DIE AKADEMIE FRESENIUS

Where experts meet!

13th International Fresenius Conference

THE BIOCIDAL PRODUCTS REGULATION

10 and 11 September 2013 in Dusseldorf/Germany

New: Legal Seminar on DATA SHARING on 9 September 2013

HIGHLIGHTS:

Strategic choice: mutual recognition, union authorization or biocidal product family
- Comparing procedures
- Industry perspective on BPR routes for authorization
- Estimating costs

BPR: developments and implementation
- Implementing the BPR: key elements and milestones
- Status report on the Biocidal Products Committee and the Coordination Group
- Implementation of the BPR in Spain and Hungary

Treated articles and materials
- What are they and how will they be regulated?
- Obligations and challenges for treated article manufacturers under the BPR

Overcoming practical and legal challenges
- An SME's perspective and approach on how to comply with the new regulatory requirements
- Data sharing disputes under the BPR
- Borderline products: legal setting, experiences and views on the changed conditions under the BPR

THE EXPERTS:

Darren Abrahams Steptoe & Johnson | **Oliver Bisazza** EDANA/CheMI | **Teresa Borges** Portuguese General Directorate of Health | **Camilla Buchanan** European Chemicals Agency (ECHA) | **Samantha Champ** BASF | **Robert Collins** Tarn-Pure | **Luisa González Márquez** Spanish Ministry of Health, Social Services and Equality | **Lena Gruhn** German Federal Institute for Occupational Safety and Health (BAuA) | **Ludger Grunwald** Ecolab | **Jürgen Gutknecht** Independent Consultant | **Steve Hollins** European Chemicals Agency (ECHA) | **Peter Kugel** Kugel Legal | **Alfonso Las Heras** European Commission | **Claudio Mereu** Field Fisher Waterhouse | **Burkhard Mielke** Lanxess | **Maartje Nelemans** Dutch Ministry of Infrastructure and the Environment | **Gosia Oledzka** International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.) | **Magda Solti** EUMON, representing the Hungarian Biocide Competent Authority | **Carly Vulders** Intracare | **Michael Werner** SCC

INSTITUT FRESENIUS

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THE PROGRAMME

Get-together on Monday, 9 September 2013

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

Tuesday, 10 September 2013

8.30 Registration & coffee

9.00 **Welcome address by the organisers and the Chair**

Burkhard Mielke, Lanxess, Germany

Strategic choice: mutual recognition, union authorization or biocidal product family

9.10 **Mutual recognition vs. union authorization: comparing procedures**

Claudio Mereu, Field Fisher Waterhouse, Belgium

9.40 **An industry perspective on BPR routes for authorization**

- Union authorisation vs. national authorization followed by mutual recognition
- BPR and "Joint Authorization" concept
- Concerns of Disinfectants Industry in view of BPR

Gosia Oledzka, International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.), Belgium

10.10 Coffee break

10.40 **Biocidal product families**

- Regulatory and scientific requirements
- Strategies on family building

Michael Werner, SCC, Germany

11.10 **The costs involved in each BPR market access procedure**

- Maximising value and strategic choices
- Lessons from other regimes

Darren Abrahams, Steptoe & Johnson, Belgium

11.40 Panel discussion
12.15 Lunch break

BPR: developments and implementation

13.30 **Implementing the BPR: key elements and milestones**

- BPR overview: key elements
- Implementing the BPR: state of play in terms of secondary legislation and Technical guidance
- Transitional measures (Art. 89-95)
- Upcoming deadlines (2015/2016/2017/2025)
- Challenges and opportunities

Alfonso Las Heras, DG Environment, European Commission, Belgium

14.15 **Status report on the Biocidal Products Committee and the Coordination Group**

- Progress so far
- Outlook for coming months

Steve Hollins, European Chemicals Agency (ECHA), Finland

14.45 Q&A with the European Commission and ECHA
15.30 Coffee break

16.00 **Implementation of the BPR in Spain and experiences with the regulatory change**

- Coexistence of different procedures: experiences in Spain
- Main challenges in the implementation of the BPR
- BPR: increase or decrease of workload?

