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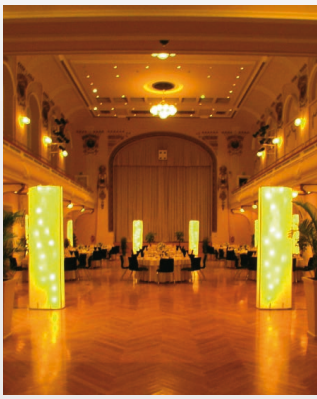
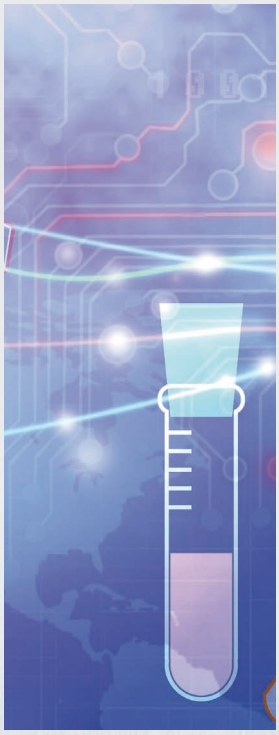
# BIOCIDES SYMPOSIUM '15

## LJUBLJANA, SLOVENIA





**The 6th Symposium focusing on Authorisation of Biocidal products within the Biocidal Product Regulation (BPR)**

**PROGRAMME COMMITTEE:**

*Edmund Plattner, Consultant, Austria*
*Dave Dillon, UK*
*Marko Susnik, Austrian Economic Chamber, Austria*
*Emma Chynoweth, Chemical Watch*
*Vanessa Zainzinger, Chemical Watch*

**Seats Strictly Limited. Book now to avoid disappointment**

11
12
MAY 2015
13

***TWO DAY CONFERENCE + WORKSHOPS***

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# BIOCIDES SYMPOSIUM 2015

## 11-13 MAY

## LJUBLJANA, SLOVENIA

## About this event

A symposium focusing on authorisation of biocidal products within the biocidal product regulation (BPR)

**Programme Advisory Committee:**

- Edmund Plattner, Consultant, Austria
- Dave Dillon, UK
- Marko Susnik, Austrian Economic Chamber, Austria
- Emma Chynoweth, Chemical Watch
- Vanessa Zainzinger, Chemical Watch

This two day Symposium will focus on Regulation (EU) No 528/2012 and examine in depth the various product authorisation processes foreseen within the Regulation and will include presentations on applications for first Union Authorisation together with authorisation of product families. The symposium will feature a keynote presentation from the European Commission with regard to product authorisation for biocides and an update on progress on the various implementation activities relevant to product authorisation.

Other key issues to be addressed within the symposium include:

- Treated articles - new guidance and Regulation
- Article 89 and the 1 Sept. 2015 deadlines
- Fees and costs
- In-situ systems under the BPR
- Data sharing and consortia formation
- Problem areas with Letters of Access
- EU Enforcement on treated articles
- and an update on regulatory requirements for new EU Member State Croatia and other Member States including Slovenia, Czech Republic, Hungary and Sebia

## 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

## 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 Biocides 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 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

# DAY 1: Monday 11th May 2015

***Symposium Co-Chairs: Dave Dillon, Darren Abrahams, Partner, Steptoe and Johnson, LLP, Belgium, Marko Susnik, Austrian Economic Chamber and Edmund Plattner, Consultant, Austria***

09:00 Coffee and Registration

09:15 Chair's Introduction

## SESSION 1

09:25 Keynote Address:

***Goran Novokovic, On behalf of the President of the Chamber of Commerce and Industry of Slovenia (CCIS) (Mr Samo Hribar Milic)***

09:40 The BPR In Force , update on status quo, changes, new Annex 1, overview on fees, 1st authorisation, mutual recognition, upcoming deadlines, DG Sanco BPR-PPP synergies for product authorisation

***Ludovic Chatelin, European Commission, Belgium (tbc)***

10:15 Treated Articles – new Guidance and Regulation

- What has changed by the amendment of the BPR?
- Trends in the interpretation and guidance
- Views from different industries
- Potential workload for all parties involved

***Piet Blancquaert, Piet Consulting, Belgium***

10.40 Q&A Panel Discussion on Session 1

11:00 Refreshments and networking

## SESSION 2

11:15 Current Hot Issues

- Art. 95 list (how to check your supplier is on the list, implications on companies after 1 September 2015, practical hint and tips;
- List of pending Article 95 Applications (structure, who and when can appear on the list, how long companies are listed)
- Update on the review programme including upcoming deadlines
- IT tools - new functionalities and planned in the near future
- Union authorisation

