TRAINING COURSE

Risk Assessment for Biocides

Part 1: Environmental Risk Assessment
Part 2: Human Health Risk Assessment

Chemical Watch

Course introduction

The environmental risk assessment (ERA) and human health risk assessment (HHRA) for biocides are an important part of the dossier for active substance approval as well as for biocidal product authorisation. In the changing landscape of the regulatory requirements for ERA and HHRA it becomes more and more challenging for industry to stay up-to-date and to meet constantly rising standards.

This training course offers two days of intensive training, providing a comprehensive overview of ERA and HHRA. The training course is designed for environmental and human health risk assessors and regulators from industry, authorities and consultancies. Both days consist of a theoretical and a practical session. In the theoretical sessions, the essential principles of an ERA or a HHRA are demonstrated, while in the practical sessions, the participants learn how to use software tools and models. Participants can attend either day or both days.

On day one, participants will be introduced to the key principles of ERA – from basic aspects to more complex issues. They will become familiar with relevant input parameters, different emission pathways and product types. They will also get to know available guidance documents. In the practical part, participants will learn how to estimate emissions and exposure to the environment, either using the software tool EUSES or generated EXCEL- sheets. At the end of the day the participants will gain a complex idea of ERA, having developed understanding which parameters might influence the results of the environmental risk assessment and which refinement options can help get a safe ERA.

Day two is focused on HHRA including livestock exposure (LE) and dietary risk assessment (DRA). The requirements for HHRA are constantly changing and getting increasingly complex which raises the bar for passing the HHRA. While new guidance has been published during the past years, guidance is still lacking the description of major uses in several product types. This applies especially to LE and DRA, but also to the assessment of disinfection by-products. On day two, attendees will learn about key HHRA topics, including:

- How to use TNsG or generic models;
- Exposure assessments;
- Effect assessments and risk characterisation; and,
- How to use software tools like ConsExpo and ART to estimate exposure for different types of substances, intended uses and product types.

Meet the trainers

Michael Schweitzer

Senior Manager Regulatory Affairs
Biocides, Environmental Risk Assessments & Modelling
SCC Scientific Consulting Company GmbH

Michael Schweitzer is a geographer and environmental scientist. He has worked for over 11 years inthe biocides department of SCC GmbH as an expert for the environmental risk assessments of biocidal active substances and products, including groundwater assessments using FOCUS models. Over the years he has gained experience in nearly all product types

Katja Ribbers

Assistant Manager Regulatory Affairs Biocides,
Environmental Risk Assessments & Modelling
SCC Scientific Consulting Company GmbH

Katja Ribbers graduated in environmental sciences from Bielefeld University and Giessen University. She gained practical experience as a chemical laboratory technician and student assistant in the field of environmental analytics. After her graduation, she joined the Biocides Business Unit at SCC GmbH where she has meanwhile acquired substantial experience in the emission estimation and risk characterization of biocidal products with particular focus on disinfectants and wood preservatives.

Martina Galler

Head of Biocides, SCC Scientific Consulting Company GmbH

Martina Galler has a PhD in biology and has more than 16 years of experience in biocides regulatory affairs. Her field of expertise comprise all BPR activities relating to biocidal active substances and products as well as risk assessments of biocides.

Meike Rünz

Manager Regulatory Affairs Biocides,
Toxicology, Human Health Risk Assessment
SCC Scientific Consulting Company GmbH

Meike Rünz studied food chemistry and acquired her PhD in chemistry at the University of Kaiserslautern. She participates in the further education program for expert toxicologists of the German Society of Pharmacology and Toxicology (DGPT). Meike joined SCC GmbH as a member of the regulatory science department and was involved in the approval of plant protection products as well as registration of chemicals. Now as member of the biocides team her focus is on toxicology, human health risk assessment, and classification & labeling of various active substances and biocidal products.

Katharina Gläser

Manager Regulatory Affairs Biocides Toxicology, Human Health Risk Assessment, SCC Scientific Consulting Company GmbH

Katharina Gläser graduated in biomedical engineering and acquired a PhD in toxicology at the University of Würzburg, with main focus on genotoxicity. She is a member of the German Society of Pharmacology and Toxicology (DGPT) and participates in the further education program for expert toxicologists. In 2016, Katharina joined the Biocides Business Unit at SCC GmbH as an expert for human health risk assessment, toxicology and classification & labelling for various active substances and biocidal products.

