



STEPTOE & JOHNSON LLP

REACH SERVICES
2010 Edition

REACH Past Pre-Registration

Now that Pre-Registration is complete, companies subject to Regulation (EC) 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) must focus on the process leading up to Registration. Strict time limits must be respected in order to maintain market access. For substances properly Pre-Registered, the first Registration deadline is 30 November 2010. Substance de-selection and new restrictions on use of dangerous substances are expected. REACH also obliges mandatory sharing of registration data and extensive supply chain communications.

REACH transfers responsibility for generation of data on chemical safety to industry. All actors in the supply chain — not only chemical substance producers but also formulators and manufacturers of finished products — are affected. When the first major compliance deadline passed on 1 December 2008, over 2.6 million Pre-Registrations had been submitted by EU producers, importers and Only Representatives of non-EU producers. It is clear that this regulation will have significant impact on business. With a multi-disciplinary team of regulatory lawyers and regulatory and technical consultants, Steptoe applies an unrivalled depth of understanding to the practical challenges which REACH presents.



What does REACH cover?

REACH regulates chemical substances:

- on their own
- in preparations (formulations)
- released from articles (finished products)

This means that manufacturers of finished products, and not only chemicals companies, will have to deal with REACH.

Even substances in small quantities (under the one tonne threshold for compulsory Registration) may be subject to obligations under REACH, including those concerning Restrictions, Authorisation, and Safety Data Sheets.

**“No data, no market”
failure to Register will result in a ban on
market access**

Does REACH affect my business?

REACH affects the following operators in the chemical substances supply chain:

Established in the EU
<ul style="list-style-type: none"> • manufacturers • importers • exporters • downstream users • distributors • producers of articles
Established outside the EU
<ul style="list-style-type: none"> • manufacturers • formulators • exporters • producers of articles

REACH places specific obligations on businesses established in the EU. In practice, however, it also has an important impact on non-EU businesses. Over and above technical compliance, REACH imposes significant financial and logistical demands which will need to be met. Wherever your business is established, whatever its size, and whatever your role, proactive management of your supply chain is crucial.

Why choose Steptoe & Johnson LLP?

- Steptoe is a **one-stop shop** for REACH compliance. We apply an unrivalled depth of understanding to the practical challenges presented by REACH.
- Our **cost-effective compliance strategies** draw not only on our conventional role of legal counsel to our clients, but also from hands-on practical experience acting as *Only Representative* (for non-EU companies) and *Third Party Representative* (for EU companies).
- The **multi-disciplinary REACH team**—located in Brussels, London, and Washington—brings together regulatory lawyers and regulatory and technical consultants with over 30 years experience in EU chemical control.
- Steptoe’s **legal interpretation** benefits from an understanding of the wider legal context, knowledge of approaches taken in other regulatory fields, case law, and enforcement practices.
- We have many years of **experience forming, participating in, and running chemicals consortia** (“task force agreements”) established for data sharing and/or joint dossier submissions to obtain regulatory approvals.
- Steptoe has a wealth of experience on the key issues of (1) **data valuation and fair compensation** and (2) managing the **competition law / antitrust risks** which arise when companies cooperate.
- Our legal drafting supports **all stages of REACH compliance** including tailor-made agreements for consortia, confidentiality protection, data licensing, cost-sharing, lead registrant obligations, and contracts with research organisations.
- We have defended clients’ core substances through **years of constructive interaction with policy makers** in both Europe and the US. We help overcome the adoption of unwarranted substance restrictions and product de-selection by informing policy makers and those in the value chain of issues which are arising and providing creative solutions to real and perceived difficulties.
- Our lawyers have been involved in a **wide range of legal challenges** to adverse decisions before the European Courts of Justice and the World Trade Organization.



Our Experience

We have been working with the REACH regime since it was first proposed in the European Commission's 2001 White Paper and helped businesses and industry associations influence the shape of REACH.

