) | Emily McVey Dutch National Institute for Public Health and the Environment (RIVM) | Eva Vanna Lorenza Negri University of Bologna | Katie Paul Friedman United States Environmental Protection Agency (US EPA) | Vera Ritz German Federal Institute for Risk Assessment (BfR) | Bieke Scharlaken knoell Germany | Alice Tagliati Enviresearch | Helen Tinwell Bayer CropScience | Christian Unkelbach German Federal Institute for Occupational Safety and Health (BAuA) | Lennart Weltje BASF | James Wheeler Corteva Agriscience | Jordane Wodli European Commission





Thursday, 30 November 2023

Morning Session 09:30 – 13:05 CET

09:00 On-site registration & opening of the virtual meeting room

09:30 Welcome address by the organisers and the Chairs

Lennart Weltje, BASF, Germany

Emily McVey, National Institute for Public Health and the Environment (RIVM) The Netherlands

The presentation slots include sufficient time for questions and answers.

Regulatory Developments

09:40 Update on endocrine disruptors-related activities

- Information requirements for the REACH Annexes
- · PPP-relevant activities

Jordane Wodli, European Commission, Belgium

10:15 State of play of ED under REACH

- · Way forward under CLP
- · Interplay of Candidate List and Annex VI
- Consulting the crystal ball: Outlook and pitfalls

Christian Unkelbach, Federal Institute for Occupational Safety and Health (BAuA), Germany

10:50 REACH Revision and impact on requirements for ED substances - an indutstry view

- Information requirement for the Reach Annexes
- REACH Annexes update

Heli Hollnagel, Dow Europe, Switzerland

11:25 Coffee break

11:55 Linking adverse outcome to the endocrine activity in the context of the EU regulation for endocrine disrupting

Iris Mangas, European Food Safety Authority, Italy (virtual presentation)

12:30 Biocides and plant protection products: Recent regulatory developments (human health-relevant)

- New Hazard Classes for ED in the CLP Regulation
- Changes in the Guidance
- Impact on Biocides and Plant Protection Products

Vera Ritz, Federal Institute for Risk Assessment, Germany

13:05 Lunch

Timings are in Central European Time CET.

Afternoon Session 14:15 - 17:40 CET

14:15 Industry perspective on the ECHA ED Draft **Guidance CLP**

- Presentation of cases for ED category 1 or 2 / no classification
- Challenges in using NAMs for classification purposes
- Expanding scope of ED

Helen Tinwell, Bayer CropScience, France

14:50 Global perspectives on the regulatory framework for endocrine disrupting chemicals

- Regulatory situation in the EU 'one substance, one assessment'
- · Considerations and/or approaches to regulate EDCs in a global context
- Challenges

Bieke Scharlaken, knoell Germany, Germany

15:25 Coffee break

Methods: Studies, NAMs & AOPs

15:55 Thyroid-relevant bioassays in ToxCast: Aligning with the Adverse Outcome Pathway Network

- Thyroid-relevant bioassay data in the publicly available ToxCast database and their review
- Example case studies of a few chemicals and interpretation of bioactivity assay data
- Work-in-progress on understanding thyroid-relevant bioactivity in the maternal-fetal dose context

Katie Paul Friedman, United States Environmental Protection Agency (US EPA), United States (virtual presentation)

16:30 Better assessment of endocrine disruptors using non-animal approaches

- JRC's scientific and strategic input to the activities relevant to the Community Strategy on Endocrine Disruptors
- Thyroid validation study
- APCRA classifier for chemicals with ER- and AR-mediated activity
- · Better use of academic data for ED identification
- Readiness criteria for validation of in vitro methods relevant to characterisation of endocrine disruptors

Effrosyni Katsanou, European Commission's Joint Research Centre, Italy

17:05 Population relevance of endocrine disruptors

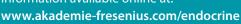
- · Presenting different modelling solutions
- Consideration of field studies and monitoring approaches

Alice Tagliati, Enviresearch, United Kingdom

17:40 End of the first day 18:30 Evening event



Book now



Friday, 1 December 2023

Morning Session 09:30 – 13:30 CET

09:30 Brief address by the Chairs

Lennart Weltje, BASF, Germany Emily McVey, National Institute for Public Health and the Environment (RIVM) The Netherlands

Continuation: Methods, Studies, NAMs & AOPs

09:40 ED-related activities

- General updates on recent TGs approved and draft TGs on the work plan
- In-vitro thyroid assays and work of the OECD Expert Group
- OECD GHS group on ED

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

10:15 Human epidemiology: Trends in hormone-related diseases and conditions – an epidemiological analysis?

Eva Vanna Lorenza Negri, University of Bologna, Italy

Thyroid

10:50 Mechanistic modelling of thyroid hormone disruption as a new approach methodology (NAM) for human risk and hazard assessment: the state of the science

- · Current approaches
- Quantitative and qualitative differences between humans and laboratory species
- A mathematical model of thyroid homeostasis for multiple mammalian species, including humans
- The different approach taken in current mathematical models
- Future steps identified

Alex Charlton, Syngenta, United Kingdom

11:25 Coffee break

To conclude the first day, we invite you join us on a stroll through the famous Cologne Christmas markets, followed by a cozy dinner afterwards. Come along to continue the day's interesting discussions in a relaxed and comfortable atmosphere.

