



DIE AKADEMIE
FRESENIUS

Where Experts Meet!

5th International Fresenius Conference

Environmental Risk Assessment of Biocides

23 and 24 March 2017
in Dusseldorf/Germany

Highlights

Regulatory Aspects

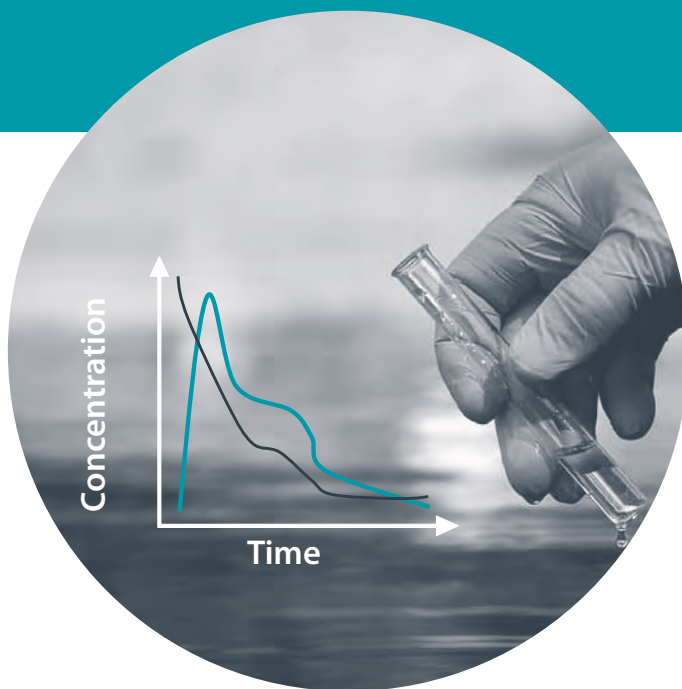
- ECHA: Latest developments of guidance documents
- Mixture toxicity for product authorisation
- New guidance on substances of concern
- Endocrine Disruptors

Effect/Hazard Assessment

- Technical equivalence Tier II assessment for biocides
- Industry and Member States view on assessment of persistence, bioaccumulation and toxicity (PBT) of biocides
- New guidance on disinfection by-products

Exposure assessment

- Member State experience with product authorisation under the BPR – Challenges on the risk assessment side
- Industry view on challenges in the exposure assessment of biocides
- Use of the new MAMPEC Model for antifoulings
- Working with software COMLEAM: Processes, challenges and advantages for assessments
- Environmental exposure assessment for Veterinary Medicinal Products compared to biocides



The Experts

Jan Achtenhagen Dr. Knoell Consult | **Michael Burkhardt** University of Applied Sciences Rapperswil | **Béatrice Chion** French Agency for Food, Environmental and Occupational Health and Safety (ANSES) | **Fabienne Ericher** Cambridge Environmental Assessments (CEA, ADAS UK Ltd) | **Annekathrin Faupel** Troy Chemie | **Simon Gutierrez** European Chemicals Agency (ECHA) | **Maike Habekost** BASF | **Bert van Hattum** Vrije Universiteit Amsterdam | **Silke Hickmann** European Medicines Agency, Environmental Risk Assessment Working Party (EMA, ERAWP) | **James Hingston** Health and Safety Executive, Chemicals Regulation Directorate (HSE, CRD) | **Bernhard Jene** BASF | **Anja Kehrer** German Environment Agency (UBA) | **Paul Mason** SC Johnson | **Anne Munch Christensen** Danish Environmental Protection Agency (EPA) | **Elmar Rump** Bayer | **Heike Schimmelpfennig** European Chemicals Agency (ECHA) | **Maura Schwander** German Environment Agency (UBA) | **Els Smit** Dutch National Institute for Public Health and the Environment (RIVM)

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The Programme

Get-together on Wednesday, 22 March 2017

Will you arrive on Wednesday?
Come to the hotel bar at 8 p.m. and meet other participants and experts in a relaxed atmosphere.