***Katarzyna Szymankiewicz, ECHA, Finland***

11:40 Fee Overview under the BPR - Update

- EU Fee regulation
- Fee structure: Basic fee and Top-up fee
- National Fees
- Consequences for Industry

***Nathalie Hanon, Regulatory Affairs Manager Europe, Troy Chemical Company B.V., The Netherlands***

12:05 Management of in-situ systems under the BPR

- Legal background - In-situ systems in the scope of the BPR
- Requirements and transitional measures
- Any news? Latest developments on in-situ systems

***Daniel ESCH, Scientific Officer, BAuA, Germany***

12:30 Q&A Panel Discussion on Session 2

12:45 Lunch and networking

## SESSION 3

13:45 Authorisation issues for biocidal products including information on:

- Cost and fees
- Mutual recognition
- Data issues and data sharing
- National product authorisation issues for SMEs in the specific countries
- Strategies to maintain your product on the market recommended by CA

In the following countries:
Slovenia, Croatia – the youngest EU Member State, Hungary and Serbia

***Vesna Ternifi, Ministry of Health, Chemicals Office of the Republic of Slovenia***

***Ivana Vrhovac Filipovic, MSc, Ministry of Health, Department of Chemicals and Biocidal Products, Croatia***

***Attila Szasz, Office of the chief Medical Officer, Department of International Affairs, Hungary***

***Biljana Milenkovic, Serbia***

14:45 Panel Discussion on Session 3

15:20 Refreshments and networking

## SESSION 4

15:45 Data Sharing and consortia formation for active substance/product data and product authorisation

***Peter Kugel, Partner, VVGB, Belgium***

16:10 Problem areas with Letter of Access before and during the authorisation process.

***Koen van Maldegem, Partner, Field Fisher Waterhouse, Belgium***

16:35 Consortium for Biocides

**1 Biocides Consortium Launch**
- Goals
- Benefits
- Structure

**2 Cost Comparison**
- National Authorisation
- Union Authorisation

**3 Case study Analysis**

***Leondina della Pietra & Rita Sookrit, ReachCentrum, Belgium***

17:00 Panel Discussion on Session 4

17:30 Cocktails/Close of Day One

# DAY 2: Tuesday 12th May 2015

## SESSION 5

**08:45 Surviving the BP Legislation – Experience of the Slovenian Chemical Industry**

***Branko Petrovic. TRC Jub, d.o.o., Chair of the Working Group on Biocides, CCIS - Association of Chemical Industries of Slovenia***

**09:00 An SME Company's view on cost cutting issues: BP vs REACH and CLP**

***Marko Grcar, Belinka Perkemija d.o.o., Slovenia***

**09:15 Experiences gained during the preparation for First Union Authorisation**

- Experiences with Evaluating Competent Authority and external experts
- Key learnings
- Potential burdens for future applicants
- List of dos and don'ts for future applicants

***Gosia Oledzka , Ecolab, Belgium***

**09:40 Authorisation of Product Families – first lessons learned**

The presentation will focus on how applicants should approach preparation of an application for a product family and the benefits of this type of authorisation. The following topics will be discussed:

- Organisation of the application: The definition of a biocidal product family (BPF) and the introduction of meta SPC
- Justifying a BPF product grouping
- Consortia and BPF authorisations
- Determination of a test programme
- How to approach the risk assessment
- Post-approval activities.

***Sara Kirkham, Senior Consultant, CEHTRA UK Ltd***

**10:05 Example of an SME application for authorisation of an antifouling substance**

***Cecilia Ohlauson, Regulatory Affairs Manager, I-Tech AB, Sweden***

**10:30 Q&A Panel Discussion on Session 5**

**10:45 Refreshments and networking**

## SESSION 6

**11:00 EU enforcement on treated articles**

- CLEEN – project on Treated Articles
- Involved countries
- The regulation
- Labelling
- The outcome so far

***Margareta Daho, Kemi (Swedish Chemicals Agency). Sweden***

**11:25 Industry Review on Present Developments on Treated Articles**

- Why are Treated Articles so Important?
- Synopsis of Regulatory Approaches
- Recent Developments in Treated Article Regulation
- Industries Wish List

***Adrian Krygsman,Director, Product Registration, Troy Corporation, USA***

**11:50 Q&A Panel Discussion on Session 6**

**12:15 Lunch and networking**

## SESSION 7

**13:15 BPR and recent developments in REACH and CLP**

- CLP: Deadline 1 June 2015 for the classification of mixtures
- REACH: Deadline 1 June 2015 for safety data sheets
- general overview on potentially relevant adaptations in the area of REACH, CLP and GHS

