CW+ BiocidesHub

Biocides Symposium 2018

3-4 May, Berlin, Germany

Biocides Symposium

The 9th Symposium focusing on Authorisation of Biocidal Products within the Biocidal Product Regulation

About the event

This two-day Symposium will focus on Regulation (EU) No 528/2012 and will examine in depth the various product authorisation processes foreseen within the Regulation. It will include presentations on the Authorization of Biocidal Product Families. A special feature of Day One of the Symposium will be key presentations from the European Commission and the European Chemicals Agency.

Other key issues to be addressed within the symposium, include:

- The first five years with BPR – what next?
- Updates from the Biocidal Product Families Working Group discussions
- Union Authorization of Biocidal Product Families of disinfectant active substances
- In-situ generation; substances and devices – requirements and equivalence
- Efficacy requirements for preservative PTs
- Biocide active substance/product assessment; repellents and disinfectants
- Enforcement and an overview of the ECHA Forum Subgroup
- The BPR and its impact on downstream users, including electronics and retailers
- The need for and approaches to developing new biocides
- Biocides and innovation
- Triple challenge: timing/content/cost - an SME perspective on BPR
- The new scientific criteria for identifying endocrine disruptors: practical implications
- BPR related cases at the Board of Appeal
- The impact of Brexit

Why attend?

Expert panel
Listen to senior representatives from European Institutions, Regulators from Member States, together with Industry representatives and service providers from across the EU

Current thinking
Gain valuable insight into the current state of BPR product authorisation

Time efficiency
Bring yourself completely up-to-date with the complex and changeable landscape of Biocidal Product Authorisation 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 any question you might have in respect of Biocides Product Authorisation and Active Substance Approval in writing in advance of the Symposium

Focus
Bring yourself up to date on the various implementation activities relevant to product authorisation under the BPR

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.

Day one - 03 May 2018

Chair: Dave Dillon, Senior Scientist, Exponent, UK

08:45 Coffee and registration

Session 1: Overviews

09:15 ECHA overview

Valerio Spinosi, Scientific and Regulatory Officer, Biocides Unit, ECHA, Finland

09:45 Update from the Commission

- Latest policy developments in relation to the implementation of the scientific criteria for the determination of endocrine disrupting properties
- Implementation of the interim approach on maximum residue limits
- Management of product authorisations for in situ cases
- Reporting on the implementation of the BPR

Martinus Nagtzaam, Policy Officer, DG Sante, EU Commission, Belgium, via video link

10:15 Q&A for video link

10:25 Member State Overview from France

- Feedback on the BPR implementation from an MS perspective: quantitative outcomes and progress
- Interest and difficulties encountered in the harmonization of the assessment and in the working procedures
- Focus on a key stage in the BPR implementation: From the approval of the active substance to t he product(s) application. What are the main challenges for IND and for eCA ? Recommendations for dossier preparation
- Overview of the expected challenges for the BPR implementation. How to best prepare ourselves?

Catherine Gourlay-Francé, Deputy Director, Regulated Product Assessment Directorate, ANSES, France

10:50 The first five years with BPR – what next?

Gosia Oledska, Senior Regulatory Specialist Biocide EMEA, Ecolab, Belgium

11:15 Q&A

11:30 Refreshments

Session 2: Product Authorisation

12:00 Experiences with approval of Biocidal Product Families

Marcel Hulsman, Account Manager Biocides, CTGB, NL

12:25 Feedback from the BPF Working Group discussions – possible changes to and limitations on BPF applications

Adrian Gray, Johnson & Johnson, UK

12:50 Dow experience with BPF submissions under BPR

- Introduction
- Concept of Biocidal Product Families (BPF)
- Example of Glutaraldehyde BPF
- Example of CMIT/MIT BPF
- Outlook for next 2-3 years (upcoming BPR submissions for blends)

Mandy Osterloh, Regulatory Manager, Dow Microbial Control, Switzerland

13:15 Q&A

13:30 Lunch

Session 2: Product Authorisation ctd.

14:30 In-situ generation; substances and devices – requirements and equivalence

- Evolvement of evaluation of in-situ systems, from BPD to BPR
- Different types of system in scope
- Use of devices
- Implications to Technical Equivalence
- Determining the data requirements

Sara Kirkham, Biocides Expert, Arrow Regulatory, UK

14:55 Union Authorization of Biocidal Product Families of disinfectant active substances – experiences from the consultancy perspective

- Regulatory requirements of biocidal product families
- Definition of meta SPCs considering C&L and intended uses
- Definition of concentration ranges of meta SPCs: Impact on classification and risk assessments
- Approaches for efficacy testing: Identification of reference products and read-across
- Identification of and dealing with Substances of Concern (SoCs)

Michael Werner, Dr Knoell Consult

15:20 The future of BPFs: how to balance workload and cost for industry as well as regulators

- How BPFs can reduce workload for industry and eCAs
- Case study: the 'risk envelope' in practice
- BPF flexibility restrictions: impact and consequences
- The future of BPFs

An Vanden Bosch, Senior Project Scientist, Arche Consulting cvba, Belgium

15:45 Q&A

16:00 Refreshments

Session 3: Enforcement

16:30 **An Overview of the ECHA FORUM subgroup & treated articles (1st enforcement project)**

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

16:55 **Competent Authorities panel session on enforcement Focus: labelling and claims**

- verifiability of label claims
- legal consequences
- options to ensure conformity with the BPR
- tips for industry

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

Participants:

Rosemarie Greiwe, Senior Desk Officer for Chemical Safety, Ministry of Labour, Health and Social Affairs of North Rhine-Westphalia, Germany;

Heribert Buergy, Head of Section Market Control and Advice, Federal Office of Public Health, Switzerland;

