About the event

Regulators, authorities and biocides businesses are continuing to get to grips with the intricacies of the EU Biocidal Product Regulation - putting the provisions into practice and, where necessary, developing further explanation and understanding of the application of this hugely complex piece of legislation.

As implementation progresses, an increasing number of companies, across more industrial sectors, are feeling the effects and increasingly need to know their obligations in order to remain within the law. Companies also need to understand the likely impacts of the regulation on the supply of ingredients that are often critical to the performance of their products.

The 2018 conference focuses on key aspects of Regulation (EU) No. 528/2012 concerning the approval of active substances and authorisation of biocidal products. Presentations include the latest developments from the European Commission and ECHA. As well as drilling down to the recent detail of this complex regulation, speakers will address topics such as:

- Biocidal Product Families updates
- In situ product authorisation
- Dietary and nanomaterial risk assessment
- The impact of Brexit
- Data sharing issues - BPR related cases at the Board of Appeal
- The implementation of ED criteria under the BPR
- Innovation: new biocides and alternatives
- Revision of efficacy guidance for PT 14 and PT 19
- Strategy for efficacy testing for disinfectants in biocidal product families
- Efficacy testing for PT 11/12 and PT 18/19
- Compliance strategies with the BPR
- National Enforcement Authority panel
- Biocides regulation in South Korea, China and Canada

Why attend?

Expert panel
Listen to senior representatives from European institutions, regulators from member states together with industry representatives from across the EU and elsewhere in the world.

Current thinking
Gain valuable insight into the state of play of the BPR.

Time efficiency
Bring yourself up-to-date with the complex and changeable regulatory landscape concerning biocides by attending two conference days.

Q&A panel sessions
Have your specific questions answered by making use of the multiple Q&A sessions! Remember - you can send in writing any questions you might have in respect of the biocides' regime in advance of the conference.

Focus
Bring yourself up-to-date with the BPR since implementation and learn about developments in the rest of the world.

Who should attend?

Representatives of authorisation/registration holders, national Competent Authorities as well as other involved Stakeholders (producers, retailers, formulators, consultants, etc.) dealing with these issues.

+44 (0)1743 818 293 sales@chemicalwatch.com https://events.chemicalwatch.com
Day one - 27 November 2018

Chair: Dave Dillon, Senior Managing Scientist, Exponent International, UK

Session 1: Overviews

09.00 Update from the Commission: latest developments in the biocides field
  - Endocrine-disruptors
  - In situ
  - Substitution
  Martinus Nagtzaam, Policy Officer, EU Commission, Belgium

09.30 ECHA’s latest updates
  - Renewal of active substances approval
  - Union Authorisation
  - IT updates
  - Brexit IT adaptation
  Valerio Spinosi, Scientific and Regulatory Officer, Biocides Unit, ECHA, Finland

10.00 Member State overview from the Netherlands
  - EU Fact Finding Mission in the Netherlands
  - BPR workload and available resources
  - First experiences with Union Authorisation
  - First Experiences with Biocidal Product Families
  Ingrid Becks, Manager Board Advice and Project Planning, Deputy Secretary/Deputy Director, Ctgb (Board for the Authorisation of Plant Protection Products and Biocides), the Netherlands

10.25 Q&A

10.40 Refreshments

Session 2: Authorisation/approval related issues

11.05 Annex I inclusion
  - Basic functioning of Annex I
  - Simplified authorisation route
  - Update of Annex I for food and feed substances
  - On-going discussions in CA meeting on Annex I
  Martinus Nagtzaam, Policy Officer, EU Commission, Belgium

11.25 BPF Working Group: progress and some feedback from an industry perspective
  - New guidance under development for the biocidal product family
  Danielle van Corven - Kloosterman, Regulatory Affairs & Registration Europe Lead, Diversey Europe, Netherlands

11.50 Management of in-situ product authorisation
  - Brief introduction of the concept of in-situ, including a) categories of in-situ generated biocidal systems (IGS) and b) variants of precursors.
  - In the light of the various categories and variants, information needed to apply for authorisation of an IGS is presented.
  - What is the role of the device in the assessment prior IGS authorisation?
  - Some thoughts about the options of an IGS biocidal product family concept.
  - Open the floor for suggestions for ‘fit for purpose’ regulatory guidance for in-situ product authorisation
  Lucas Kalkers, Policy Advisor, Ctgb, the Netherlands

12.15 The challenge of a successful technical equivalence application
  - When is it needed?
  - Who needs to apply for it?
  - At what level: Tier I or Tier II?
  - What are the requirements?
  - What could the impact be for the business?
  Nathalie Hanon, Manager Cehtra SL, Cehtra, Spain