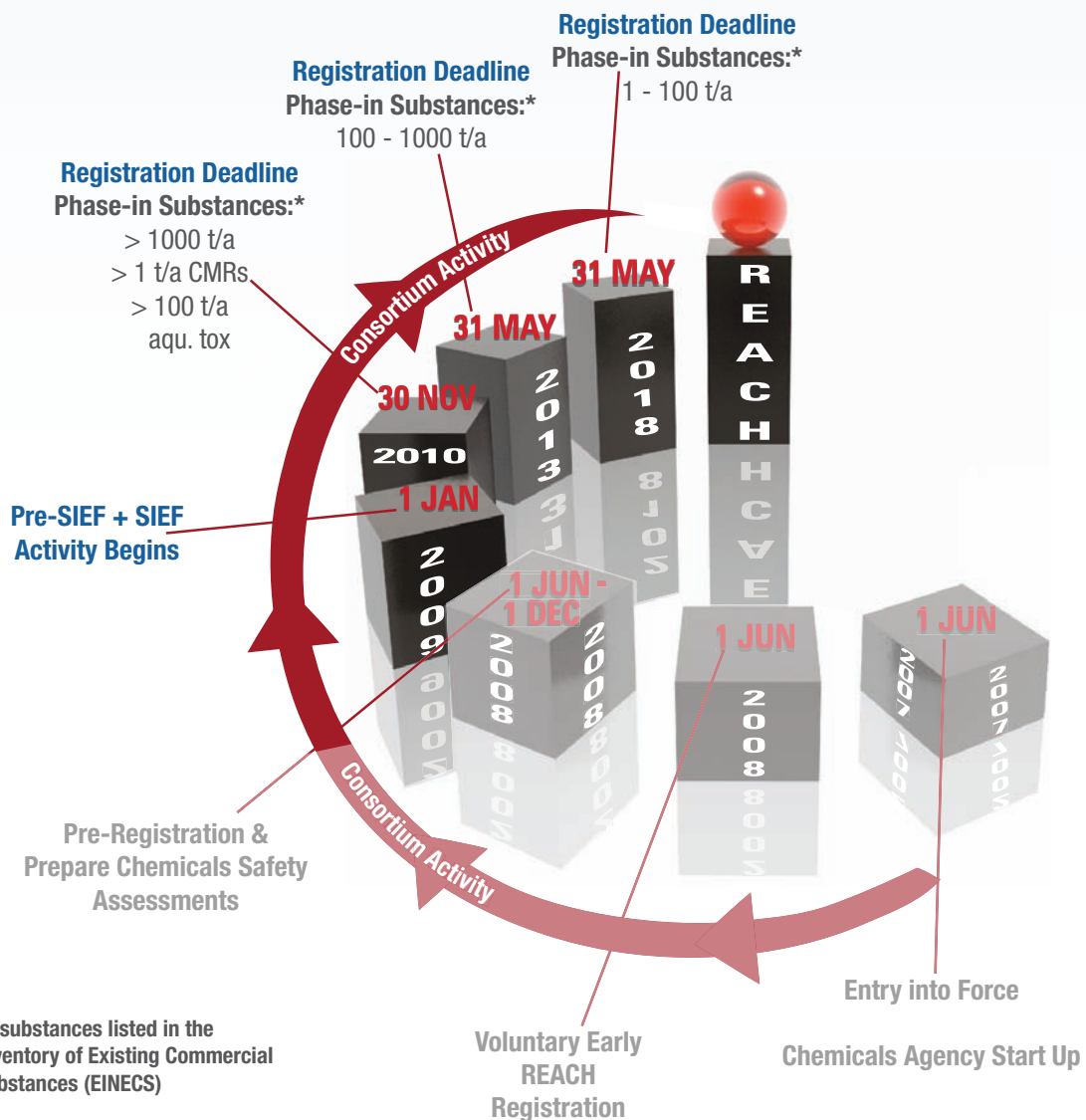
Our experience in a wide range of sectors provides clients with a wealth of knowledge on prior authorisation and substance restriction regimes in the EU:

- biocides
- biotechnology
- commodity chemicals
- cosmetics
- electronics
- flavours
- food
- fragrances
- medical devices
- metals
- personal protective equipment
- pesticides

- petrochemicals
- plastics
- polymers and textiles
- textiles
- toys
- waste

The **interaction between product-specific legislation and REACH** is complex and requires a close analysis to resolve regulatory conflicts, avoid duplication of costs and unnecessary erosion of data protection. (Specific fact sheet on REACH, biocides and pesticides can be found in our REACH Resource Center at <http://www.steptoec.com/reach>).

