

## 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

**AgroChemicals**



## Current Regulatory Status

Directive 91/414/EEC is currently being revised by the Pesticides Safety Directorate (PSD). The proposal includes provisions to increase the level of protection given to human health, animal welfare, and the environment, but also includes some simplification of the existing regime. The changes will include:

- ◆ The creation of three zones covering all Member States and compulsory mutual recognition of product authorisations in Member States belonging to the same zone;
- ◆ New criteria for approval of active substances, including toxicity and environmental “hazard triggers”;
- ◆ Comparative assessment and substitution of products containing active substances identified as candidates for substitution;
- ◆ Abolition of provisional authorisations for active substances at the Member State level, and the introduction of strict deadlines to accelerate the decision making at the European Commission (EC) level; and
- ◆ Simplified provisions on data protection and data sharing, including rules for sharing vertebrate studies.

Along with the revision of Directive 91/414, the new sustainable use directive (the Pesticides Thematic Strategy) will establish a framework to promote “best practices” in the storage, use, and disposal of pesticides and their waste products and packaging. It includes proposals for four new pieces of legislation, two of which are already addressed.

Acta EU focuses on agrochemical product submissions and support services to assist industry in tackling ever increasing agrochemical regulatory challenges within the European Union (EU). Acta EU's experience in the agrochemical sector allows it to offer a complete package of consultancy services under the Plant Protection Products Directive 91/414 and related regulatory authorities.

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 agrochemical regulatory services.

## Agrochemical Product Submissions and Support Services

- ◆ Design, implement, and complete a cost-effective testing program
- ◆ Review product data to identify data gaps
- ◆ Interact regularly with regulatory authorities
- ◆ Prepare EU National reregistration submissions
- ◆ Prepare part or full dossiers, safety data sheets, and risk assessments
- ◆ Schedule and monitor testing for data submission
- ◆ Prepare endpoints and tiered summaries, and review of completeness checks
- ◆ Conduct literature searches and reviews
- ◆ Prepare biological assessment dossiers
- ◆ Act as the “Only Representative” for companies that are not legal entities in the EU
- ◆ Offer post-regulatory support

## Other EU Chemical Directives/Programmes Served

- ◆ Registration, Evaluation, and Authorisation of Chemicals (REACH)
- ◆ Engineered Nanoscale Materials and Nanotechnology
- ◆ Biocides 98/8/EC
- ◆ EU Classification 67/548/EEC & Labelling 1999/45/EEC
- ◆ OECD