12.40 Q&A

13.00 Lunch

Session 3: Risk Assessment

14.00 Dietary risk assessment for non-professional use of biocidal products - adapting the IDREAM model to the EU
  - Current risk assessment requirements and approaches under the BPR
  - Drivers for developing a higher tier exposure model
  - Current development of the EU IDREAM model and next steps
  Namali Corea, Senior Regulatory Toxicologist, SC Johnson, UK

14.25 Developing guidance for dietary exposure assessment for professional uses
  - Dietary risk assessment
  - CA residue policy
  - Residue limits
  - Dietary exposure assessment for professional uses
  - Examples
  Stephan Gregorini, Senior Manager Regulatory Assurance Consumer Product Ingredients EMEA – Lonza AG, Switzerland
14.50 Experiences with nanosilver: creating a substance dossier including human health and environmental risk assessment - an SME’s perspective
- Introduction to nanosilver: production, applications, benefits
- BPR data requirements for nanomaterials
- OECD WPMN sponsorship programme and availability of data
- Risk assessment and substance dossier creation
  Gregor Schneider, Head of Business Unit „agpure® nanosilver“, RAS AG, Germany

15.15 Q&A

15.30 Refreshments

Session 4: Legal and regulatory issues

15.55 Grouping for in-situ biocides? Regulatory considerations/practical issues
- Short introduction of related legislation
- Which combinations have been notified?
- A spot of chemistry
- Guidelines involved
- Current issues, such as family groupings
- Grouping approaches/issues for in-situ systems based on devices
  Francesca Fasano, Head of Biocides and Agrochemical Service, Chemsafe, Italy

16.20 Brexit - State of play and implications for chemical policy
- Update on policy developments, Article 50 negotiations and withdrawal agreement
- Transposition of EU chemicals legislation into UK law
  Darren Abrahams, Partner, Steptoe & Johnson LLP, Belgium

16.35 Brexit – consequences and recommendations for companies
- Consequences for UK companies on EU market
- Consequences for EU companies on UK market
- Field report from a biocidal products authorisation consortium
  Recommendations for action
  Henning Krueger, Managing Director, Pure Sodium Hypochlorite Biocidal Products Group EWIV, Germany

16.55 Five years of BPR data sharing: Recap and lessons learned
- BPR scope of data sharing
- Relation to other data sharing regimes
- “Every effort” requirement
- ECHA data sharing decisions
- The growing influence of the Board of Appeal
- Some conclusions
  Koen van Maldegem, Partner, FieldFisher LLP, Belgium
Day two - 28 November 2018

Session 5: - ED Criteria

08.30 ED criteria: impact on processes and stakeholders
Valerio Spinosi, Scientific and Regulatory Officer, Biocides Unit, ECHA, Finland

08.50 ED properties of biocidal active substances and co-formulants - where to start and how to proceed
- Regulatory background on Endocrine Disruptors: history, criteria and available guidance
- Identification and assessment of ED properties for human health: studies, data bases, QSAR, hazard vs. risk
- Regulatory consequences: implications on active substance approval/renewal, biocidal product authorisation and derogation options
- Assessment of ED properties with a focus on co-formulants and disinfection by-products – possible strategies, issues and implications
Michael Werner, Senior Expert, Regulatory Toxicology Biocides, knoell Germany GmbH., Germany

09.20 Endocrine disruptors and biocides: Where to start? What to expect?
- Brief reminder on ED and exclusion criteria for biocidal active substances
- Entry into force of scientific criteria for identification of ED: implications for active substance approvals and biocidal product authorisations
- Screening, priority setting, conditions for early review of approved substances, procedure and actors
- Harmonisation issues regarding substances in products subject to other legal regimes (ppp, medical devices, veterinary hygiene, cosmetics, …)
- Guidance documents, case law
Indiana de Seze, Avocat EU & Regulatory Law, Belgium

10.50 Innovation
Ian Watt, European Product Stewardship and Regulatory Manager, Dow Microbial Control, UK

10.50 Innovation within consumer-facing preservation markets
- Why the need for innovation in preservation?
- Multiple stakeholders dictate multiple market preferences
- Innovation is critical across each element of the product lifetime
- Industry is actively committed to meeting current and future needs in sustainable next-generation preservation
Phil Hindley, Head, Global Marketing Preservation and Laundry, Lonza Consumer Product Ingredients, UK

11.00 Q&A

11.55 Revision of Efficacy Guidance for PT 14 and PT 19: where are we and what will change
- Revised Technical Guidance for PT 14 in force since January 2017
  - Which requirements are new?
  - What has changed?
  - What needs to be considered for the next renewal?
- Revision of Technical Guidance for PT 19 in progress
  - Current status & time frame
  - What changes can be expected?
  - Which new test methods will be included?
Christiane Stahr, Scientific Officer, German Environment Agency (UBA), Germany

