19th International Akademie Fresenius Conference

The Biocidal Products Regulation

21 and 22 October 2020 in Cologne/Germany

Highlights

Regulatory Aspects
- Latest update from the EU Commission
- ECHA’s current activities regarding biocides
- Progress and challenges regarding the aims of the BPR
- Latest developments of the Korea BPR

Endocrine Disruptors
- Application regarding the ED criteria – authority and industry view

Treated Articles
- Methods to assess the risk of human contact with treated articles
- Preservation of articles

Specific Regulatory Areas
- Member state experience with in situ generated active substances
- In situ substances in the BPR – a device manufacturer’s view
- Industry perspective on biocidal product families
- The Ctgb on their experience with biocidal product families

Current Legal Challenges
- BPR and Medical Device Regulation (MDR)
- New challenges of data sharing under the BPR

The Experts
Wednesday, 21 October 2020

8.30 Registration and coffee

9.00 Welcome address by Akademie Fresenius and introduction by the Chair
Michael Werner, Prosacon, Germany

Regulatory Aspects

9.10 ECHA’s current activities regarding biocide
Carmen Estevan Martínez, European Chemicals Agency (ECHA), Finland

9.35 Updates from the EU Commission
Vincent Delvaux, European Commission, Belgium

10.00 An authority perspective on the aims of the BPR
• An overview of aims of the BPR
• Progress and challenges
• The place of the BPR in ongoing chemical legislation development
• Will we achieve the aims?
Mary Iakovidou, Swedish Chemicals Agency (KEMI), Sweden

10.25 Coffee break

10.55 Korea BPR – Implementation
• Brief overview of K-BPR
• Current progress and future direction
• Implementation for applicants
• EU-BPR vs K-BPR
Sam Lee, Chemtopia, South Korea

11.45 Applying the ED criteria to biocides – have we lost the plot?
• Availability, sufficiency and more delays
• The nightmare facing biocidal products
• Time for a reality check
Andy Adams, Bayer Crop Science, France

12.10 Panel discussion
12.50 Lunch

Treated Articles

14.15 Treated Articles – efficacy of treated articles, what does this mean and how to prove it?
• Preservation of articles
• Proof of effect required for those with secondary claims
David Ashworth, Klarus Consulting, United Kingdom

14.40 Treated Articles – human health risk assessment, is there a risk and how should we manage it?
• Methods used to assess the risk of human contact with treated articles
• Role of the ‘precautionary principle’ in the decision making process for biocide active substances
• Improvements to the regulatory process
Andrew Goodyear, ERM, United Kingdom

15.05 Coffee break

15.35 Data sharing under the BPR – old and new challenges
• EU data sharing principles revisited
• Lessons learnt from Board of Appeal Decisions
• Emerging data issues
• Impact of Brexit on data sharing
• New BPF concept
• New data requirements (endocrine disrupting properties)
• Global data sharing
Darren Abrahams, Steptoe & Johnson, Belgium
Hannah Widemann, Steptoe & Johnson, Belgium

16.15 BPR and MDR – a comparison
• Requirements and registration process
• Products under both regimes
• Significant challenges of BPR and MDR
N.N.

Endocrine Disruptors

11.20 Endocrine disruption – authority view
• Experiences with applying the ECHA/EFSA ED guidance
• Experiences with reviewing the first ED assessments
• Experiences and developments for ED assessment of biocidal products
Stine Jensen, Environmental Protection Agency (EPA), Denmark
Thursday, 22 October 2020

9.00  Welcome address by the Chair
Hannah Widemann, Steptoe & Johnson, Belgium

Specific Regulatory Areas

9.10  “Anything that, in happening, causes something else to happen, causes something else to happen”: In situ substances in the BPR – a device manufacturer’s view
• Looking back at our personal experience with regulatory issues on in situ substances
• Where are we now? Two different approaches for product authorisation
• What will the future bring?
Tatjana Röder, aquagroup, Germany

9.35  In situ generated active substances – authority experience
• Major challenges in the evaluation of in situ generated active substances
• Data requirements for the in situ generation system
• Recommendations for the applicants
Dominik Altmann, Environment Agency Austria, Austria

10.00 Panel discussion

10.20  Biocidal product families – authority view
Marcel Hulsman, Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), The Netherlands

10.45 Coffee break

11.15  How to approach the new BPF concept?
• Similar composition: Backbone composition and grouping of co-formulants
• Similar uses: Decision tree and matrix of uses
• Similar level of risk and efficacy: Core composition, subset and extension
Nathalie Hanon, Cethra, Spain