Thursday, 23 March 2017

8.30 Registration and coffee

9.00 Welcome address by Akademie Fresenius and introduction by the Chair

Maike Habekost, BASF, Germany

Regulatory Aspects

9.10 Environmental risk assessment for biocides: Latest developments of guidance and guidance-related documents

Heike Schimmelpfennig, European Chemicals Agency (ECHA), Finland

9.40 Member state experience with product authorisation under the BPR – Challenges on the risk assessment side

Anne Munch Christensen, Danish Environmental Protection Agency (EPA), Denmark

10.10 Environmental risk assessment and union authorisation: Advantages and limitations – an industry assessment

Annekathrin Faupel, Troy Cooperation, Germany

10.40 Panel discussion

11.10 Coffee break

11.40 State of the art of the mixture toxicity assessment within the environmental risk of biocides

- Environmental risk assessment
- Guidance on mixture toxicity assessment
- Guidance on substance of concern

Anja Kehrer, German Federal Environment Agency (UBA), Germany

12.10 An industry perspective on Endocrine Disruptors

Elmar Rump, Bayer, France

12.40 Panel discussion

13.00 Lunch

Effect/Hazard Assessment

14.30 Challenges in PBT assessment for biocides

- Assessment of PBT criteria considering biocidal data requirements
- Use of QSAR models
- Impact for active substances approval

Béatrice Chion, French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France

15.00 Industry perspective on PBT assessment for biocides

Bernhard Jene, BASF, Germany

15.30 Panel discussion

16.00 Coffee break

16.30 Technical equivalence Tier II assessment for biocides: challenges and lessons learned

Simon Gutierrez, European Chemicals Agency (ECHA), Finland

17.00 Guidance for the human and environmental risk assessment of disinfection by-products (DBPs)

- DBPs may pose risk to human health or the environment
- Steps taken to develop a harmonised approach to risk assessment
- Outline of the guidance and challenges for future development

Els Smit, National Institute for Public Health and the Environment (RIVM), The Netherlands

17.30 Panel discussion

18.00 End of the first conference day

19.00 Departure time for the evening event



As always you are most welcome to attend our evening event, which will take us to the rustic historic district of Dusseldorf for an unhurried evening of good food and leisure time. Please join us to continue the day's interesting discussions in a relaxed and comfortable atmosphere.

 Friday, 24 March 2017

8.30 Welcome address by the Chair

Simon Gutierrez, European Chemicals Agency (ECHA), Finland

Exposure Assessment

8.40 Considerations for estimating environmental exposure to biocides

Paul Mason, SC Johnson, United Kingdom

9.10 Environmental exposure assessment for veterinary medicinal products: Comparison to the exposure scenarios of biocides under Product Type 3

Silke Hickmann, European Medicines Agency (EMA), United Kingdom

9.40 Coffee break

10.10 Product Type 21 product authorisation manual – environmental risk assessment

- Harmonised product assessments
- Service life – commercial shipping and pleasure craft
- Core scenarios and Member State specific issues
- Application, maintenance and repair – the role of risk mitigation

James Hingston, Health and Safety Executive, Chemicals Regulation Directorate (HSE, CRD), United Kingdom

10.40 MAMPEC for exposure assessment of biocides and contaminants from antifouling paints and ballast water treatment installations

Bert van Hattum, Vrije University Amsterdam, The Netherlands

11.10 Working with the software COMLEAM: Processes, challenges, advantages for assessments

- Modelling
- Leaching
- Risk Assessment

Michael Burkhardt, University of Applied Sciences Rapperswil, Switzerland

11.40 Panel discussion

12.20 Lunch

13.20 Product Type 6: Latest changes in the emission scenario document on preservatives for products during storage

- Simplification and harmonisation of environmental risk assessment
- Selection of realistic worst-case scenarios for several end-products
- Overview of agreed changes in the revised ESD Product Type 6
- Open points and need for further work

Maura Schwander, German Environment Agency (UBA), Germany

13.50 Challenges within Product Type 18

Fabienne Ericher, Cambridge Environmental Assessments (CEA, ADAS), United Kingdom

14.20 Environmental risk assessments of disinfectants – new aspects and developments (e.g. Product Type 2)

Jan Achtenhagen, Dr. Knoell Consult, Germany

14.50 Final discussion

15.20 End of second day



Information available online at:
www.akademie-fresenius.com/2396

The Experts

Jan Achtenhagen holds a PhD in soil science and a Master degree in environmental science. He is responsible for the environmental exposure and risk assessment of biocides at Dr. Knoell Consult.

