

## Fast-track regulatory response

Acta EU is a leading international specialist in chemical product approval, support, and regulatory defence.

With a global base in Washington, D.C. and a strategic business centre near Manchester, UK, Acta EU offers an international service for product registration, regulatory issues, and toxicology and is a “centre of expertise” for industry.

The Acta EU regulatory team provides project management for fast-track product approval by building support and defence packages for product portfolios.

## The Acta Group EU, Ltd

The Heath Business and Technical Park  
Runcorn  
Cheshire WA7 4QX  
United Kingdom

+44 (0) 1928 500056  
www.actagroup.com



Approval, Support, and  
Regulatory Defence

INDUSTRIAL CHEMICALS  
AGROCHEMICALS • BIOCIDES  
BIOTECHNOLOGY • NANOTECHNOLOGY

**Biocides and Biocidal  
Products Regulation  
98/8/EC**



## Current Regulatory Status

The EU Biocides Product Directive (BPD) (98/8/EC) seeks to remove barriers to trade by harmonising controls for marketing across Europe. The BPD also seeks to ensure a high level of health and environmental protection. The onus is therefore on industry to conduct hazard and risk assessments on their products and seek approval from the relevant regulatory authorities.

Acta EU focuses on biocides and biocidal products regulation and support services to assist industry in tackling the intimidating landscape of increasing chemical regulation.

Acta EU's experience in the biocide, industrial chemical, agrochemical, biotechnology, and nanotechnology sector allows it to offer a complete package of consultancy services for the European Union's (EU) regulatory framework.

Acta EU professionals, working closely with their U.S. affiliates, The Acta Group, L.L.C. and Bergeson & Campbell, P.C., offer a full range of biocides and biocidal products regulatory services.

## General Chemical Hazard Identification and Risk Assessment Services

- ◆ Assess the need for registration under BPD, including the identification of the need for Annex 1 listing or the possibility of application by "Letters of Access"
- ◆ Identify data gaps
- ◆ Prepare summaries, partial or full dossiers, and International Uniform Chemical Information Database (IUCLID) files and management for both active substances and biocidal products
- ◆ Submit dossiers to relevant Member States for Application for Annex 1 listing of an active and/or biocidal product authorisation
- ◆ Identify companies with structurally similar products or products of a similar nature to create and manage a consortia for testing and data submission
- ◆ Provide hazard data appraisal and literature reviews (toxicology, environmental, physical/chemical)
- ◆ Prepare risk assessments and appraisals for all exposure groups via all routes of exposure
- ◆ Offer study design and management (human health and environmental)

- ◆ Prepare safety data sheets, product labels, chemical safety assessments, and reports
- ◆ Provide product support from concept to approval
- ◆ Prepare risk management proposals
- ◆ Design, implement, and complete a cost-effective testing program
- ◆ Discuss specific needs and issues with appropriate legislators and regulators
- ◆ Act as the "Only Representative" for companies that are not legal entities in the EU
- ◆ Offer post-regulatory product support

## Other EU Chemical Directives/Programmes Served

- ◆ Registration, Evaluation, and Authorisation of Chemicals (REACH)
- ◆ AgroChemicals 91/414/EC
- ◆ Engineered Nanoscale Materials and Nanotechnology
- ◆ EU Classification 67/548/EEC & Labelling 1999/45/EEC
- ◆ OECD