THE BIODICAL PRODUCTS REGULATION

18 and 19 October 2011
in Frankfurt/Germany

HIGHLIGHTS:

Regulatory Aspects
- European Commission and industry view on the revision of the Biocidal Products Directive
- Borderline to other products’ legislation

Product Authorisation and Mutual Recognition
- Dossier evaluation
- ECHA’s role
- What authorities can do to get mutual recognition working
- Industry experiences with mutual recognition
- Challenges for a medium-sized active substance producer to provide regulatory support throughout the supply chain
- Experience with the post Annex I authorisation of biocidal products
- In situ generated active substances
- Efficiency and practicability of risk mitigation measures

Outlook
- Dietary exposure assessment
- Impact of the future BPR on imported treated articles and food contact materials
- Impact of the future BPR on innovation
- What have we learned from the BPD?

THE EXPERTS:


Prepare your business for the regulatory challenges!
Get-Together on Monday, 17 October 2011

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

Tuesday, 18 October 2011

8.45  Registration & coffee

9.10  Welcoming speech by the organisers and the chairperson
Jürgen Gutknecht, Independent Consultant, Germany

Regulatory Aspects

9.15  Directive 98/8/EC; the time before and what we will have to expect afterwards
■ National practices of placing biocidal products on the market before Directive 98/8/EC
■ Short overview on the Directive 98/8/EC including its borderline to other products’ legislation
■ Outlook
Edmund Plattner, Federal Ministry of Agriculture, Forestry, Environment and Water Management, Austria

9.45  Revision as it currently stands – commission view
Pierre Choraine, European Commission, Belgium

10.15  Revision as it currently stands – industry view
■ Description and analysis of the current situation
■ Second reading and industry’s expectations
Alexander Grube, Chemical Industry Association (VCI), Germany

10.45  Discussion
11.15  Coffee break

Product Authorisation and Mutual Recognition

11.45  Challenges for a medium-sized active producer to provide regulatory support throughout the supply chain
■ Preparation of active substance dossiers, biocidal product dossiers and risk assessments
■ Coordinate regulatory support for customers with contract laboratories and consultants
■ Strategies for European companies and implications for relevant non European markets
Ellen Thom, Endura, Italy

12.15  Experience with the post Annex I authorisation of biocidal products
■ Experience with biocidal products authorisation and mutual recognition of authorisation
■ Strategic and scientific aspects when applying for product authorisation

Product authorisation after coming into force of the BPR
Holger Zitt, SCC, Germany
12.45  Discussion
13.10  Lunch break

14.20  Member State experience with the post Annex I authorisation of biocidal products
■ First authorisation
■ Mutual recognition
■ Harmonisation
Anna Nordberg, Swedish Chemicals Agency (KEMI), Sweden

14.50  Dossier evaluation – experiences in France
■ Current situation and issues
■ New process
■ Expectations for the future
Philippe Juvin, Agency for Food, Environmental and Occupational Health Safety (ANSES), France

15.20  ECHA’s role under the Biocidal Products Regulation
■ Approval of active substances
■ Union authorisation
■ Data sharing
Tom Uotila, European Chemicals Agency (ECHA), Finland

15.50  Discussion
16.15  Coffee break

16.45  Mutual recognition: what can authorities do to get it working
■ Mutual recognition: mutual interest
■ Critical factors for success
Jan Willem Andriessen, Ctgb – Board for the Authorisation for Plant Protection Products and Biocides, The Netherlands

17.15  Mutual recognition – First experience from industry
■ Mutual recognition procedure in Germany different from Austria
■ What happens with mutual recognition if the first authorisation is not in time with the deadline of compliance with Article 16(3) „Erfüllungsfrist“?
■ How the products on the market are effected by this in Germany and Austria?
Josef Theo Hein, Dyrup, Germany

17.45  Discussion
18.15  End of the first conference day
19.00  Departure time for the evening event
Wednesday, 19 October 2011

Chairperson:
Burkhard Mielke, Lanxess, Germany

Product Authorisation and Mutual Recognition

9.00 In situ generated active substances; more efficiently regulated in the BPR
- New guidance document published
- Data requirements for precursors and actives
- Methods of in situ generation
Helmut Kraus, Lanxess, Germany

9.30 Efficiency and practicability of risk mitigation measures for biocidal products
- Biocides and risk mitigation measures
- Environment
- Wood preservatives, insecticides
Jürgen Fischer, Federal Environment Agency (UBA), Germany

10.00 Discussion
10.20 Coffee break

Outlook

10.50 Dietary exposure assessment for biocides – view from industry
- Regulatory background
- Exposure assessment via food/feed for PT 2,3 and 4
- Current discussions within EU

THE EXPERTS

Andy Adams was trained as an entomologist and received his PhD in insect physiology from Imperial College, University of London. He has held responsibilities in UK, Germany and France as Head of Biology, Business Support Manager and, since 2003 as Head of the Regulatory team for Bayer Environmental Science in Europe. In 2008 he was elected Chairman of the Cefic European Biocidal Products Forum.

Jan Willem Andriessen is a specialist in regulatory affairs in the Dutch national legislation and the EU process. He is involved in the assessment of biocides since 1997 and is currently account manager for biocides at Ctgb.

Pierre Choraine is Policy Officer for the biocidal products Directive at the European Commission.