Michael Burkhardt is an environmental scientist with a Masters in geoscience and PhD in agronomy. He has been working in the area of pollutants (e.g. pesticides, biocides,

nanomaterials) released to aquatic systems for more than 15 years. His prime research interests are on source-control and end-of-pipe measures to reduce environmental impact.

Béatrice Chion has been involved in environmental risk assessment of biocides and industrial chemicals since 2007. She is currently the Head of the Ecotoxicology and

Environmental Evaluation Unit for Biocides and Reach Regulations in the Regulated Products Department at ANSES in France.

Fabienne Ericher holds a Dipl.-Ing. in Bioprocess and a Masters in Environmental Engineering. She has been working as a chemical exposure modeller at Cambridge Environmental Assessments since 2010, with a focus on environmental exposure of biocides.

Annekathrin Faupel holds a PhD in Agriculture and she joined Troy Chemie GmbH as Registration Manager Europe in 2013. She has more than 10 years of experience with the Biocidal Product Regulation and besides various regulatory issues, at Troy she is responsible for environmental exposure and risk assessment under the BPR.

Simon Gutierrez is an Ecotoxicologist by training with more than 10 years of experience in the field of ecotoxicology, environmental risk assessment and regulatory issues. He has a wide experience in biocides both in the public and private sector. Simon is currently Team Leader of the environmental team in the biocides unit in ECHA and is Deputy-Chair of the Environmental Working Group of the BPC at ECHA.

Maike Habekost's PhD work was related to plant biodiversity. At BASF, Maike is responsible for the ecotoxicological assessment of plant protection products

and biocides. From 2014 till late 2016, she worked in the US where she supported US registrations with her ecotoxicological knowledge.

Bert van Hattum (PhD) is a Senior Scientist in environmental chemistry and ecotoxicology with more than 30 years of experience at the VU University in Amsterdam and Deltares in Delft (since 2014). He has been involved in many field-, experimental- and modelling studies within the scope of PhD projects, contract research for government, industry, NGOs, and various EU Framework projects.

Silke Hickmann is the vice-chair of the Environmental Risk Assessment Working Party of the Committee for Medicinal Products for Veterinary Use (CVMP) at the European Medicines Agency. She works as an environmental risk assessor for veterinary and human medicinal products at the German Environment Agency.

James Hingston currently leads a team of 28 regulatory environmental fate specialists at the Chemicals Regulation Division, part of the UK Health and Safety Executive. He was actively involved in EU wide discussions on active substance approval issues under the BPR and led the development of guidance documents on selecting kinetic input parameters and on assessing multiple exposure routes for Product Type 21.

Bernhard Jene is Environmental Scientist at BASF in Limburgerhof with more than 20 years of experience in the area of environmental fate and exposure modelling of pesticides (17 years in industry).

Anja Kehrer works as a Scientific Officer within the field of environmental risk assessment of biocides at the German Environment Agency (UBA), where she is responsible for the environmental risk assessment of biocidal active substances and products in the context of the directive 98/8/EC and regulation 528/2012. During her diploma- and PhD-thesis she focused on ecotoxicology and investigated mixtures of chemicals.

Paul Mason is a Manager at SC Johnson where he is responsible for evaluating environmental safety for a range of consumer products, including biocides. Paul is current

Vice-chair of the CEFIC EBPF Insecticides Working Group and has contributed to the development of emission scenario documents, as well as coordinating industry input to consultations on evolving environmental guidance.