Joe Hermes, Chemical Substances and Products Unit, Ministry of Sustainable Development and Infrastructure, Luxemburg

Jorun Holme, Senior Adviser, Section for Chemicals and Product Control, Norwegian Environment Agency, Norway

17:40 Conclusion and close of Day one

Day two - 04 May 2018

Session 4: Efficacy and Risk Assessment

09:20 **Efficacy requirements for preservative PTs, especially PT 5**

David Ashworth, Klarus Consulting Ltd

09:45 **Biocide active substance/product assessment; approaches and issues:Experiences with PT 19 (repellents) and PT2/3/4 (disinfectants)**

- Experience dealing with the various aspects of preparing a submission to ECHA
- Issues with efficacy and rates of use
- Toxicology and defining suitable endpoints
- Design of specific studies
- Approaches to preparing Exposure assessments and sources of data

Scott Samuels, Principal Consultant – Human Safety: Toxicologist, Environmental Resources Management, (ERM), UK

10:10 Q&A

10:25 Refreshments

Session 5: The Impact of the BPR on Downstream Users

10:55 **Biocides and electronics**

Alex Paul, Principle: Chemical Regulatory Services, Yordas Group, UK

11:20 **How a retailer deals with biocides requirements and alternatives**

- Status from all European Coops
- Use of biocides in transportation
- Requirements for daily use products

Malene Teller Blume, Quality Manager, Coop Danmark A/S, Denmark

11:45 Q&A

12:00 Lunch

Session 6: The need for and approaches to developing new biocides

13:00 **Biocides and innovation**

- BPR aim of development of safer alternatives
- How is innovation possible in the biocides market?
- Examples from different biocides market segments

Nathalie Hanon, Manager Cehtra SL, Cehtra, Spain

13:25 **The Danish EPA project for alternatives for wood protection or biocidal products used in construction**

- Challenges with traditional wood preservatives
- Leaching of active substances to the environment
- Emerging alternative techniques

Nina Falk Gregersen, Ecotoxicologist, Environmental Protection Agency, Denmark

13:50 **Triple challenge: timing/content/cost - an SME perspective on BPR**

- How we deal at present with diversified regulations throughout EU
- How we intend to deal with BPR and our portfolio

- The (un)known pitfalls
- General thoughts of and suggestions for BPR by an SME

Rik Daneels, Aqua Ecologic BVBA, Belgium

14:15 Q&A

14:30 **Refreshments**

Session 7: Legal/regulatory issues

15:00 **BPR related cases - view from inside the Board of Appeal**

- Board of Appeal's assessment of every effort
- Contractual freedom in data sharing negotiations
- Cost sharing discussions as part of the data sharing negotiations

Sari Haukka, Legally Qualified Member of the ECHA Board of Appeal, ECHA, Finland

15:20 **The Board of Appeal – an advocate's view**

- Issues raised before the BoA but not yet answered
- The role of national courts in data sharing
- Personal perspectives from an advocate before the BoA

Darren Abrahams, Partner, Steptoe and Johnson LLP, Belgium

15:40 **The new scientific criteria for identifying endocrine disruptors: practical implications**

- Regulatory background and the new scientific criteria
- The ED guidance document: drafting, testing, critique
- Implications for substance approval and product authorisation

Glenn Lurman, Scientist, German Federal Institute for Risk Assessment (BfR), Germany

16:05 **The impact of Brexit**

- Product regulation
- R&D
- Funding
- Intellectual property
- Competition
- Cross-border trade
- Data privacy

Gunnar Sachs, Lawyer, Maître en droit (Paris), Expert Lawyer for Intellectual Property Law Clifford Chance Deutschland LLP, Germany

16:30 Q&A

16:45 **Conclusion/close of conference**

Optional Pre-Conference Workshops, Wednesday 2 May

1. One day workshop - ECHA Training: R4BP3 and SPC editor for Biocides

09.15 Registration

09.30 Introduction to the basics of the Biocides IT tools

10.30 Practical demonstration on how to build SPCs

13.00 Lunch break

14.00 Practical demonstration on how to get National Authorisations

16.45 Final questions

17.00 Close of workshop

Workshop leader: Valerio Spinosi, Scientific and Regulatory Officer, Biocides Unit, ECHA, Finland & Roberto Gilioli, R4BP 3 and SPC editor Product Manager, Biocides Assessment Unit, ECHA, Finland

2. Half-day workshop - Treated Articles

13.00 Registration

13.30 What are treated articles?

14.00 BPR obligations including the Transitional Period

15.15 Refreshment break

15.45 Claims and labelling

16.15 Marketing considerations

16.45 Final questions

17.00 Close of workshop

Workshop leader: Alex Paul, Principle: Chemical Regulatory Services, Yordas Group, UK

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Prices

Full price	-	**€945 + VAT (19%)**
Early Bird price *(valid till 31 of March 2018)*	-	**€895 + VAT (19%)**
CW subscriber price	-	**€895 + VAT (19%)**
EB CW subscriber *(valid till 31 of March 2018)*	-	**€845 + VAT (19%)**
One-day Workshop	-	**€495 + VAT (19%)**
Half-day Workshop	-	**€295 + VAT (19%)**

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 Symposium starts

Three ways to register

(w) **www.events.chemicalwatch.com/conferences**

(e) **sales@chemicalwatch.com**

(t) **+44 (0)1743 818 293**

Location

Courtyard Berlin City Center

Axel-Springer-Str. 55
10117 Berlin, Germany

We have arranged a special bedroom rate for Symposium participants at the Courtyard Berlin City Center

Standard rooms = €135 per night

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

Sponsoring this event

If your organisation would like to join those already sponsoring this event – gaining access to our high quality delegates over the course of the two days – please contact our sales team today on the number below

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