



knoell

worldwide
registration

GLOBAL SUPPORT

BIOCIDES AUTHORISATION STRATEGIES

Your go-to partner for biocides authorisation all over the world. Our experts are located around the globe and have a long standing expertise on local and regional regulations.

Disinfectants, insecticides, antimicrobials, preservatives, and other forms of pest control are regulated heavily by many jurisdictions across the globe, resulting in challenging global marketing strategies for biocides.

Data requirements and timelines are not globally harmonised and country-specific regulatory hurdles have to be overcome. At the same time, more global alignment and monitoring with regard to the overall use and risk of chemical substances is taking place. A well-planned authorisation strategy is crucial to ensure the economic success of your active substances or products worldwide. And the experts at knoell are perfectly suited to help you achieve this. With over 25 years of experience knoell will accompany your marketing strategy step by step, from project design, through data generation and documentation up to its successful conclusion.

Our global service portfolio includes

- ▶ Understanding the regulatory context of the country of your interest
- ▶ Worldwide registration of your products
- ▶ Support on active substances (a.s.), Biocidal Products (BP), Biocidal Product Families (BPF) and treated articles approval, renewal and authorisation
- ▶ Assistance on data sharing and Letter of Access (LoA) negotiations
- ▶ Consortia management
- ▶ Only representative services
- ▶ Liaising with authorities at global level

Furthermore we offer a wide range of technical services

- ▶ Data gap analysis
- ▶ Study management & monitoring

- ▶ Structure definition for BPF
- ▶ Human and animal health, dietary and environmental risk assessment
- ▶ Endocrine Disrupting (ED) properties assessment, for a.s. and BP
- ▶ Efficacy testing strategy evaluation and/or development
- ▶ Dossier preparation and submission (including draft assessment report, IUCLID, R4BP and other tools)
- ▶ Support on Article 95 applications
- ▶ Technical Equivalence (TE)
- ▶ Dietary safety and residues
- ▶ Product label analysis, classification, and labelling

Our experts are at your service

We are aware of the differences and peculiarities of the biocidal scenario across the world and understand the strategic requirements of our clients. For the rapidly evolving global regulations we can assist with the necessary global notifications, utilizing the expert knowledge of our affiliates, and our network of local contacts.

As your partner we will be there for you along the way to your market access, providing a fully personalised service. Regardless whether you need support in Europe, Asia, North America or any other region, our experts and local partners will support you, answering your questions, and providing technical and regulatory support.

Think globally, act locally.

For further information on regulatory compliance for biocides, please contact us:

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www.knoell.com