TRAINING COURSE

Guidance for Identifying Endocrine Disrupting Chemicals

Equipping you with the necessary know-how and tools in the challenging landscape of EDCs

Chemical Watch

Course introduction

This workshop will provide you with useful information and insights into the new EU Endocrine Disruptor (ED) criteria and the recent ECHA/EFSA guidance.
Ideal for:

- Risk assessors
- Regulatory managers
- toxicologists and ecotoxicologists
- Those tasked with the assessment of biocidal/ crop protection active substances and products

Background

The EU has finally agreed upon the long awaited scientific criteria for the evaluation of substances with a potential for 'endocrine disruption'. The new ECHA/EFSA guidance for the identification of endocrine disruptors, published in June 2018 and applicable for plant protection products and biocides, 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 phaseAs a consequence, from 07 June 2018 the evaluating competent authorities 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.

Expert trainers:

Dr Martina Duft

Biologist, Expert Environmental Safety/Regulatory Affairs, knoell Germany GmbH, Germany

Dr. Martina Duft studied biology at the Ludwig Maximilian University Munich and is holding a Ph. D. in Ecotoxicology from the JW Goethe University Frankfurt. After several years in endocrine disruptor related research, she joined knoell in 2005 and has since then worked in the REACh and Biocides sectors, with a focus on ecotoxicology and regulatory affairs. She is coordinator of the knoell environmental expert team and key contact for the topic endocrine disruptors.

Dr Michael Werner

Senior Expert, Regulatory Toxicology Biocides, knoell Germany GmbH, Germany

Dr. Michael Werner is chemist and certified/ Eurotox registered toxicologist. He has got a > 20 years track record in hazard, exposure and risk assessments in various regulatory areas including classification and labelling. In his present role as a senior expert regulatory toxicology, he provides regulatory and scientific/technical advice to clients for the preparation of biocidal active substance/product dossiers. Another focus of his work is the development of tailor-made dossier strategies for the authorisation of biocidal products/product families in their various and sometimes non-standard applications including animal safety and dietary risk assessment of biocides.

TUESDAY
4
JUNE
2019

Day one

Registration from 08:45 - 09:15

09:15 **Background and introduction**

09:30 **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

10:00 **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

10:30 **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

11:00 Refreshment break

11:20 **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

11:50 **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

12:20 **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

12:50 Lunch

13:50 **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

14:50 **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

15:20 Refreshment break

15:40 **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

16:10 **Questions and Discussion**

16:40 End of workshop

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Prices

Full price - €950 + VAT (20%)

Early-bird discount price - €850 + VAT (20%)

CW subscriber price - €850 + VAT (20%)

CW subscriber Early-bird discount price - €750 + VAT (20%)

Early-bird discount expires 12 April 2019

Three ways to register

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Van der Valk Hotel Brussels Airport

Culliganlaan 4b, Diegem, Brussels, 1831, Belgium
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We have arranged a special bedroom rate for course participants: €189,00 including breakfast and excluding city tax (€5.00 per room per night)

Payment options

- Invoice payable by bank transfer, credit card or cheque made payable to Chemical Watch
- Online using our secure order form
- Payment must be made before the event starts
- The full price is payable in advance and includes tuition, course materials, refreshments and lunch on each day.

Event timings

4 June 2019 09:15-16:40