COMPLYING WITH BIOCIDAL REGULATION

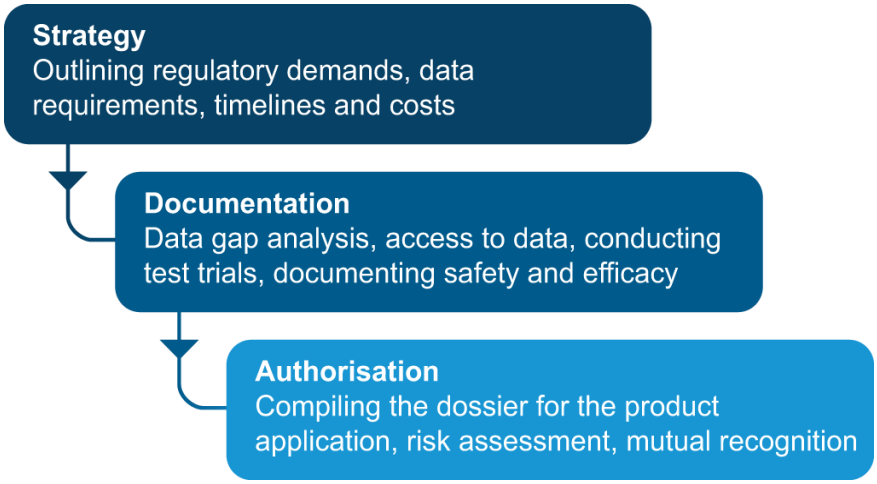
Taking you every step of the way when placing biocides on the European Union market

The Biocidal Products Regulation (BPR) covers 22 different product types including disinfectants, preservatives, rodenticides, insecticides and antifoulants. Many of the biocidal active substances are used in a wide range of products, all of which have to be considered in the regulatory process. We have the scientific, regulatory and industry-specific knowledge needed to support you in the complete biocide authorisation programme, including the testing and evaluation scheme.

THREE STEPS TO PLACE YOUR BIOCIDE ON THE MARKET

First, we perform the data gap analysis as well as identify the data requirements, timelines and costs involved in the authorisation process. On the regulatory side, we assess your product in accordance with the requirements of the BPR, perform preliminary risk assessments and provide you with a strategic regulatory road map outlining different market scenarios - including the possibility of applying for a group of biocidal products (a biocidal products family).

This is followed by a plan to generate missing data. Waiving data at this stage presents an opportunity to save both money and time – this may include read-across as well as QSAR analyses. If additional test trials are needed, we can assist you with setting up test regimes, conducting and monitoring trials, as well as writing study reports.



We offer a three-step solution for placing a biocidal product on the market. © DHI

CLIENT

- Suppliers and distributors of biocidal active substances in the European Union (EU)
- Producers and importers of biocidal products in the EU

CHALLENGE

Need for companies to:

- assess the impact of the Biocidal Products Regulation (BPR) on their biocidal products – especially during the R&D phase
- prepare for re-application of approval for any biocides already on the market

SOLUTION

We provide assistance from beginning to end with the authorisation process of biocidal products, including:

- professional monitoring and validation of test trials
- expert examination and compilation of data
- documentation for product dossiers

VALUE

Ensures:

- cost-efficient development of biocidal products
- up-to-date compliance with regulatory requirements in the EU
- substantiated safety and efficacy due to professional monitoring and validation of test trials

The authorisation step concludes the process – we compile the dossier for the product application in IUCLID, prepare the Summary of Product Characteristics (SPC), and submit the application from the online submission platform R4BP. We have extensive experience in all the sections of the dossier and our services for this step include:

- compilation and submission of the dossier in accordance with EU and ECHA guidelines
- completion of the overall risk assessment
- preparation for the mutual recognition process

QSAR ANALYSES HELP TO PREDICT TOXICOLOGICAL ENDPOINTS

Using QSAR models is a fast and economical method to generate data and fill data gaps. With QSAR analyses, we can predict a large variety of toxicological endpoints—including skin irritation and sensitisation, carcinogenicity, mutagenicity, genotoxicity and reproductive toxicity. Ecotoxicological endpoints can also be predicted. We apply QSAR models for risk assessments, regulatory decisions and for the optimisation of existing products.

It is important to assess the impact of the new BPR regulation, especially during the R&D phase. Photo: iStock © Mihajlo Maricic

REFERENCE

DHI led a consortium of companies that place generators on the EU market that generate electrolytic-produced chlorine in-situ for disinfection purposes. A specific requirement under the BPR is the article 95 compliance, according to which a company must be listed as an approved supplier of biocidal active substances if the company wants to keep placing their products on the market.

We used our expertise in product safety to compile a complete article 95 dossier for the consortium that was accepted by ECHA. As a result of our work, the members of the consortium became listed as approved suppliers of their active substance and their business was secured due to their compliance with the BPR.

We combine our regulatory and toxicological knowledge to support you in the complete biocide authorisation programme. Photo: iStock © Saturated

AUTHORITIES

We helped the Danish Environmental Protection Agency (EPA) evaluate biocidal active substance dossiers for IPBC, Diuron, Icaridin, Triclosan and other biocidal actives. We also assist the Danish EPA with evaluating applications for biocidal product authorisation. In addition, we conduct training courses on exposure and toxicological risk assessment for the staff of Danish authorities.

INDUSTRY

We provide strategic advice to the industry on the most cost-efficient and safe route of compliance for their biocidal active substances or biocidal products. We have assisted the industry in active substance dossier work as well as in every step of the biocidal product authorisations. Furthermore, we give training courses on how to prepare a dossier for biocidal product authorisation and how to work with IUCLID for biocidal applications.

In recent years, DHI has worked intensively to assist companies that market in-situ generated biocidal active substances and products. These kind of products and their precursors are now within the scope of the BPR and need to be authorised.

Contact: info@dhigroup.com
For more information, visit: www.dhigroup.com