



European Biocides
Information Network

BIOCIDES SYMPOSIUM '14



**A Symposium Focusing on
Authorisation of Biocidal Products
within the Biocidal Product
Regulation (BPR)**

PROGRAMME COMMITTEE:

Viktor Prachar, CCSP, Slovakia (Head of Committee)

Edmund Plattner, Consultant, Austria

Dave Dillon, SC Johnson, United Kingdom

Robert Feierl, Feierl-Herzele, Austria

Mamta Patel, Chemical Watch, United Kingdom

TWO-DAY CONFERENCE

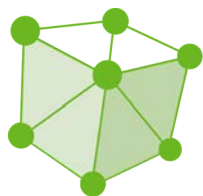
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Biocides Symposium

BIOCIDES SYMPOSIUM 2014

22-23 May, Bratislava

A Symposium Focusing on Authorisation of Biocidal Products within the Biocidal Product Regulation (BPR).

Programme Advisory Committee:

- Viktor Prachar, CCSP, Slovakia (Head of Committee)
- Edmund Plattner, Consultant, Austria
- Dave Dillon, SC Johnson, United Kingdom
- Robert Feierl, Feierl-Herzele, Austria
- Mamta Patel, Chemical Watch, United Kingdom



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 also include presentations on applications for first authorisation, mutual recognition and Union Authorisation.

The symposium will feature keynote presentations from both the European Commission and ECHA with regard to product authorisation for biocides together with 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;
- Mandatory data sharing;
- Biocides in the health-care sector;
- Nanobiocides;
- Enforcement of biocides;
- The Appeals process and the ECHA Board of Appeal;
- And an update on regulatory requirements for new EU Member State Croatia and the Accession Member States in the Balkans.

Who should attend?

- ✔ Representatives of authorisation holders
- ✔ Representatives of registration holders
- ✔ National Competent Authorities
- ✔ 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

FOCUS

Meet the experts and learn more about the various implementation activities relevant to product authorisation under the BPR

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

DAY 1: THURSDAY 22 MAY

Symposium Co-Chairs: Dr Dave Dillon, Manager, Regulatory Affairs Registration, SCJohnson, EurAFNE Limited and Viktor Prachar, CCSP, Slovakia

09:00 Registration & refreshments

SESSION 1


09:30 Chair's introduction

09:40 Overview of the BPR and Authorisation Procedures
Ludovic Chatelin, European Commission, Belgium (To be confirmed)

10:10 Application for First Authorisation of Biocidal Products Submitted Before and After 1st September 2013, Including Transitional Measures

- Overview of the time-lines;
- Legal setting;
- The applicable procedures to different cases;
- The ongoing discussions.

Lena Gruhn, BAUA, Germany

10:40  Q&A Panel Discussion

10:50 Refreshments & networking

SESSION 2

11:15 Application for Mutual Recognition in Sequence According to the BPR and Submitted Before and After 1st September 2013, Including Transitional Measures

- Mutual recognition procedure in general, before and after 1st of September - main differences;
- Mutual recognition in sequence - submission of the application, scheme of the procedure and timelines;
- Transitional measures and handling of the applications submitted before 1st of September 2013;

Anna Fraczowska, The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland

11:40 Union Authorisation

- Overview (and timing of application) of UA as set out in 528/2012;
- Practical applications of UA;
- Advantages/disadvantages of UA;
- Industry view of the UA concept.

Gosia Oledzka, Technical and Scientific Affairs Manager, Biocides, AISE, Belgium

12:05 Regulatory Requirements in Croatia and the Accession Countries of the Balkan Region


- General information about the region and countries in question;
- Croatia: Procedures in place before joining EU, changes after joining the EU in 2013;
- Serbia: Registration requirements in place, status of implementation of EU rules;
- Bosnia and Herzegovina: Two legal entities influencing registration requirements;
- Macedonia/Montenegro/Kosovo/Albania;
- Any specifics relevant for applicants per country.

Bojana Zgonec, Managing Director, TSGE d.o.o., Slovenia

12:30 New Legal Situation for Biocidal Products in Slovakia

- National administrative authorities for BPR in Slovakia;
- Changes in transitional measures after November 1st 2013 - new responsibilities for industry;
- New fee system for biocides in Slovakia;
- Perspectives.

