



18th International Fresenius Conference

The Biocidal Products Regulation

2 and 3 April 2019
in Dusseldorf/Germany

Highlights

Regulatory Aspects & Market Developments

- Up-to-date information on Brexit from HSE
- ECHA's current activities regarding biocides
- Cefic: Biocides in 21st century's Europe

Endocrine Disruptors

- How to deal with the new ED regulation – authority and industry perspective

Specific Regulatory Areas

- Ctgb on their experience with biocidal product families
- Member state experience with in-situ

Current Legal Challenges

- Dossier preparation for renewals
- Data sharing under the BPR

Developments Outside Europe

- Implementation of the Korean BPR and what industry needs to be aware of



The Experts

Eugen Anwander ECHA BPR Enforcement Forum/Vorarlberg State Service | **David Ashworth** Klarus Consulting | **John Bewley** British Health and Safety Executive (HSE) | **Samantha Champ** BASF | **Flore Cognat** Fieldfisher | **Helena Gräf** Ecolab | **Rixta Hempenius** Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) | **Sylvia Jacobi** Albemarle | **Stine Jensen** Danish Environmental Protection Agency (EPA) | **Hyunpyo Jeon** Korea Institute of Science and Technology Europe | **Sara Kirkham** Arrow Regulatory | **Alfonso Las Heras** European Commission | **Camelia Mihai** European Chemical Industry Council (Cefic) | **Stefan Nave** Lanxess | **Laura Ruggeri** European Chemicals Agency (ECHA) | **Gerhard Thanner** Environment Agency Austria | **Ian Watt** DowDuPont | **Michael Werner** knoell Germany

Receive the latest information directly
from the most relevant regulatory
authorities and experts from industry
and the consulting sector!

The Programme

Get-together on Monday, 1 April 2019

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

Tuesday, 2 April 2019

8.30 Registration and coffee

9.00 Welcome address by Akademie Fresenius and introduction by the Chair

Samantha Champ, BASF, Germany

Regulatory Aspects & Market Developments

9.10 Biocides in 21st century's Europe

- About protection goals
- Market demands versus regulatory restrictions
- Challenges for an innovative EU Biocides industry

Camelia Mihai, European Chemical Industry Council (Cefic), Belgium

9.35 Update from the European Commission

- 21 years since the Biocide Directive – where do we stand?
- Product authorisations – harmonisation and agreements between member states?
- Is the BPR proving to be a stimulus for innovation?

Alfonso Las Heras, European Commission, Belgium (preliminarily confirmed)

10.00 Overview of the UK Biocidal Products Regulation following the withdrawal of the United Kingdom from the European Union

- Basis of the UK legislation
- Specific requirements needed to obtain an approval/authorisation or remain on the market in the UK
- Summary of transitional arrangements

John Bewley, Health and Safety Executive (HSE), United Kingdom

10.25 Coffee break

10.55 ECHA's current activities regarding biocides

Laura Ruggeri, European Chemicals Agency (ECHA), Finland

11.20 Substantiating claims for biocidal products – what is required and where to find it

- Guidance available for demonstrating efficacy for disinfection and other product types
- Efficacy and treated articles

David Ashworth, Klarus Consulting, United Kingdom

11.45 Panel discussion

12.15 Lunch

Endocrine Disruptors

13.45 Endocrine disruption – authority view

- Practicalities of applying the guidance
- Experiences on reviewing the first ED assessments
- Applicant involvement

Stine Jensen, Environmental Protection Agency (EPA), Denmark

14.10 Endocrine disruption – industry view

- 6 months after implementation – status and influence on the review programme
- What challenges have arisen?
- Experiences with the Endocrine Disrupter Expert Group at ECHA
- What happens after a recommendation of the working group – legal and practical aspects
- Possibility to address dose response and risk if an ED mode of action has been claimed

Sylvia Jacobi, Albemarle, Belgium

14.35 Panel discussion

15.05 Coffee break

Developments Outside Europe

15.35 Korean BPR – implementation

- Final text and timelines
- Submission deadlines
- Special requirements industry should be aware of

Hyunpyo Jeon, Korea Institute of Science and Technology Europe, Germany

Current Legal Challenges

16.00 Lessons learnt in over five years of data sharing under the BPR

- Most common data sharing disputes and board of appeal cases
- Recommendations and upcoming challenges such as Brexit