Anne Munch Christensen graduated as environmental engineer from the Technical University of Denmark (DTU). She holds a PhD from its Pharmaceutical Faculty focusing on pharmaceuticals in the environment, and works with pesticides and biocides at the Danish EPA.

Elmar Rump has a PhD in chemistry and is currently Team Leader in the Regulatory Affairs Department for EU Biocides at Bayer S.A.S. – Environmental Science. Previous to this position he has been a Regulatory Manager at Bayer since 2006.

Heike Schimmelpfennig has worked in the field of exposure and risk assessment for biocides and other chemicals for more than 15 years. She currently works as senior Scientific Officer in the biocides unit in ECHA. Heike is the Chair of the BPC-Environmental Working as well as the Chair of the Ad hoc Environmental Exposure Working Group (AHEE) and also advises the Biocidal Product Committee on environment related topics.

Maura Schwander has been working as a scientific officer for UBA within the field of environmental risk assessment of biocides since 2006. Priorly she has worked as a seconded national expert at ECHA for 18 months. Her focus is on exposure and risk assessment of preservatives, insecticides and antifoulings.

Els Smit has been active in risk assessment of biocides and PPPs in working groups on development of emission scenarios, test guidelines and guidance for study evaluation. Her main tasks at RIVM are guidance development and derivation of environmental quality standards, methodology development for biocides, and policy advice on environmental quality with a focus on surface water.

About

Who do you meet?

Groups that should take part:

Professionals working in the fields of

- Ecotoxicology
- Exposure assessment
- Risk assessment
- Regulatory affairs
- Registration

Sectors that should take part:

- Biocides and chemical industry
- Biocidal product producers
- Regulatory authorities
- Research institutes
- Scientific and regulatory consultants

Trade Exhibition

Our conference provides you with the opportunity of presenting your company in a trade display. Present your products and services and reach out to your specific target groups. We would be happy to provide you with information on all the various options available – from displaying product information to an exhibition stand – with no further obligation on your part.

Use the attached fax reply sheet to request our information material. Or simply call us. We would be more than pleased to assist you personally.

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The Organiser

For over 20 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 Cognos, 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



6 and 7 April 2017 in Dusseldorf

16th International Fresenius Conference

"The Biocidal Products Regulation"

Please order information now!

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www.akademie-fresenius.com/2395



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Do you have any questions?

Registration

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Participation

- ☐ I would like to take part in the 5th International Fresenius Conference "Environmental Risk Assessment of Biocides", 23 and 24 March 2017 in Dusseldorf/Germany.
Fee: € 1,795.00 plus VAT.
- ☐ I am a representative of an authority or a public university and therefore eligible for a reduced fee of € 795.00 plus VAT per person (please provide evidence).
The reduced fee cannot be combined with other rebates.
- ☐ I would like to take part in the evening event on 23 March 2017 (included in the above price).

Event Documentation

- ☐ Unfortunately, I am unable to attend. Please send me the complete documentation for € 295.00 plus VAT.

Trade Exhibition

- ☐ Please send me information on available options for trade and presenting product information.

Your Account Number (if available):

Title / First name / Name

Position

Department

Phone / Fax

Email

Company (complete company name including legal form)

Street / Number or P.O. Box / Building

ZIP-code / City / Country

Your order number / Cost unit (if required)

Your VAT ID No. (for registrations from EU countries except Germany)

Date

Signature

Billing Address (only if different from the above address)

Terms of Participation and Purchase

The registration fee includes the event participation, event documentation, 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 a hard copy of the documentation as well as an access code to the secure Akademie Fresenius download area. Both the documents and the secure access code will be dispatched around two weeks 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

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. Please note that you can name a substitute 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. In signing this form you consent to our occasionally contacting you by mail, email, fax or phone (please strike through if unwanted) in order to provide you with further information from our company. You can, of course, withdraw your consent whenever you wish. Occasionally we go around taking photos at our events. These are then published anonymously on our website. Further information can be found at: www.akademie-fresenius.com/dataprotection.

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Venue/Event Hotel

Lindner Congress Hotel Dusseldorf/Germany
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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 "Fresenius" as reference.