Dr. Viktor Prachar, CCSP, Slovakia

12:55  Q&A Panel Discussion

13:15 Lunch & networking

SESSION 3

14:15 ECHA: Progress Report on Tasks Related to Biocidal Products Authorisation

- Overview of work programme for Biocidal Products Committee for active substance approval for 2014 and 2015;
- Overview of relevant working procedures and templates in the Biocidal Products Committee and its Working Groups for active substance approval;
- Developments on implementing measures for the Review Programme.

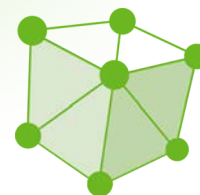
Erik Van de Plassche, Chair of the ECHA Biocidal Products Committee, ECHA, Finland

14:40 Authorisation of Biocidal Products with Two or More Active Substances or Belonging to More Than One Product Type

- Multiple active products;
- Multiple PT products;
- An outline of the regulatory and procedural principles;
- Specific exceptions and distinctions to be made.


Raf Bruyndonckx, Sector Group Manager, European Biocidal Products Forum, Cefic, Belgium





DAY 1, continued...

- 15:05 **Mandatory Data Sharing**
- BPR mandatory data sharing scope;
 - BPR regime and free riding/ alternative suppliers;
 - BPR contrasted with REACH;
 - BPR data negotiations procedure.
- Darren Abrahams, Partner, Steptoe and Johnson, Belgium**

- 15:30  **Q&A Panel Discussion**

- 15:45 Refreshments & networking


SESSION 4

- 16:15 **Environmental Exposure Risk Assessments and Refinement Options for Biocides**
- The application of Emission Scenario Documents as a basis for emission estimation;
 - Potential options for refining emission estimation of consumer biocidal products, with a particular focus on household insect control products (PT18);
 - Information that may be used to characterise the spatial and temporal patterns of product use, comparing findings with the default assumptions typically applied for these products;
 - Such approaches may usefully be applied to supplement ESD calculations, providing credibility checking.

Paul Mason, Senior Risk Assessor Scientist, SC Johnson EurAFNE Ltd

- 16:40 **Changes of Biocidal Products: National Experiences**
- National cases of application for changing products already authorized according to national transitional rules, according to new requirements:
- Composition;
 - RMM;
 - Claim;
 - Use destination.

Maristella Rubbiani, ISS, Italy

- 17:05  **Q&A Panel Discussion**

- 17:45 Close of Day One

DAY 2: FRIDAY 23 MAY

- 09:00 Refreshments & Networking

SESSION 5

- 09:30 **The Work Programme for Active Substances - ECHA's Approach to Tackle the Workload**

Erik Van de Plassche, Chair of the ECHA Biocidal Products Committee, ECHA, Finland

- 10:00 **The Challenge of Getting Product Authorisation for Nanobiocides**


- What do we know about the use of nanomaterials in biocides and biocidal products based on material available in open literature?;
- What does it mean when article 19 on "Conditions for granting an authorisation" says "where nanomaterials are used in that product, the risk to human health, animal health and the environment has been assessed separately" and how can this be done?;
- How would one do ecotoxicity testing of e.g. nanoCu in order to meet the requirements in the regulation (what does it mean to follow the OECD TGs for sample prep and test of NMs);
- Pros and cons analysis of the nanospecific requirements that BPR puts on registrants.

Steffen Foss Hansen, Associate Professor at DTU Environment and NanoDTU, Technical University, Denmark

- 10.25 **Treated Article or Biocidal Product? A Small Difference with Huge Consequences**

- How is a treated article and a biocidal product defined?;
- Can I get away with not mentioning a biocidal effect?;
- What obligations do I have when I place a treated article on the market?;
- Hygienic products: are they biocidal products?

Ulrike Frank, Senior Scientific Officer, Kemi (Swedish Chemicals Agency), Sweden

- 10:50  **Q&A Panel Discussion**

- 11:05 Refreshments and networking





DAY 2, continued...