11.40  Biocidal product families – consultancy view
• Impact of the revised BPF concept and challenges in setting up BPF strategies
• Experiences with authorities – diverging eCA approaches and need for a level playing field
• Role of service providers – Identification of authorisation options and advice for priority setting
Michael Werner, Prosacon, Germany

12.05  Biocides: Part of the solution for a sustainable economy
• The value of biocides in the current regulatory framework
• Recognising the benefits of biocides: some case examples
• Ensuring the future: where do we go from here?
Ian Watt, DowDuPont, United Kingdom

12.30 Panel discussion

13.00 Lunch and end of the conference
Darren Abrahams works at Steptoe & Johnson and enables clients throughout the chemicals and life sciences supply chain to get and keep their products on the European Union market. He has a wealth of experience with the EU regulation of biocidal products, plant protection products, REACH, classification, labelling and packaging, GM food and feed, cosmetics, and endocrine disruptors.

Andrew Adams has many years of experience working in European regulatory affairs for biocides and moved into a public and governmental affairs role at Bayer Crop Science in 2014 where he is now the Global Issues Lead for Insecticides and Fungicides. With specific focus on endocrine disruptors, he currently represents Crop Life International and the ECPA as Chair of their ED Expert Groups.

Dominik Altmann is an Ecotoxicologist and joined the Environment Agency Austria in 2012. He is evaluating active substance approvals and product applications and has been the project manager for the approval procedure of active substances since 2013.

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.

Carmen Estevan Martínez joined ECHA’s Biocides Assessment Unit in 2014 and is currently the Process Coordinator for the active substance approval process. She has been the Chair of the Ad hoc Biocidal Product Committee Working Group on Human Exposure (HEAdhoc) since 2016.

Vincent Delvaux is assistant policy officer in the biocides team of DG SANTE that he joined in 2018. He has many years of experience working on EU chemical legislation. He contributed to the revision of the EU Fertiliser Regulation.

Andrew Goodyear has over thirty years of experience in regulation and risk assessment of chemicals, working in industry, contract research and consultancy sectors. He concentrated on the regulation of biocides since 2007 and has a lead consulting position providing technical advice, regulatory awareness and strategy for a wide range of biocide companies supporting active substance approval and product authorisation within the EU.

Nathalie Hanon has over 20 years of experience, in the plant protection products business as well as the biocides business. Among her past activities she has led the EU regulatory department of a major biocides production company. For more than two years, Nathalie has been appointed manager of CEHTRA SL (Spain) and Head of the EU biocides group of CEHTRA SAS.

Marcel Hulsman works as a Team Leader Board Advice and is responsible for the Project Planning biocides at the Ctgb.

Mary Iakovidou represents Sweden at the Standing Committee and Competent Authority Meetings for biocides. She acted as expert advisor during the negotiation of the Biocidal Products Regulation and also has recently monitored developments in chemical legislation review and forward planning on chemical policy within the EU.

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

Sam Lee is currently working in K-BPR regulatory affairs as a Junior Consultant in Chemtopia, South Korea. He participated in a project of the South Korea Ministry of Environment on the legislation of the K-BPR sub regulation and K-BPR regulatory consulting support for small and middle sized enterprises.

Tatjana Röder has accompanied aquagroup from the very beginning in 2004. Today she is responsible for business development, IT, marketing and regulatory issues. Since aquagroup is specialised in building in-situ devices to generate active chlorine from sodium chloride by electrolysis, her special interests are in-situ active substances and products.

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 a Chemist and EutroX Registered Toxicologist with an over 20 years track record in hazard, exposure and risk assessments. In his present role as a Senior Regulatory Affairs Manager and Assistant to the Managing Director at Prosacon, he leads the biocides team and provides regulatory as well as scientific/technical advice to clients for the preparation of biocidal active substance/product dossiers.

Hannah Widemann works for Steptoe & Johnson and advises clients on EU regulatory compliance questions in the areas of chemical and product regulations, including REACH, CLP, biocides, plant protection products, and fertilisers. Her work includes product defense and litigation strategies before the European Court of Justice and the Board of Appeal of the European Chemicals Agency (ECHA), as well as supporting clients with (data sharing) negotiations, contracts, and potential disputes.
Who do you meet?

Managing directors, boards of directors, managers, consultants and scientists 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, professional and downstream 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 25 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.

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Participation

☐ I would like to take part in the 19th International Akademie Fresenius Conference “The Biocidal Products Regulation”, 21 and 22 October 2020 in Cologne/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 21 October 2020 (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 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
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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.

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