



### UPCOMING REGULATORY DEADLINES

**31 December 2016:** active substances within wood preservatives, rodenticides, insecticides and antifoulants

**31 December 2017:** active substances within disinfectants for veterinary use, food production and water disinfection

**31 December 2019:** active substances within hand disinfectants, public health disinfectants and algaecides

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*



*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.

### 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.

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