



Akademie Fresenius Intensive Training

Approval Process and Core Principles of the BPR

+++ ONLINE TRAINING+++

24 and 25 March 2021

This Training will cover

- Core principles of the EU BPR Regulation
- Active substances approval process
- Treated Articles
- BPR Transitional period
- Article 95
- Product Authorisation Introduction and Criteria
- Product Authorisation Routes
- Core principles of Product families
- Data Requirements
- Practical exercises



Learning Outcomes

- Find out how your products fall within the scope of the biocide legislation in Europe
- Learn about your obligations to become compliant
- Comprehend the options available for biocidal product authorisation in the EU
- Understand the steps leading to a successful product application submission

The Expert

Rosalinda Goia, Yordas Group

Wednesday 24 March 2021

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

Morning Session 9:15 - 12:40 CET

- 9:15 **Welcome address by Akademie Fresenius and introduction by Rosalinda Gioia**
- 9:30 **Introduction and Core principles of the EU Biocidal Product Regulation (EU BPR)**
- Overview on the basic principles and terminology of the Biocides legislation
 - Introduction to the new concepts and definitions of the regulation
- 9:50 **Active substances approval process**
- Overview of the evaluation and approval process of active substances used in biocidal product(s)
- 10:10 **BPR Transitional Period**
- The transitional provisions of the BPR explained
 - Implications for companies placing their biocidal product(s) on the market
- 10:30 **Questions and Answers**
- 10:40 **Coffee break**
- 11:00 **Article 95**
- Article 95 of the EU BPR
 - Remarks on how it ensures a fair sharing of costs of generating data and supporting actives substances
 - How to ensure compliance with article 95?
- 11:20 **Treated Articles**
- Definition of 'treated article'
 - Regulatory obligations to meet for 'treated articles' under the EU BPR
- 11:40 **Summary of the session**
- 11:50 **Activity 1**
- 12:20 **Questions and Answers**
- 12:40 **End of the first day**

Thursday, 25 March 2021

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

Morning Session 9:20 - 12:50 CET

- 9:20 **Welcome address by Akademie Fresenius and introduction by Rosalinda Gioia**
- 9:30 **Borderline Products**
- The thin border between different types of products
 - The product definition as prerequisite for the respective regulatory requirements
 - Examples of the criteria that are decisive for a classification
 - How to enable the applicant to understand which regulatory framework is relevant for compliance
- 9:50 **Product Authorisation Introduction and Criteria**
- Introduction on the criteria that must be met to get biocidal product(s) authorised in the EU
- 10:10 **Product Authorisation Routes**
- Discussion of the different routes of product authorisation
 - How decide which type will be the most suitable and cost-effective?
- 10:30 **Activity 2**
- 10:50 **Questions and Answers**
- 11:00 **Coffee break**
- 11:20 **Core principles of Product Families**
- Overview of Product Families under EU BPR
 - Definition
 - What principles and approaches must be followed to group products into families
- 11:40 **Data Requirements for Product Authorisation**
- Data requirements for dossier preparation and product authorisation
- 12:00 **Introduction to IUCLID 6, R4BP 3 and the SPC Editor**
- Introduction to the necessary IT Tools for preparing and submitting your application
- 12:20 **Summary of the session**
- 12:30 **Take home messages & last questions**
- 12:50 **End of the training**

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Information available online at:
www.akademie-fresenius.com/2958

Registration

By web www.akademie-fresenius.com/2958
By email registration@akademie-fresenius.com
By fax +49 231 75896-53

Participation Fee:
€ 595.00 plus VAT

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Do you have any questions?



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The Organisers

For more than 25 years, Akademie Fresenius has been your partner for practice-orientated training on all the latest topics surrounding the safety and quality of food, consumer goods and chemical products along the whole production chain. Our portfolio not only includes international conferences but also offers national trade meetings, intensive practical seminars and training in small work groups. Our events are designed to promote an active exchange amongst our participants and offer the perfect platform for bringing the industry, the scientific sector, the authorities and the consulting field together. Excellent service, all-inclusive. Our wide-ranging advanced training opportunities contribute to giving our customers the competitive edge in all quality assurance, risk assessment, legal, production and technical questions.

Akademie Fresenius is a joint venture between Cognos, one of the largest private and independent education groups in Germany, and SGS Institut Fresenius, one of the leading German providers of chemical laboratory analysis.

You can find details on upcoming and new events at www.akademie-fresenius.com

Who should attend this training?

Professionals working in the fields of:

- ✓ Registration, regulatory affairs
- ✓ Manufacturing of biocidal products and treated articles for the EU market
- ✓ Import of biocidal products and treated articles into the EU

Sectors that should take part:

- ✓ Biocidal Industries
- ✓ Professional Associations
- ✓ Consultancies

Terms of Participation and Purchase: The registration fee includes the participation in the online event and the event documentation for download. You will receive written confirmation of your registration. Upon receiving our invoice, please transfer the amount due without further deductions before the event begins.

Group Reductions: For joint bookings received from one company we grant a 15% discount from the third participant onwards.

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