Luisa González Márquez, Unit of Biocides and Chemical Products, Ministry of Health, Social Services and Equality, Spain

16.30 **Implementation and impact of the BPR on the Portuguese market**

Teresa Borges, General Directorate of Health, Portugal *(invited)*

17.00 **Implementation and impact of the BPR on the Hungarian market**

- Active substance authorization in Hungary
- Procedure for authorization of a biocidal product in Hungary
- Impact of BPR on big Hungarian companies and SME's
- Benefits and losses
- Costs

Magda Solti, EUMON, representing the Biocide Competent Authority, Office of the Chief Medical Officer of State, Hungary

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

At the end of the first conference day, Akademie Fresenius invites you to a leisurely evening in Dusseldorf. After a short city walking tour, we will have dinner at a traditional brewpub with local beer. Use this opportunity to deepen the contacts you made during the day.

Wednesday, 11 September 2013

8.30 Welcome address by the Chair

Jürgen Gutknecht, Independent Consultant, Germany

Treated articles and materials

8.40 Treated articles: what are they and how will they be regulated?

- General definitions of treated articles
- New requirements for treated articles
- Labelling requirements: how is a labelling claim triggered?
- Turning theory into practice: the practicalities of the new requirements

Samantha Champ, BASF, Germany

9.10 Treated articles: between theory and practice

- Treated articles: simple texts, but many questions
- Biocide versus treated article
- Frequently asked questions and possible answers

Maartje Nelemans, Ministry of Infrastructure and the Environment, The Netherlands

9.40 Obligations and challenges for treated article manufacturers under the BPR

- The borderline between 'biocidal product' and 'treated article'
- Article 58: new challenges for the entire supply chain?
- Implementation options: striking the right balance through guidance documents

Oliver Bisazza, EDANA/CheMI, Belgium

10.10 Panel discussion
10.40 Coffee break

Overcoming practical and legal challenges

11.10 An SME's perspective and approach on how to comply with the new regulatory requirements: a case study

- Implications of the BPR for SME companies
- How to use available information for dossier building
- Registration and sales: how to keep the sales guys happy
- How biocides can help to reduce the amount of antibiotics
- A case study for PT5 registration

Carly Vulders, Intracare, The Netherlands

11.40 Data sharing disputes under the BPR

- How much should an applicant pay for a Letter of Access, and when?
- What types of data sharing litigation can be envisaged before EU and domestic courts?
- Is the BPR mechanism of mandatory data sharing practicable?

Peter Kugel, Kugel Legal, Belgium

12.10 Borderline cases: legal setting and practical impacts

- Background and provisions of the BPD/BPR
- Guidance
- Examples

Lena Gruhn, Federal Institute for Occupational Safety and Health (BAuA), Germany

12.40 Borderline products: experiences and views on the changed conditions under the BPR

- Borderline to medical devices
- Borderline to cosmetic products
- Borderline to medicinal products
- Borderline to veterinary medicinal products
- Borderline between biocide product types

Ludger Grunwald, Ecolab, Germany

13.10 Panel discussion
13.45 Concluding remarks by the Chair, end of conference and lunch buffet

Legal Seminar on Data Sharing (30 seats available only)

Monday, 9 September 2013

13.00 Lunch buffet

14.00 Article 95 and the obligations on suppliers

- Article 95: obligations on suppliers, making the submission
- The submission process
- Scope of the list of approved suppliers
- State of the discussion on the potential changes to Article 95

Camilla Buchanan, European Chemicals Agency (ECHA), Finland

14.45 Mandatory data sharing and data protection

- Procedure
- Requirements
- Data access agreements and Letter of Access
- Critical remarks

Peter Kugel, Kugel Legal, Belgium

15.15 Panel discussion
15.45 Coffee break

16.15 The challenges of Article 95 and Task Force Membership for the SME

- What challenges will face an SME embarking, for the first time, on the journey to support an active substance under the BPR through membership of a Task Force?
- Process? Steps? Timeframe? Methodology?
- Cost?
- What is a "Fair, Transparent and Non-Discriminatory" environment?
- What resources and skill sets will be required?
- How do you share a table with your competitors?
- How do you address the issue of data ownership and mandatory data sharing as established under Article 95, especially in respect of valuation?
- Are you a buyer or a seller?
- How do you decide whether to fully participate in the process or seek to acquire data access at a later stage?