***Marko Susnik, Austrian Economic Chamber, Austria***

**13:40 Application, Regulation and Potential Health Hazards of Biocidal Products in Food Contact Materials**

- Introduction: Biocides and food contact materials
- Surface biocides, process biocides, biocides in active packaging
- Regulatory background
- Migration, exposure and contamination
- Health hazards and environmental impact

***Dr Birgit Geueke. Scientific Officer, The Food Packaging Forum, Switzerland***

**14:05 Biocidal Products (BP) & Plant Protection Products (PPP)**

- Borderline between the two regimes
- Main commonalities and differences; dual authorizations
- Examples of borderline cases and effect of the claim

***Dr Antje Armstroff, Dr Knoell Consult, Germany***

**14:30 Relevant Products Types in the Food Packaging Industry – Update on Regulatory Requirements**

- Regulatory overview: Past, present and future
- The process to ensure safe use
- Dual uses - dual requirements?
- Legislative follow-up

***Dr Anna Gergely, Director, EHS Regulatory, Steptoe & Johnson, Brussels***

**14:45 Q&A Panel Discussion on Session 6**

**15:00 Refreshments and networking**

## SESSION 8

**15:15 Early Warnings for producers on sustainable use issues**

***Elisabeth Ruffinengo, Health & Environment Advocacy Officer, WECF France***

**15:40 Maximum residue levels and their role in the authorisation process – Status Quo**

***Stephan Solloch, Environmental & Food Safety - Regulatory Affairs Emea - Product Testing & Assessment, Ecolab, Germany (tbc)***

**16:05 Q&A Panel Discussion on Session 8**

**16:45 Close of Symposium**

# DAY 3: 13 May 2015

## Optional half-day workshop sessions:

Morning 09:00–12:30

### Workshop One: Electronic Submissions tools – IUCLID/ R4BP3.2

With the introduction of mandatory electronic data submission under the BPR, many companies are facing the IUCLID data management software and R4BP biocides IT system for the first time. For those new to the information systems, or those that are lost and bewildered, this session is designed to unravel the mysteries.

***Dr Thomas Gildemeister, Reach ChemConsult GMbH***

Afternoon 13:30–16:00 (choice of 2 or 3)

### Workshop Two: Rodenticides

- How companies can put new guidance into practice, to include labelling, comparative assessment and timelines for product and substance renewal
- CEHTRA

***Estelle Beltran, CEHTRA***

***Pierre-Gerard Pontal, CEHTRA***

***Sandor Karikas, Babolna Bio, Hungary***

### Workshop Three: Labelling for biocides and treated articles

- This workshop will provide you with the basic labelling requirements for biocidal products, comparing products which are already authorized under the BPR with those still in the transition period. Based on practical examples the influence of the CLP Regulation focussing in particular on the transition from the dangerous preparation directive, the changes based on UN GHS and the re-classification of ingredients will be explained. Additionally, possible solutions for labelling of treated articles as well as labelling requirements for biocidal products/treated articles in other jurisdictions (eg detergents, paints, medical devices, plant protection products, cosmetic products) will be discussed.

***Christian Gruendling, FCIO, Austria***

## 3 WAYS TO REGISTER

1 https://chemicalwatch.com/biocideshub/biocidessymposium2015

2 orders@chemicalwatch.com

3 +44(0)1743 818 297

## PRICES

**11–12 MAY**
TWO-DAY SYMPOSIUM — **€850** +VAT (22%)

**HALF-DAY WORKSHOPS**
13 MAY (MORNING) — **€250** +VAT (22%)
13 MAY (AFTERNOON) — **€250** +VAT (22%)

**FULL 3 DAYS**
11, 12, 13 MAY. INCLUDING BOTH WORKSHOPS — **€1350** +VAT (22%)

Payment options:

*1. **Invoice** payable by bank transfer, credit card or check made payable to CW Research LLC.*

*2. **Online** using our secure order-form*

*Payment must be made before the Symposium starts*

## LOCATION & TIMINGS

**GRAND HOTEL UNION D.D.**
Miklošičeva cesta 1,
1000 Ljubljana, Slovenija
Tel: +386 1 308 1070
Fax: +386 1 308 1918
www.union-hotels.eu

We have arranged special bedroom rate for Symposium participants at the Grand Hotel Union.
Standard rooms = Đ105 per night
Delegates will be sent a special link to make reservations directly with the hotel.

**EVENT TIMINGS:**

**Monday 11 May 2015**
09:00-17:45

**Tuesday 12 May 2015**
09:30-16:40

**Wednesday 13 May 2015**
Morning Workshop: 09:00–12:30
Afternoon Workshop: 13:00–16:30