The Biocidal Products Regulation

6 and 7 April 2017 in Dusseldorf/Germany

Highlights

Regulatory Aspects
- ECHA’s activities in the legislation of biocides
- Maximum residue levels: Legislation on limits for residues of active substances in biocidal products
- Criteria for endocrine disruption – What happens next?
- Industry perspective on union authorisation: Specific regulatory changes in the ‘same biocidal product’ regulation
- Dossier preparation for in situ generated active substances under BPR requirements
- Korean and European legislation of biocides.

Specific Regulatory Areas
- Obligations in the supply chain: Enforcements in the biocidal market
- Product families: Perspectives, challenges and updates
- Authority view on product families
- Regulatory perspective on obligations in the supply chain

Legal Challenges
- New guidance on disinfection products
- Industry perspective on future challenges with disinfectants and disinfectant by-products under the BPR
- Availability of nanobiocides and treated articles in the EU and challenges in implementing the BPR

The Experts

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.

Get-together on Wednesday, 5 April 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, 6 April 2017

8.30 Registration and coffee
9.00 Welcome address by Akademie Fresenius and introduction by the Chair
Samantha Champ, BASF SE, Germany

Regulatory Aspects

9.10 Update from the Commission: latest developments in the biocides field
Alfonso Las Heras, European Commission, Belgium

9.40 Criteria for endocrine disruption – What happens next?
• Criteria for regulatory purposes or political compromise?
• Practical implications for biocide dossiers
• Guidance, derogations and potential impact on the review programme
• Will the proposed criteria deliver improvements in human and environmental safety?
Andrew Adams, Bayer CropScience, France

10.10 Panel discussion
10.40 Coffee break

11.10 ECHA’s current activities in the legislation of Biocide
Paloma Lopez Serrano, European Chemicals Agency (ECHA), Finland

11.40 Biocide residue levels in food – Industry opinion & Status Quo BPR Article 19.1.(e) – implications
• Status quo on ARTFood guidances
• Industry opinion
• Interim approach
Christian Brieden, CEFIC/AISE Collaborative Working Group European Biocidal Products Forum (EBPF), Belgium

12.10 K-REACH and the new biocide regulation in Korea
Nick Choi, Chemtopia, South Korea

12.40 Panel discussion
13.10 Lunch

14.30 Dossier preparation for in situ generated active substances under BPR requirements
Michael Werner, Dr. Knoell Consult, Germany

15.00 Industry perspective on union authorisation
• Procedure and experience
• Same biocidal product
• Benefits, challenges and perspectives
Helena Ufelmann, Ecolab, Belgium

15.30 Panel discussion
16.00 Coffee break

Specific Regulatory Areas

16.30 Authority view on product families
Annette Schmedt, Federal Institute for Occupational Safety and Health (BAuA), Germany

17.00 Product families: Perspectives, challenges and updates
Adrian Gray, Janssen PMP, Belgium

17.30 Panel discussion
18.00 End of the first conference day
19.00 Departure time for the evening event

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Friday, 7 April 2017

8.30  Welcome address by the Chair  
  Jürgen Gutknecht, Prosacon, Germany

8.40  Authority perspective on restrictions on approvals of active substances  
  • Exclusion criteria and derogations from exclusion (Article 5)  
  • Criteria for candidates for substitution (Article 10)  
  • Developing the processes – pitfalls and potential  
  Mary Iakovidou, Swedish Chemicals Agency (KEMI), Sweden

9.10  Comparative assessment: Restriction of active substances and candidates for substitution  
  • The regulatory basis  
  • Practical implementation  
  • Likely impact for industry  
  Ian Watt, The Dow Chemical Company, United Kingdom

9.40  Panel discussion

10.10  Coffee break

10.40  Regulatory perspective on obligations in the supply chain: Enforcement of the BPR in the Polish market  
  Representative of Polish competent authority, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland

11.10  The importance of enforcement under the BPR  
  • Needs and benefits of enforcing regulation  
  • Industry's support of BDP and BPR  
  • Industry requirements to ensure safe and sensible investment into innovation  
  Jack Poppleton, Lonza Wood Protection, United Kingdom

11.40  Panel discussion

12.10  Lunch

13.10  BPR authorisation of disinfection products: Guidance and challenges  
  • Outlook on the forthcoming approval of (disinfection) active substances  
  • Guidance on disinfection products  
  • First experiences of the Competent Authorities  
  Marcel Hulsman, Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), The Netherlands

13.40  Current challenges for disinfectants under the BPR  
  • Gaining experience of regulating disinfectants under the BPR  
  • Efficacy requirements and test methods  
  • Disinfection by-products  
  • Fitting in situ products and commodity chemicals into the BPR regime  
  Mike Baldry, Antec International, United Kingdom

14.10  Availability of nanobiocides and treated articles in the EU and challenges in implementing the BPR  
  • Introduction to BPR nanospecific requirements  
  • Availability of nanobiocides in the EU  
  • Treated articles  
  • Challenges related to testing of nanobiocides  
  Steffen Foss Hansen, Technical University of Denmark, Denmark

14.40  Final discussion

15.10  End of second day

Information available online at:  
www.akademie-fresenius.com/2395
The Experts

Andrew Adams collected many years of experience working in European regulatory affairs for biocides, before moving into a public and governmental affairs role at Bayer CropScience in 2014. With specific focus on Endocrine Disruptors, he currently represents ECPA as Chair of their ED Expert Group and contributed to the ED High Level Group in CEFIC on behalf of the Biocides sector group.

