

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.

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Approval, Support, and
Regulatory Defence

INDUSTRIAL CHEMICALS
AGROCHEMICALS • BIOCIDES
BIOTECHNOLOGY • NANOTECHNOLOGY

Engineered Nanoscale
Materials and
Nanotechnology



Current Regulatory Status

Government authorities globally are considering emerging regulatory frameworks to manage the potential risks and promote the considerable benefits of diverse engineered nanoscale materials and structures. Research laboratories, start-up companies, small- and medium-sized enterprises, and larger entities all must be aware of emerging regulatory regimes, voluntary programs, and related regulatory and private initiatives to avail themselves of unique opportunities for collaboration and regulatory compliance. The Department for Environment, Food, and Rural Agriculture's (Defra) Voluntary Reporting Scheme, emerging Organisation for Economic Cooperation and Development (OECD) programs, the U.S. Environmental Protection Agency's (EPA) Nanoscale Materials Stewardship Program (NMSP), and related programs offer advantages and disadvantages. Staying ahead of the curve requires knowledgeable insiders with a complete understanding of the global nanotechnology playing field.

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 nanotechnology regulatory services.

Engineered Nanoscale Materials and Nanotechnology Consulting Services

- ◆ Prepare part or full dossiers, safety data sheets, and chemical safety assessments and reports
- ◆ Prepare health and environmental assessments of engineered nanoscale materials
- ◆ Provide hazard data appraisal and literature reviews (toxicology, environmental, physical/chemical)
- ◆ Identify data gaps
- ◆ Offer study design and management (human health and environmental)
- ◆ Prepare risk assessments and appraisals for all exposure groups via all routes of exposure
- ◆ Prepare risk management proposals
- ◆ Assist in product approval via the appropriate regulations (Notification of New Substances, Cosmetics Directive, etc.)
- ◆ Offer regulatory nanoscale material product support from concept to product approval
- ◆ Review medical device assessments

- ◆ Develop and manage testing consortia
- ◆ Offer confidential business information protection and counselling
- ◆ Conduct characterisation of engineered nanoscale materials for regulatory purposes
- ◆ Offer customised in-house education seminars on nanotechnology and work practices
- ◆ Provide study placement and management
- ◆ Act as the "Only Representative" for companies that are not legal entities in the European Union (EU), and act as the "Third Party Representative" of legal entities in the EU to allow them to retain their anonymity
- ◆ Offer post-regulatory support

Other EU Chemical Directives/Programmes Served

- ◆ Registration, Evaluation, and Authorisation of Chemicals (REACH)
- ◆ AgroChemicals 91/414/EC
- ◆ Biocides 98/8/EC
- ◆ EU Classification 67/548/EEC & Labelling 1999/45/EEC
- ◆ OECD