



20<sup>th</sup> International Akademie Fresenius Conference

# The Biocidal Products Regulation

+++ ONLINE CONFERENCE +++

21 and 22 June 2021

## Highlights

### Regulatory Aspects

- Latest update from the EU Commission
- ECHA's current activities regarding biocides
- EU Green Deal and what it means for the biocides industry

### Brexit

- Update from HSE on new regulatory positions, establishment rules and practical arrangements
- Legal challenges: tips, tricks and pitfalls

### Biocidal Product Families

- German BAuA on their handling of applications
- Experience from the industry and consulting sector
- Latest development of efficacy guidance for disinfectants

### Endocrine Disruptors

- ECHA on their experience with ED assessments for actives and non-actives in biocidal products and crosstalk with REACH
- The path forward – an industry perspective

### Product Authorisation and Renewal Processes

- New developments concerning national authorisation procedures
- Preparation of applications – previous considerations in 2021



## The Experts

**Darren Abrahams** Steptoe & Johnson | **Marta Cainzos Garcia** European Commission | **Carmen Estevan Martínez** European Chemicals Agency (ECHA) | **Eulàlia Fàbregas** knoell Germany | **Nicola Gregg** British Health and Safety Executive (HSE) | **Nathalie Hanon** A.I.S.E. International Association for Soaps, Detergents and Maintenance Products | **Tine Lykke Thomsen** Novadan | **Camelia Mihai** European Chemical Industry Council (Cefic) | **Gesine Müller** European Chemicals Agency (ECHA) | **Evelyn Roßkamp** German Chemical Industry Association (VCI) | **Nigel Sarginson** ExxonMobil | **Anette Thiel** SCC | **Thilo Walther** German Federal Institute for Occupational Safety and Health (BAuA) | **Michael Werner** Prosacon | **Hannah Widemann** Steptoe & Johnson

# Monday, 21 June 2021

Timings are in  
Central European Summer Time [CEST](#).

 **Morning Session 10:00 – 13:00 CEST**

 **Afternoon Session 14:00 – 16:00 CEST**

**Welcome address by Akademie Fresenius and introduction by the Chairs**

**Michael Werner**, Prosacon, Germany

**Hannah Widemann**, Steptoe & Johnson, Belgium

## Regulatory Aspects

### Updates from the EU Commission

- COVID-19: impact on biocides
- Risk mitigation measures for biocidal products and treated articles
- Renewal of anticoagulant rodenticides
- Biocidal products potentially hazardous to bees: warning sentence
- Technical assistance to Member States

**Marta Cainzos Garcia**, European Commission, Belgium

### ECHA's current activities regarding biocides

- Update on guidance
- Review programme – progress and active substance action plan
- Updates on IT tools
- Concluding remarks

**Carmen Estevan Martínez**, European Chemicals Agency (ECHA), Finland

### Biocides legislation: status and challenges from the industry point of view

**Camelia Mihai**, European Chemical Industry Council (Cefic), Belgium

### EU Green Deal – a view from biocidal industry

**Evelyn Roßkamp**, German Chemical Industry Association (VCI), Germany

**Q&A and panel discussion**

## Brexit

### Regulation of biocides in UK: Great Britain and Northern Ireland

- New regulatory positions
- GB transitional arrangements
- Establishment rules
- Practical arrangements

**Nicola Gregg**, Health and Safety Executive (HSE), United Kingdom

### Brexit: first experiences – tips, tricks and pitfalls

- Data sharing
- Transitional arrangements
- Consortia & Task Forces
- Regulatory divergence

**Darren Abrahams**, Steptoe & Johnson, Belgium

**Hannah Widemann**, Steptoe & Johnson, Belgium

**Q&A and panel discussion**

## Product Authorisation and Renewal Processes

### Product authorisation and renewal processes – consultancy view

- New developments concerning national authorisation procedures
- Preparation of applications – previous considerations in 2021
- Renewals – experiences so far

**Eulàlia Fàbregas**, knoell Germany, Germany

**Q&A**

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Information available online at:  
[www.akademie-fresenius.com/2965](http://www.akademie-fresenius.com/2965)

## Morning Session 10:00 – 13:00 CEST

## Afternoon Session 14:00 – 16:15 CEST

### Biocidal Product Families

#### Differences between BPF core and single BP assessment

- How the German Competent Authority is handling BPF applications now
- Workflow and basic principle behind
- Misunderstandings, pitfalls and aha effects

**Thilo Walther**, Federal Institute for Occupational Safety and Health (BAuA), Germany

#### Biocidal product families – industry view

**Tine Lykke Thomsen**, Novadan, Denmark

#### Biocidal product families – consultancy view

- Interpretation of similarity criteria between authorities: challenges in efficacy and risk assessment sections
- Acceptance of risk assessment approaches during active substance approval/BPC WG discussions
- Importance of communication with authorities: pre-submission meeting, communication during dossier preparation and defence
- Union authorisations: actions for UK

**Michael Werner**, Prosacon, Germany

#### Latest development of guidance for biocidal product families

- New notes for guidance: efficacy guidance for disinfectants in a BPF status and splitting of application of BPFs
- Status, discussion and expected issues

**Nathalie Hanon**, A.I.S.E. International Association for Soaps, Detergents and Maintenance Products, Belgium

#### Q&A and panel discussion

### Endocrine Disruptors

#### Endocrine disruptors: the path forward – an industry perspective

- Need for balanced communication
- Chemical sustainability strategy, substitution and regulations – strengths and weaknesses
- Importance of robust weight of evidence assessments
- Path forward

**Nigel Sarginson**, ExxonMobil, Belgium

#### Experience with ED assessments for actives and non-actives in biocidal products and crosstalk with REACH: screening, strategy and testing scheme

**Gesine Müller**, European Chemicals Agency (ECHA), Finland

#### Experience with ED assessments – consultancy view

- Experience with the ECHA/EFSA guidance for identification of endocrine disrupting substances for biocides
- Risk versus hazard assessment
- ED assessment of co-formulants under the BPR

**Anette Thiel**, SCC, Germany

#### Q&A and panel discussion

#### How will this online conference work?

Our online conference will be live – with interactive participation – and will be held in the English language. Prior to the conference, we will provide you with your login details which will allow you to participate and ask questions from your preferred location. All you need is a stable internet connection and an audio hardware system – and away you go!



# Registration

By web [www.akademie-fresenius.com/2965](http://www.akademie-fresenius.com/2965)  
By email [registration@akademie-fresenius.com](mailto:registration@akademie-fresenius.com)  
By fax +49 231 75896-53

## Participation Fee: € 895.00 plus VAT

Representatives of an authority or a public university are eligible for a reduced fee of € 495.00 plus VAT per person (please provide evidence). The reduced fee cannot be combined with other rebates.

If you are unable to attend the online event, you can order the event documentation for € 295.00 plus VAT. It will be available after the online event through the download area of our website where you will find the latest versions of the presentations as pdf files.

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## Do you have any questions?



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## The Organisers

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## Who should attend this conference?

### Professionals working in the fields of:

- ✓ Legal and regulatory affairs
- ✓ Registration and authorisation
- ✓ Research and development
- ✓ Product safety
- ✓ Product management
- ✓ Regulatory science

### Sectors taking part:

- ✓ Chemical and biocides industry
- ✓ Producers of biocidal products
- ✓ Industrial, professional and downstream users of biocides
- ✓ Research institutes
- ✓ Regulatory authorities
- ✓ Environmental and health risk consultants
- ✓ Professional associations

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