SESSION 6

- 11:30 **The Need for Biocides in the Health-Care Sector (Special Focus on Prevention of Nosocomial Infections)**
- A short general sketch on nosocomial infections in the EU and worldwide;
 - Overview of biocides and disinfection procedures used in health care - their efficacy and sensitivity vs resistance;
 - Good disinfection practice in health-care units;
 - Laboratory testing of biocides intended to be used by health and social care institutions - EU (OECD) legislation.
- Elena Pieckova, Assoc. Professor in Public Health, Head of Mycology, Slovak Medical University, Slovakia*
- 11:55 **Practical Aspects of the Efficacy of the Use of Biocidal Disinfectants in the Food Industry or Food Contact Industry**
- Description to follow
- Juergen Gutknecht, Proszakon*
- 12:20 **Overview of the Global and European Biocides Market**
- Current global market for specialty biocides;
 - Focus on the European market: Leading product type, key applications, overview of the supplier landscape;
 - Outlook for biocides consumption globally and in Europe.
- Nikola Matic, Industry Manager, Chemicals & Materials, Kline & Co, Prague*
- 12:45  Q&A Panel Discussion
- 13:00 **Lunch & Networking**

SESSION 7

- 14:00 **Enforcement of the BPR in the UK**
- The Enforcement Regime in the UK;
 - Common Compliance Issues;
 - Actives;
 - Products;
 - How Non-Compliance is dealt with;
 - Summary of work in 2013/14;
 - A brief look forward.
- Mike Potts, HM Inspector of Health and Safety, Health and Safety Executive, Chemicals Regulation Directorate*

- 14:25 **The Appeals Process and the Work of the ECHA Board of Appeal under the Biocidal Products Regulation**

- Appeals under the BPR;
- A brief overview of the appeals process;
- Experience with appeals under REACH.


Andrew Fasey, ECHA Board of Appeal, Finland

- 14:50 **Refreshments and networking**

- 15:15 **Overview of the Emerging Plans for Fees for National Competent Authorities and EU Biocidal Product Authorisation**

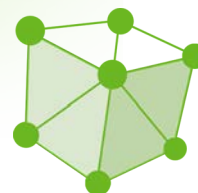
- Fees: Article 80 of the BPR - main requirements;
- Common principles for fee regimes according to Art. 80 BPR;
- Overview on the procedures for which fees are due;
- Types of fees according to the BPR (EU/national);
- Fees payable to ECHA (Commission Regulation No. 564/2013);
- Overview on fee regimes in the Member States;
- Fees payable/modalities for payments in certain Member States;
- Conclusions.

Hermann Goetsch, Austrian Ministry of Environment

- 15:40  Q&A Panel Discussion

- 16:40 **Close of Symposium**





3 WAYS TO REGISTER

1  www.europeanbiocides.net/ticket

2  orders@europeanbiocides.net

3  +44 1743 818 297



TICKET PRICES

TWO-DAY SYMPOSIUM €850 + VAT (20%)

CHEMICAL WATCH SUBSCRIBERS €800 + VAT (20%)

Please note: payment must be made before the start of the Symposium

Payment options:

1. Invoice payable by Credit card, bank transfer or cheque made payable to CW Research Ltd.

2. Online using our secure order-form

LOCATION & TIMINGS

Radisson Blue Carlton Hotel Bratislava
Hviezdoslavovo nam. 3
811 02 Bratislava, Slovakia
Tel: +421 2 5939 0500
Web: www.radissonblu.com/hotel-bratislava



We have arranged a special bedroom rate for Symposium participants at The Radisson Blu Carlton Bratislava: €100 per night (single) and €110 per night (double). To make a reservation, go to: <http://bit.do/BiocidesBooking>

EVENT TIMINGS:

Thursday 22 May 2014:

0900-1745

Friday 23 May 2014:

0930-1640

Getting to Bratislava by air:

- The main international airport of Slovakia is the M.R. Stefanik Airport located just a mere 15-minute drive from the city centre. The airport is served by a number of low-cost airlines, including Ryanair, Danube Wings and Wizzair.
- Many visitors to Slovakia use the nearby Vienna International Airport at Schwechat in Austria, located just a short drive from Bratislava. There is a frequent bus service from Vienna Schwechat Airport to Bratislava. For timetables go to: <http://www.slovaklines.sk>. The one-way fare from Vienna Airport to Bratislava Central Bus Station is approximately €7.70.
- Alternatively, you can take a taxi from Vienna Airport to downtown Bratislava. The cost is approximately €60 - €80 and the journey time is 40 - 60 minutes.

Getting to Bratislava by train:

- The main train station - Hlavna stanica - is about a 10-15 minute walk from the City Centre. It is possible to travel to Bratislava by train from many countries.

Getting to Bratislava by boat:

- Hydrofoils travel between Vienna and Bratislava from May to September.

SPONSORING THIS EVENT

If your organisation would like to join those already sponsoring this event - gaining access to our high quality delegates over the three day event, please contact Judy at judy@europeanbiocides.net (please note, only limited spaces remaining).