



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

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disappointment**

11
12
MAY 2015
13

TWO DAY CONFERENCE + WORKSHOPS

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GLOBAL RISK & REGULATION NEWS

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 Serbia

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 Blanquaert, Piet Consulting, Belgium

10:40  Q&A Panel Discussion on Session 1

11:00 Refreshments and networking

SESSION 2

11:15 Current Hot Issues (mainly on 'Article 95')

- How to check your supplier is on the list, what to do if not,
- What happens after the 1 Sept 2015 deadline?
- Update on the review programme including upcoming deadlines

Speaker from 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
- Czech Republic
- Hungary
- 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

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

4 Wrap Up

Leondina della Pietra, 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 crosscutting 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 Ohlsson, 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  Q&A Panel Discussion on Session 6

14:45 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

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 Gruending, FCIO, Austria



3 WAYS TO REGISTER

1  www.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)
13 MAY (AFTERNOON)

€250 +VAT (22%)

€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.

Mikloševa 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 = 105 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