Robert Collins, Tarn-Pure, UK

16.45 Calculating the price of data

17.15 Panel/open discussion
18.00 (approx.) End of seminar

If you have any **questions regarding the programme:**
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If you have any **questions regarding the organisation:**
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YOU WILL MEET

Attendee job titles and responsibilities include Directors, Heads, Managers and Consultants of:

- Legal and Regulatory Affairs
- Registration and Authorisation
- Research & Development
- Product Safety, Product Management
- Regulatory Science

Sectors taking 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 ORGANISERS

AKADEMIE FRESENIUS is a joint venture of SGS INSTITUT FRESENIUS and COGNOS, one of the leading private educational institutes in Germany. Akademie Fresenius organises national and international conferences and congresses on current topics from the economic and scientific sectors for both specialists and the industry. You can find details on upcoming and new events at **www.akademie-fresenius.com**

SGS INSTITUT FRESENIUS is one of the main providers for non-medical laboratory analysis in Europe in the range of chemical, biological and physical analysis. The neutral institute belongs to the internationally acting SGS Group, the corporation that is worldwide at the forefront of testing, verification and certification of goods and service. SGS Institut Fresenius has become a competent partner for companies from various industrial sectors.

SGS INSTITUT FRESENIUS Agrochemicals Product Registration Services provides GLP compliant laboratory and field studies for the registration of agrochemicals, biocides and chemicals. **www.institut-fresenius.de**

THE EXPERTS

Darren Abrahams is an English barrister and a partner in Steptoe's Brussels office. His practice is focused on EU regulatory requirements and the related commercial issues in the environment, chemicals, and life sciences area. He has particular experience in chemicals regulation.

Oliver Bisazza is Regulatory Affairs Manager at EDANA, the international association serving the nonwovens and related industries. He represents the CheMI Platform, the European Platform for Chemicals Using Manufacturing Industries, at the European Union's Competent Authority meetings.

Teresa Borges graduated in biology and holds a Master's degree in food science and technology. Since 2002, she has been Senior Technical Adviser at the Portuguese General Directorate of Health.

Camilla Buchanan is a Legal Advisor in the Legal Affairs Unit of ECHA, advising on the implementation of the BPR. Camilla is a UK qualified lawyer with a Master's degree in EU law from the College of Europe. Prior to joining ECHA she worked as a lawyer in private practice for eight years.

Samantha Champ received a PhD in physical chemistry from the University of Salford, UK. She has been based in Germany since 2001 and after various positions within BASF is currently leading the Regulatory Affairs team for Biocides Europe in the company's Care Chemicals Division.

Robert Collins started his career in accountancy before moving into contracts, business development and general management with businesses in Europe, the Middle East and Africa. Since 1994 he has established himself as a company director providing leadership to high growth businesses.

Luisa González Márquez received a degree in pharmacy and a Magister in toxicology. She held positions as Inspector of Public Health and Technician in Service of Biocides before she became Head of Service (Biocides) at the Ministry of Health, Social Services and Equality in Spain.

Lena Gruhn is a German lawyer and has been working as a legal officer for the German competent authority for the authorisation of biocidal products (BAuA) for the last two years. Her key area of work is concerned with the legal aspects relating to biocidal products.

Ludger Grunwald holds a PhD in food chemistry. He is Director Regulatory Affairs EMEA at Ecolab, member of the management committee and several working groups of EBPF (European Biocide Product Forum) of CEFIC and member of AISE Biocides working groups.

Jürgen Gutknecht is an independent Consultant and former Head of Bactria GmbH. Prior to the company foundation in 1990, he held different positions at Diversey GmbH and Rohm & Haas in France.

Steve Hollins joined ECHA in 2007 where he has worked in establishing and running the ECHA Committees. His background is in biochemistry, and he has worked in the chemical regulatory field for 20 years, in industry and with the European Commission.