Flore Cognat, Fieldfisher, Belgium

16.25 BPR renewals – update or rebuild? An industry perspective

- Timelines for dossier preparation
- Dossier update work with view to compliance with BPR requirements
- Feedback from regulatory bodies

Stefan Nave, Lanxess, Germany

16.50 Panel discussion

17.20 End of first conference day

18.30 Departure time for the evening event



As always you are most welcome to attend our evening event, which will take us to the historic district of Düsseldorf. We will enjoy a leisurely dinner at the brewery "Zum Schiffchen", Düsseldorf's oldest restaurant that even had Napoleon among its guests. Please join us to continue the day's interesting discussions in a relaxed and comfortable atmosphere.

 Wednesday, 3 April 2019

9.00 Welcome address by the Chair

Flore Cognat, Fieldfisher, Belgium

Specific Regulatory Areas

9.10 In-situ – authority experience

Gerhard Thanner, Environment Agency Austria

9.35 In-situ – industry experience

- Accepted definitions
- Data requirements and how are they to be filled?
- Experience with dossier submissions etc.

Helena Gräf, Ecolab, Germany

10.00 Assessment of halogenated disinfection by-products – current status

- Scope of work of the DBP Consortium – what we set out to achieve
- What has been done to date
- What is still needed and what can we expect during evaluation
- Lessons learned and how these can be used in assessing DBP for other active substance groups

Sara Kirkham, Arrow Regulatory, United Kingdom

10.25 Challenges in dietary risk and animal safety assessment

- Identification of relevant scenarios and gathering of data
- Tools and approaches in exposure assessment
- Uncertainties in regulatory acceptance

Michael Werner, knoell Germany

10.50 Panel discussion

11.20 Coffee break

11.50 ECHA Forum Biocidal Products Regulation Subgroup (BPRS) coordination of BPR Enforcement

- Overview on current activities and topics dealt with
- Upcoming plans
- Ongoing EU enforcement project on treated articles "BEF-1"
- Treated articles under the BPR: what is in the focus of enforcers

Eugen Anwander, ECHA BPR Enforcement Forum/
Vorarlberg State Service, Austria

12.15 Biocidal product families: a nightmare or a way forward? – authority perspective

- Outcome of the working party on the biocidal product families concept
- Experience of an evaluating competent authority
- Challenges for the applicant

Rixta Hempenius, Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), The Netherlands

12.45 Biocidal product families – industry perspective

- Experiences during dossier validation/evaluation
- What does the future look like?

Ian Watt, DowDuPont, United Kingdom

13.10 Panel discussion

13.40 Lunch and end of the conference



Information available online at:
www.akademie-fresenius.com/2638

The Experts

Eugen Anwander has been employed at the Federal State Government Service Vorarlberg in the Institute for Environment and Food Safety and the Chemical Safety Unit since 1992. Being a

chemical inspector, he is currently the Chair of the Biocidal Products Regulation Subgroup within the ECHA Enforcement Forum.

David Ashworth is the Managing Director of Klarus Consulting, which advises the biocides and biocidal products community on building and delivering safe and effective claims. He is also Chairman of

BluTest, a contract microbiology testing and development company.

John Bewley joined the Health and Safety Executive (HSE) in 2003 and is currently working in the International Chemicals Unit. A key part of his work focusses on the development of the legislation and

procedures necessary for the approval and authorisation of biocidal active substances and products following the UK withdrawal from the European Union.

Samantha Champ is currently employed by BASF SE, leading the regulatory affairs team for Biocides Europe, in the company's Care Chemicals division. Her responsibilities cover all BPR activities, national

biocide registration schemes and borderline legislations such as cosmetics and medical products. Since 2014 she is the Vice-chair of the CEFIC European Biocides Product Forum and will become the Chair as of 2018.

Flore Cognat is a Legal Consultant in the competition, regulatory and trade department of Fieldfisher, a law firm in Brussels. Her focus is on regulatory matters involving biocides and chemicals. Previously,

she worked for the European Chemical Industry Council (CEFIC) for five years and was leading different biocide policy groups and consortia and providing support, information and advice on implementation of biocide and chemical regulations.

Helena Gräf holds a PhD in food chemistry and toxicology and has been working in the regulatory area of biocides since 2012. After working for a consultancy, she joined Ecolab's regulatory affairs team in

2016 working with focus on European biocide dossiers and risk assessment for human health.