TUESDAY

22

OCTOBER
2019

Environmental risk assessment

08:30 Registration

09:00 Overview on ERA

- Input parameter for ERA
- Emission pathways into environment
- Definitions (emission estimation, exposure and effect assessment, risk characterisation)

09:15 Guidance documents

- ECHA guidance documents (Vol. IV, Part A & Parts B+C);
- Information requirements (Part A)
- Introduction in Parts B+C (i.e. input parameter and PEC-calculations)
- TAB August 2018 (agreed changes or amendments for the ERA)
- ESDs for the different Product Types (PT)

09:45 Tools and models

- Introduction of EUSES2.1.2
- EXCEL-sheets as an alternative
- Training Session: EUSES2.1.2
- Introduction of EUSES2.1.2 and creation of training file

10:15 Refreshment break

10:30 Follow-up of the training session for EUSES2.1.2

11:30 Emission estimation

- Definition of intended uses
- Life cycle stages to be assessed: formulation, application, service-life
- Selection of the relevant emission scenarios
- Tonnage based / consumption based approaches

Training session: emission estimation

- Example calculation with EXCEL-sheets or EUSES2.1.2 for 2-3 scenarios in different PTs (e.g. disinfectants: PT1-4, preservatives: PT6-10 and insecticide: PT18 or repellent: PT19)

12:30 Lunch

13:30 Follow up of the training session for emission estimation

14:00 Exposure estimation (calculation of PEC-values)

- Emission via sewage treatment plant (STP):
  - calculation of PEC-values for STP, surface water, sediment, soil
- Release to soil:
  - after application of slurry/manure on grassland or arable land (e.g. PT3/PT18) after leaching from treated surface (e.g. PT7-PT10)
- Calculation of PEC for groundwater

Training session: exposure estimation

- Example calculations with EUSES2.1.2 and EXCEL-sheets

15:30 Refreshment break

15:45 Follow up of the training session for exposure estimation

- Effect assessment and Risk characterisation
- effect assessment: PNEC derivation with EUSES and equilibrium partitioning method for sediment and soil
- environmental risk characterisation

16:30 Q&A session

17:00 Close

WEDNESDAY

23

OCTOBER
2019

Human health risk assessment

08:30 Registration

09:00 How to get started

- Definition of intended uses
- Relevant paths of exposure
- Systemic vs. local mode of action
- (Semi-)quantitative vs. qualitative assessment

Exposure assessment - Relevant guidance documents

- TNsG models (2002, 2007), User Guidance (2002)
- HEEG Opinions
- HEAdhoc Recommendations
- Biocides Human Health Exposure Methodology

10:30 Refreshment break

10:45 Exposure assessment - Frequently used models

- TNsG models (2002, 2007)
- Generic models
- ConsExpo
- ART

Effect assessment and hazard characterisation

- ECHA Guidance on the BPR, Volume III, Assessment & Evaluation (Parts B + C)
- Deduction of systemic and local reference values

Risk characterisation

- (Semi-)quantitative and qualitative risk assessment
- Refinement options

Exposure assessment - Example calculation

- Deriving scenarios from intended uses
- Selection of relevant models
- Example calculation

12:30 Lunch

13:30 Exposure assessment - Training session

- HHRA training session for different substance types, product types and intended uses

15:30 Refreshment break

15:45 Livestock exposure and dietary risk assessment

- How to get started
- Relevant scenarios and models
- BfR Livestock Exposure Calculator
- BfR Calculator for estimating transfer of biocide residues into foods (non-prof. uses)
- Refinement options

16:30 Q&A session

17:00 Close

Risk Assessment for Biocides

Prices

One-Day Workshop - 22 October - €850 (+VAT)

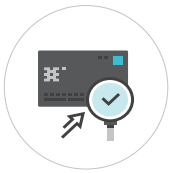
One-Day Workshop - 23 October - €850 (+VAT)

Attend both days - €1650.00 (+VAT)

Subscribers take an additional €50 off the price.

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.



Three ways to register

https://events.chemicalwatch.com/77795

events@chemicalwatch.com

+44 (0)1743 818 293

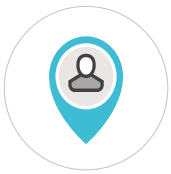
Event timings

Day One

22 October 2019, 08:30 - 17:00

Day Two

23 October 2019, 08:30 - 17:00



Venue

Hilton Mainz City

Muensterstrasse 11,

55116, Mainz

Germany

Tel: +49-6131-2780

Fax: +49-6131-278-2099

This training course is organised in partnership with SCC Scientific Consulting Company GmbH

SCC

WE CARE FOR YOUR SUCCESS

SCC is a privately owned and independent scientific consulting company, which has been supporting its global customers in the regulatory affairs business for almost 30 years. The Biocides business unit was established in 2000 and since then has successfully submitted and defended a multitude of BPD Annex I dossiers and prepared numerous product dossiers both under the BPD and BPR. With hands-on experience and detailed knowledge of the regulatory environment, we provide the Biocides industry with full-scale services, ranging from the development of the appropriate dossier strategy and identification of data gaps, through performance of exposure and risk assessments, study monitoring, to dossier submission, follow-up and defence.