Peter Kugel is founder of his ‚boutique' law firm in European chemical law, focussing on risk regulation, market access and product defence. He specialises in REACH, GHS/CLP, biocides and pesticides, and represents clients in administrative procedures, compliance issues and data protection/sharing matters.

Alfonso Las Heras joined the EC in 2012 and has been dealing with issues related to product authorisation within the biocides team of Unit D3 at DG ENV. His professional background relates to the legal and regulatory environment of veterinary medicines and to the public-private partnership for research on animal health.

Claudio Mereu is partner at Field Fisher Waterhouse in Brussels where he heads the EU Regulatory Group and the firm's Life Sciences Group. He advises on regulatory compliance issues, task force/consortia formation and product defence strategies for e.g. REACH, pesticides and biocides.

Burkhard Mielke is Head of Regulatory Affairs of the Lanxess Business Unit Material Protection Products. Also, he is Chairman of the VCI Task Force Biocides and member of the Management Committee of the Cefic Sector Group "European Biocides Products Forum".

Maartje Nelemans holds a PhD in biology from the University of Groningen. She is Coordinator International Biocides and Plant Protection Products at the Dutch Ministry of Infrastructure and the Environment. Previously, she was Policy Adviser at the Ministries of Transport and Environment.

Gosia Oledzka holds a degree in environmental engineering and an MSc in environmental management. She worked as REACH Scientific Advisor, and joined A.I.S.E. in 2011, dealing with issues related to products types 1, 2, 3, 4, 6, 18, 19.

Magda Solti holds a PhD in biochemistry. She recently retired as Head of Biocide Group from the Office of the Chief Medical Officer at the Hungarian National Public Health and Medical Officer Service. She now works as Managing Director at EUMON Ltd.

Carly Vulders has spent his career as intermediary between businesses and government for discussions related to chemicals. Currently, he works on biocides helping to reduce the amount of antibiotics used in the intensive livestock industry to tackle antibiotic overuse and resulting resistance.

Michael Werner is a chemist and certified toxicologist. He leads the toxicology group at SCC's biocides department. His primary field of expertise comprises human health hazard as well as exposure and risk assessment for industrial chemicals, agrochemicals and biocidal active substances.

REGISTRATION

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DIE AKADEMIE FRESENIUS

PARTICIPATION

Yes! I would like to take part in the 13th International Fresenius Conference **„The Biocidal Products Regulation“** in Dusseldorf / Germany.

- ❑ Seminar + Conference (9 to 11 Sep 2013): € 2,145 plus VAT
- ❑ Conference only (10 to 11 Sep 2013): € 1,695 plus VAT

Yes! I am a representative of an authority or a public university and therefore eligible for a reduced fee. The reduced fee cannot be combined with other rebates.

- ❑ Seminar + Conference (9 to 11 Sep 2013): € 995 plus VAT
- ❑ Conference only (10 to 11 Sep 2013): € 795 plus VAT

I would like to take part in the **evening event** on **10 September 2013** (included in the above price).

❑ Yes ❑ No

CONFERENCE DOCUMENTATION

❑ **No!** Unfortunately, I am unable to attend. Please send me the complete conference documentation for € 295.00 plus VAT (hard copy and electronic version).

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❑ **Yes!** Please send me information on **exhibition possibilities** during the event.

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TERMS OF PARTICIPATION AND PURCHASE

The registration fee includes the **conference participation, conference documentation, lunch, coffee breaks, conference beverages** as well as the **evening event** on 10 September 2013.
You will receive written confirmation of your registration. Upon receiving our invoice, please transfer the amount due without further deductions before the conference begins.

The price of the conference documentation includes a hard copy of the documentation as well an access code to the secure Akademie Fresenius download area where you can download the complete conference documentation, including any subsequent updates, in electronic form – subject to the approval of the respective speakers. 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 General Terms and Conditions on the internet (www.akademie-fresenius.com/general-terms) or receive them on request.

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The Akademie Fresenius will keep your personal 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. Further information can be found at: www.akademie-fresenius.com/dataprotection.

VENUE/CONFERENCE HOTEL

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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.