Rixta Hempenius holds a PhD in toxicology and has more than 20 years of experience in Regulatory Toxicology. Since 2016 she has been working as Team manager Human Toxicology and Residues at the Dutch competent authority Ctgb.

Sylvia Jacobi has been working as Corporate Toxicology Director at Albemarle since 2013. She holds a PhD in pharmaceutical chemistry – pharmacology and is a European registered Toxicologist.

Stine Jensen is Candidate of Veterinary Medicine and has been working as a Toxicologist at the Danish Environmental Protection Agency since June 2018.

Hyunpyo Jeon received his PhD from Johannes-Gutenberg University in Mainz in 2011, after working at Kumho Laboratory as Senior Researcher in Korea. He has been a member of the

Environmental Safety Group of KIST Europe Forschungsgesellschaft, which is a branch institute of the Korea Institute of Science and Technology for chemical regulation compliance, since 2011.

Sara Kirkham is a Director of Arrow Regulatory, an independent consultancy set up in 2016. She has worked on biocides since 2000, having worked on over 30 active substance applications, in particular

in-situ generation systems, and been involved with the assessment of disinfection by-products since 2012.

Alfonso Las Heras deals with issues related to product authorisation within the biocides team of Unit E4 in DG SANTÉ. His professional background relates to the regulatory framework of veterinary

medicines and to public-private partnership for research on animal health.

Camelia Mihai obtained a PhD in Sciences at the Vrije Universiteit Brussel. She started her professional career at Cefic, the European Chemical Industry Council in 2009. Since 2016, she leads The

European Biocidal Products Forum (EBPF). In this position, she actively follows the regulatory developments of the EU biocides legislation, providing support, information and advice to EBPF members in the area of compliance and implementation.

Stefan Nave holds a PhD in organic chemistry. Since 2016, he has been working at Lanxess Deutschland as a global Regulatory Manager for several active substances and biocidal products. His

previous experience included working for the German competent authority for biocides and for the biocides department at SCC Consulting.

Laura Ruggeri joined ECHA's Biocides Assessment Unit in 2013 and has been the team leader of the human health team since January 2018. She has been the Chair of the ad hoc Biocidal Product

Committee Working Group on the Assessment of Residue Transfer to Food (ARTFood) since 2014.

Gerhard Thanner is an educated chemist and has been working for several years in the field of organic analysis in the Environment Agency Austria. Since 2010 he has been

responsible for the evaluation of biocidal substances and biocidal products. Furthermore, he is alternate member in the Coordination Group for Austria, flexible member in the BPR Working Group on Analytical Methods and Physico-chemical Properties and attends ECHA's BPR IT user group regularly.

Ian Watt is the Global Advocacy and Government Affairs Manager for the Microbial Control business within the Industrial Biosciences division of DowDuPont. Ian has a degree in

chemical engineering and a career spanning more than 20 years in biocides, comprising commercial management and regulatory and product stewardship functions. Ian is currently Vice-chair of the CEFIC European Biocidal Products Forum.

Michael Werner is Chemist and Eurotox registered Toxicologist with an over 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 at knoell Germany, he provides regulatory and scientific/technical advice to clients for the preparation of biocidal active substance/product dossiers.

About

Who do you meet?

Groups that should take part:

Managing directors, boards of directors, managers, consultants and scientists in the fields of

- Registration and authorisation
- Legal and regulatory affairs
- Research and development
- Product safety
- Product management
- Regulatory science

Sectors that should take part:

- Chemical and biocides industry
- Producers of biocidal products
- Industrial and professional users of biocides
- Research institutes
- Regulatory authorities
- Environmental and health risk consultants
- Professional associations

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

Do you have any questions?



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Participation

- I would like to take part in the 18th International Fresenius Conference “The Biocidal Products Regulation“, 2 and 3 April 2019 in Dusseldorf/Germany. Fee: € 1,895.00 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 (please provide evidence). The reduced fee cannot be combined with other rebates.
- I would like to take part in the evening event on 2 April 2019 (included in the above price).

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)

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 exhibition and presenting information.

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 and videos 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

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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 six weeks prior to the start of the event. Please book early and directly through the hotel quoting “Fresenius” as reference.