11:55 An Amphibian Metamorphosis Assay (AMA) dietary restriction study: Lessons for data interpretation

- The results of an AMA study conducted with five different feeding rations equivalent to 50% to 5% of the recommended feeding rate
- · Implications for the Test Guideline and testing strategies
- Maximum Tolerable Concentration setting
- Test Guideline decision logic
- General lessons for the assessment of endocrine disrupting properties

James Wheeler, Corteva Agriscience, The Netherlands

12:30 The ENDpoiNTs project: identifying endocrine disruption-induced developmental neurotoxicity thyroid disruption and beyond

- · Establishment of novel in vitro ED-DNT assays ready for, or in the process of, pre-validation
- Sex-specific DNT effects of EDCs found using in vitro and in vivo models
- First tier ED-DNT screening in silico tools (QSARs) developed for endocrine-induced neurodevelopmental effects

Pim Leonards, Vrije Universiteit Amsterdam, The Netherlands

13:05 Summary and final discussion 13:30 Lunch and end of the Conference

On-site and in person or digitally via our Live Stream – the choice is yours!

Reconnect with your colleagues, clients and partners, network with old and new acquaintances – and just enjoy the on-site event in Cologne.

Should you have missed the opportunity to secure one of our on-site places – or prefer not to travel, you can follow the contributions and discussions from the location of your choice: Via our Live Stream!

Registration

By web www.akademie-fresenius.com/endocrine By email registration@akademie-fresenius.com

Hotline +49 231 75896-50 Die Akademie Fresenius GmbH Alter Hellweg 46, 44379 Dortmund



Participation Fee:

€ 1,995.00 plus VAT on-site in Cologne

Representatives of an authority or a public university are eligible for a reduced fee of € 895.00 plus VAT per person (please provide evidence). The reduced fee cannot be combined with other rebates.

€ 1,195.00 plus VAT Live Stream

Representatives of an authority or a public university are eligible for a reduced fee of € 695.00 plus VAT per person (please provide evidence). The reduced fee cannot be combined with other rebates.

If you are unable to attend, you can order the event documentation for € 295.00 plus VAT.

www.akademie-fresenius.com/endocrine



Book now

Do you have any questions?



Anne Möller Phone: +49 231 75896-84 amoeller@akademie-fresenius.de

The Organisers

For more than 25 years, Akademie Fresenius has been your partner for practice-orientated training on all the latest topics surrounding the safety and quality of food, consumer goods and chemical products along the whole production chain. Our portfolio not only includes international conferences but also offers national trade meetings, intensive practical seminars and training in small work groups. Our events are designed to promote an active exchange amongst our participants and offer the perfect platform for bringing the industry, the scientific sector, the authorities and the consulting field together. Excellent service, all-inclusive. Our wide-ranging advanced training opportunities contribute to giving our customers the competitive edge in all quality assurance, risk assessment, legal, production and technical questions.

Akademie Fresenius is a joint venture between Carl Remigius Fresenius Education Group, one of the largest private and independent education groups in Germany, and SGS Institut Fresenius, one of the leading German providers of chemical laboratory analysis.

You can find details on upcoming and new events at www.akademie-fresenius.com

Terms of Participation and Purchase: The registration fee includes the participation in the event, event documentation, and, in the case of on-site events, lunch, coffee breaks, beverages as well as the evening event. You will receive written confirmation of your registration. Upon receiving our invoice, please transfer the amount due without further deductions before the event begins. The price of the event documentation includes the login details for the secure download section of our webpage where you will find the presentations in a pdf format. The login details will be sent to you via email after the event and as soon as advance payment has been received.

Group Reductions: For joint bookings received from one company we grant a 15% discount from the third participant onwards.

Terms of Cancellation: For our on-site events, written cancellations or transfers will be accepted free of charge up to four weeks prior to the start of the event. After this date and up to a week prior to the start of the event we will reimburse 50% of the registration fee. We cannot, unfortunately, provide refunds for later cancellations. For our online events, cancellations or rebookings to another event will be accepted free of charge up to one week before the start of the event. In the event of later cancellations or non-login to the online event, no participation fees can be refunded. In this

Who should attend this meeting?

Professionals working in the fields of:

- Toxicology and ecotoxicology
- Research and development
- Registration, regulatory affairs
- Chemical risk assessment
- Legal and general counselling

Sectors taking part:

- Chemical/biocide/agrochemical/pharmaceutical/ cosmetic industries
- Research institutes, Regulatory authorities
- Environmental and health risk consultants
- \checkmark Testing laboratories and contract research organisations (CROs)
- NGOs
- **Professional associations**

Conference Venue

Leonardo Royal Cologne Bonn Airport Josef-Broicher-Straße 11, 51145 Cologne/Germany Telefon: +49 2203 90330

E-Mail: info.royalcologneairport@leonardo-hotels.com www.leonardo-hotels.de

We have reserved a limited number of rooms for our participants at reduced rates at the hotel. These rooms can be booked up to four weeks prior to the start of the event. Please book early and directly through the hotel quoting "Akademie Fresenius" as reference.

Of course, participation via our Live Stream is also possible.

case, however, you will receive access to the documentation download after the event. Please note that you can name a substitute participant free of charge at any time.

General Terms and Conditions: By registering, you agree to our General Terms and Conditions as well as to our Privacy Policy. You can find our GTC on the internet (www.akademie-fresenius.com/general-terms) or receive them on request.

Personal Data: The Akademie Fresenius will keep your data for the purpose of organising this event. We will under no circumstances use your data for commercial trade purposes. By registering for this event, you consent to our occasionally contacting you by mail, email or phone in order to provide you with further information from our company. You can, of course, withdraw your consent whenever you wish. At our on-site events, occasionally, we go around taking photos and videos which are then published anonymously on our website. During our online events, image and sound content is transmitted, which may originate from the speakers and from the participants. By registering, you agree that this content may be transmitted within the virtual event space. All participants are prohibited from recording this content. Further information can be found at: www.akademie-fresenius.com/dataprotection.

Picture Credit: @ Subbotina Anna/shutterstock.com, @ chestra - Fotolia.com, © RalfenByte – Fotolia.coa