Heiko Faubel is Executive Director of the Industrial Association for Hygiene and Surface Protection for Industrial and Institutional Applications. He has a more than 20 year track record in different technical roles within Henkel, Henkel-Ecolab and Ecolab. Most recently, he was the Technical Director responsible for research, development and engineering for the institutional business in the Europe, Middle East and Africa region.

Jürgen Fischer obtained his PhD in agricultural chemistry and joined UBA in 1997. Since 2000 he is a member of the biocides group. Application areas are exposure estimation, especially material preservatives and risk mitigation measures.

Alexander Grube is a chemist. He is working in the sector “Chemicals Policy and Product Safety” of the German Chemical Industry Association (VCI). His main responsibilities include activities connected with the review of the BPD.

11.20 New BPR: Treated articles, food contact materials and other issues
- Treated articles under BPD and under new BPR
- Food contact materials under BPD and under new BPR (surface biocides, etc)
- Labelling requirements
- Other issues
Marcus Navin-Jones, Keller and Heckman LLP, Belgium

11.50 Impact of the future Biocidal Products Regulation on innovation in the biocide industry
- Impact of the current BPD provisions on innovation: content and cost of dossiers, cost of registration fees, time to the market, protection of data
- Will the future BPR provisions favour innovation at the substance level? At the formulation level?
- A few case studies
Rodolphe Quérou, Dow Microbial Control, France

12.20 What have we learned from the BPD?
- Risk – benefit: it may be safe but it’s too expensive to prove it
- Loopholes: free-riding has undermined the legislation
- Resources: SMEs cannot handle the burden, Authorities were not prepared
Andy Adams, Bayer, France

12.50 Discussion
13.30 Lunch and end of the conference
Jürgen Gutknecht is an independent consultant and former Head of the Bactria GmbH. Prior to the company foundation in 1990 he held different positions with Diversey GmbH and with Rohm & Haas in France.

Josef Theo Hein is an expert in wood, wood preservation and wood coatings and responsible at Dyrup for all technical and environmental subjects in German speaking countries. Previously, he was project and marketing manager for recycling of desulfuration gypsum from electrical power plants Pro Mineral (RWE) and worked for Henkel for the product management of building chemicals, adhesives and wood coatings.

Philippe Juvin gained his PhD in Pharmacy and has extensive experience in the pharmaceutical industry where he held various positions. He has been heading the European Chemical Policy Department in the former French Agency for Environmental and Occupational Health Safety (Afisset) and is now since 2010, deputy director of the regulated product in ANSES in charge of REACH, CLP and Biocides.

Helmut Kraus started his career at the Bayer AG in 1988 as a chemist. After several positions in this company, he became a Regulatory Manager in 2004, responsible for biocides. Main focus of his work was compiling most of the Lanxess BPD dossiers for the 3rd and 4th group.

Burkhard Mielke is Head of Regulatory Affairs of the LANXESS Business Unit Material Protection Products. He is also chairman of the VCI Task Force Biocides and member of the Management Committee of the Cefic Sector Group „European Biocides Products Forum“.

Marcus Navin-Jones is a UK qualified lawyer who specializes in EU Regulatory law. His practice focuses on EU chemical control law, EU environmental law, product safety and liability law and free movement of goods/services issues. He assists clients with all aspects of BPD compliance including Annex I inclusion, product authorisation issues, data access and free riding issues, etc.

Anna Nordberg is working with authorisation of biocidal products at the Swedish Chemicals Agency (Kemi). Previously, she has also worked with authorisation of plant protection products at the same agency.

Edmund Plattner is Director of the Biocides department at the Ministry of Agriculture, Forestry, Environment and Water Management in Austria. He studied Chemistry in Vienna and Toxicology in Guildford, UK.

Rodolphe Quérou completed a PhD in agronomy and held several R&D and Regulatory Affairs positions within the plant protection products, fertilizer and biocides industry. He joined Rohm and Haas (now merged to Dow Microbial Control) as European Regulatory Manager for Biocides in 2000. He is part of the EBPF management committee, and CEPE and IPPIC antifouling working group.

Ellen Thom studied Agricultural Sciences and Soil Microbiology and worked 15 years in national and global regulatory affairs departments in Zeneca, AgrEvo Environmental Health, Aventis Environmental Science and Endura S.p.A.

Tom Uotila works for the European Chemicals Agency in Helsinki since 2009. He has expertise in business process modelling in complex multi-stakeholder environments and has contributed to the development of numerous IT solutions supporting such processes, most recently in the context of REACH.

Holger Zitt is Deputy Head of the biocides department at the German consultancy SCC. Before joining SCC, he has been working for several years in the industry. His main fields of expertise are regulatory and scientific aspects in the framework of the EU biocides legislation with a special focus on biocidal products.
WHOM DO YOU MEET?

Groups that should take part:
Professionals working in the field of legal and regulatory affairs, registration/authorisation and product safety

Sectors that should take part:
- Biocides industry
- Producers of biocidal products
- Regulatory authorities
- Professional associations

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

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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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PARTICIPATION

☐ Yes! I would like to take part in the 11th International Fresenius Conference „The Biocidal Products Regulation“, 18 to 19 October 2011 in Frankfurt/Germany.
Fee: € 1,695.00 plus VAT per person

☐ Yes! 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 18 October 2011 (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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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.

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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.

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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.