Mike Baldry holds a PhD in chemistry and is currently working in regulatory affairs and product stewardship with Antec International, a Lanxess company. Mike is a chartered Chemist and Biologist, a member of the EBPF Management Committee and chairs the British Standards Technical Committee responsible for efficacy test methods for disinfectants.

Christian Brieden is a Toxicologist at Ecolab where he is working on toxicological risk assessments. He has been working on the topic of dietary risk assessment and possible maximum residue limit setting for biocides in his master thesis and he is the vice chair of the EBPF-AISE Working Group DRA 1SG.

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.

Nick Choi is a Team Leader actively managing joint registrations under K-REACH in Chemotopia. Nick is an expert in chemical registration for Korea Toxic Chemical Control Act (TCCA) and EU-REACH. He is currently working on joint registration and especially in data sharing discussion/negotiation with EU data owners (EU Consortium and registrants).

Steffen Foss Hansen is Associate Professor at the Department of Environmental Engineering, Technical University of Denmark. He has co-authored a number of publications related to the use of nanobiocides, treated articles as well as the challenges in regard to eco-toxicological testing of nanomaterials under the BPR.

Adrian Gray is a Senior European Regulatory Manager at Janssen PMP, where he is responsible for regulatory issues concerning biocides. He is an EBPF expert at Coordination Group meetings and has significant experience of product authorisations under the BPR.

Jürgen Gutknecht is a Consultant at Prosaco (Product Safety Consulting) and former Head of Bactria. Prior to the company foundation in 1990, he held different positions at Diversey and Rohm & Haas in France and has many years of experience in assisting with the regulation for both the biocide and disinfectant products.

Marcel Hulsman has a degree as Chemical Engineer and holds a PhD in analytical chemistry. Since 2013 he has been working as Account Manager Biocides for the Dutch Ctg. Prior to his current position he gained experiences as Laboratory Manager and Business Developing Manager.

Mary Iakovidou holds a PhD in physiology. She has spent the last 16 years at the Swedish Competent Authority KEMI at EU level, contributing to the negotiation of the BPR, also representing them at CA meetings and the Biocidal Products Committee.

Alfonso Las Heras deals with issues related to product authorisation within the biocides team of Unit E4 in DG SANTE. Having joined the biocides team in 2012, his professional background relates to the regulatory framework of veterinary medicines and to public-private partnership for research on animal health.

Paloma Lopez Serrano has been a Scientific Officer in ECHA’s Biocides Assessment unit since March 2016. Previously she held positions at Nalco/Ecolab, R&D working in the area of industrial water treatment.

Jack Poppleton graduated from the Imperial College of Science and Technology with a degree in chemistry and has over 40 years of experience in the chemical industry, having held positions in R&D, manufacturing, and HSEQ. Jack is now the Head of Global Regulatory Affairs at Lonza Wood Protection.

Annette Schmedt is a Scientific Officer at the German Competent Authority for Biocides, the Federal Institute for Occupational Safety and Health (BAuA), where she works as part of the team for biocidal product authorisations. She is also a member of the biocides coordination group (EU Committee).

Helena Ugelmann 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.

Ian Watt has more than twenty years of experience within the biocides industry and was involved in the development of the legislation and guidance, as well as active substance dossier management. He is a past chair of the UK Chemical Industries Association Biocides Sector Group and a current member of the CEFIC European Biocidal Products Forum (EBPF) Management Committee.

Michael Werner is a Chemist and Registered Toxicologist, holding a PhD in biochemical toxicology. He is an expert in the human health hazard, exposure and risk assessment of industrial chemicals and agrochemicals. At Dr. Knoell Consult, he is also responsible for human health expertise and provides regulatory advice on the development of biocidal product authorisation strategies and Art. 95 listings.
About

Who do you meet?

Groups that should take part:
Professionals working in the fields of
• Legal and Regulatory Affairs
• Registration and Authorisation
• 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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Registration

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By email registration@akademie-fresenius.com
By fax +49 231 75896-53

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 product 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 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

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Niederkasseler Lohweg 179
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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.

Participation

I would like to take part in the 16th International Fresenius Conference „The Biocidal Products Regulation“, 6 and 7 April 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 6 April 2017 (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)

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