12.00 Strategy for efficacy testing for disinfectants in biocidal product families
- A group of products or a biocidal family?
- Testing products or dummy products?
- Worst case testing: check co-formulants!
- Effect of efficacy on the structure of the family
Lonne Gerritsen, Industrial Chemicals & Biocides, Biocides - Regulatory Affairs, Knoell NL, Netherlands

12.20 Efficacy Requirements for Product Types 11 and 12
- No available efficacy guidance but will look at the probable efficacy requirements
- Likely requirements for the demonstration of efficacy
- Examine the currently available efficacy tests (including those found outside of the EU) and their fitness for purpose

https://events.chemicalwatch.com
• Explore what methodologies could be used to provide additional information in support of product claims

David Ashworth, Klarus Consulting Ltd., UK

13.10 Q&A

13.25 Lunch

**Session 8 : Enforcement**

14.25 Developments FORUM subgroup including update on first project REF-6

Eugen Anwander, Senior Scientific Officer, Institute for Environment and Food Safety, Vorarlberg State Service, Austria & Chair of ECHA BPR Enforcement FORUM, Finland

14.50 Q&A

14.55 Refreshments

**Session 9 : International overviews**

15.20 Canada - new regulation on treated articles

• Overview/background on past/present status of treated articles
• PMRA communication strategy/risk-based approach to compliance and enforcement
• New regulation publication
• Issues moving forward/next steps

Teri Dickinson, Manager, Regulatory Affairs, Dell Tech Laboratories Ltd., Canada

15:50 Korea - New Regulation

• Background and current status of K-BPR
• Key provisions
• K-BPR vs EU BPR

Young-in Kim, Head Researcher, KTR, South Korea

16.20 Q&A

16.35 Latest developments in China with regards to biocides and disinfectants regulations (Pre recorded presentation)

Vivian Tang, Head of Agrochemical and Disinfection Products Department, Hangzhou REACH Technology Group Co., Ltd. (CIRS Group), China

17:00 Conclusion/close of conference
Two optional post conference workshops on Thursday 29 November:

**Workshop 1: Understanding the guidance for identifying endocrine disrupting chemicals**

*Workshop leaders: Dr Martina Duft, Biologist, Expert Environmental Safety/Regulatory Affairs, knoell Germany GmbH & Dr Michael Werner, Senior Expert, Regulatory Toxicology Biocides, knoell Germany GmbH*, Germany

09.00 - 14.50

- Introduction on endocrine disruptors: regulatory background, history, criteria and guidance
- Stepwise approach: overview on the main requirements of the new guidance
- First steps: Gathering and assembly of data – targeted literature search, data bases, QSAR profiling and reporting of data
- Investigation of ED properties with a focus on EATS endpoints: specific toxicological and ecotoxicological study types
- Identification and assessment of ED properties for human health and environment: evaluation of all available data
- Assembly of the lines of evidence, evaluation of completeness of data
- Weight of evidence evaluation: bringing together an overall argumentation

**Workshop 2: Introduction and understanding of physical chemical properties of biocidal products**

*Workshop leader: Peter Liney, Managing Scientist - Chemistry, Exponent, UK*

09.00 - 12.55

- Introduction
- Physical and chemical properties requirements for formulated biocidal products
- Group exercise
- Physical Hazard (CLP) requirements for formulated biocidal products
- Group exercise
- Non-standard requirements for formulated biocidal products; in-situ generated products, product families, carriers, substances of concern, specific formulation type and PT group requirements
- Group exercise
- Q & A
Biocides Europe 2018
27-28 November, Vienna, Austria

Prices

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<th>Price Type</th>
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<tr>
<td>Full price</td>
<td>€945 + VAT (20%)</td>
</tr>
<tr>
<td>Early Bird price (valid till 5 October 2018)</td>
<td>€895 + VAT (20%)</td>
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<tr>
<td>CW subscriber price</td>
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<td>EB CW subscriber (valid till 5 October 2018)</td>
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Post conference workshops on Thursday 29 November:

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<td>Understanding the guidance for identifying endocrine disrupting chemicals</td>
<td>€425 + VAT (20%)</td>
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<tr>
<td>Introduction and understanding of physical chemical properties of biocidal products</td>
<td>€295 + VAT (20%)</td>
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Payment options:

- Invoice payable by bank transfer, credit card or cheque made payable to CW Research Ltd
- Online using our secure order form.
- Payment must be made before the event starts

Three ways to register

- [www.events.chemicalwatch.com/conferences](http://www.events.chemicalwatch.com/conferences)
- sales@chemicalwatch.com
- +44 (0) 1743 818 293

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Event timings

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<tr>
<td>27 November</td>
<td>09.00-17.55</td>
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<tr>
<td>28 November</td>
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Location

AUSTRIA TREND HOTELS
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Standard rooms = €135

Delegates will be sent a special link to make reservations directly with the hotel