REACH is already influencing the adoption of new legislation on chemicals outside the EU. Steptoe's understanding of REACH and experience in working with legislators and policy makers means that we are particularly well placed to **represent industry concerns as these new regimes evolve in other jurisdictions.**





What services does Steptoe & Johnson LLP provide?

Steptoe offers a full range of services to help secure REACH compliance for its clients. Our focus is to ensure that clients implement an effective and efficient compliance strategy. Each client has different needs. We determine, in coordination with a client's regulatory affairs management, where we can most add value.

Our services can be provided on an hourly or project-specific basis, as appropriate. Steptoe allocates work to those team members with the most appropriate level of experience, with a view to minimizing fees.

LEGAL SERVICES

Steptoe's REACH team is prepared to help you manage the entire REACH process and coordinate activities among your separate business entities and throughout your supply chain.

PRE-SIEF AND SIEF PARTICIPATION

- supporting companies who were able to handle Pre-Registration without external support but now require additional or alternative support to meet the complex legal, technical and logistical demands of Registration
- acting as Only Representative for "Late" Pre-Registrants (where permitted in certain narrowly defined circumstances), and as a replacement Only Representative to companies dissatisfied with their original service provider
- participating as a Trustee or general adviser to the SIEF Formation Facilitator and eventual Legal Registrant within the SIEF
- advising and negotiating on data valuation and cost-sharing, ensuring that fair compensation is paid

CONSORTIA

- advising on formation, terms and management of consortia (or similar data-sharing mechanism agreed by SIEF members)
- managing consortia

- monitoring/participating in management/ legal affairs committees
- representation on contentious data-sharing issues

LEGAL AGREEMENTS

Drafting and negotiating tailor-made agreements or reviewing existing agreements on a wide range of REACH issues, including:

- consortia
- confidentiality
- data licensing
- cost-sharing
- lead registrant obligations
- work with contract laboratories

For those substances which companies Pre-Registered but do not intend to Register, we craft agreements with their suppliers to ensure that what they purchase will continue to be REACH compliant.

ANTI-TRUST / COMPETITION LAW

- drafting anti-trust policies
- reviewing competition compliance of contract terms
- advising on and supervising conduct in SIEFs and consortia
- providing compliance programmes and training

PREPARATION OF REGISTRATION DOSSIER

- preparing arguments supporting the separate submission of hazard data on grounds of commercial sensitivity, disproportionate cost, or disagreement with the lead registrant

APPEALS

- challenging ECHA decisions before the Appeal Board and/or the European Courts of Justice

AUTHORISATION

- representing interests in Authorisation procedures for Substances of Very High Concern (SVHCs) steptoe



AD HOC QUESTIONS

- responding to *ad hoc* strategic, legal, and regulatory questions as these arise

COMPLIANCE TRAINING

- running tailor-made training sessions (covering legal and/or technical aspects)
- providing briefings on latest developments

PRODUCT DEFENCE

- defending substances against de-selection and restrictions, through constructive interaction with policy makers in both Europe, the US and Asia
- managing value chain relationships as issues arise and providing creative solutions to real and perceived difficulties

TECHNICAL SERVICES

DATA MANAGEMENT

- providing a secure, dedicated, user-friendly, extranet-based IT system for management of a client's complete compliance activities

PRE-SIEF AND SIEF PARTICIPATION

- assisting with substance identification ("sameness")
- participating in the technical group/ committee

CONSORTIA

- chairing or participating in technical affairs committees

PREPARATION OF REGISTRATION DOSSIER

- developing strategies for sourcing data to fill crucial data gaps, including: literature search and review, data valuation, study protocol recommendations, provision of cost estimates, sourcing contract research organisations and studies (e.g. acquisition from other SIEF members, further testing etc.)

- reviewing the adequacy of Registration activities (including whether a data gap analysis is complete) and analysis of any further measures which would need to be taken, such as the potential for read-across

- preparing Chemical Safety Assessments and Reports
- advising on classification and labelling

POST-REGISTRATION

- responding to questions raised by the European Chemicals Agency or national authorities

AUTHORISATION

- supporting Authorisation dossier submission
- assisting with socio-economic and alternatives analysis

CONTINUING TRAINING

Steptoe offers tailored compliance training packages to meet individual business needs. These can be aimed at all audiences from board room level down. This is a cost-efficient way of staying on top of the latest REACH developments, including the regularly changing guidance from the European Chemicals Agency.

Steptoe's web seminars provide an opportunity for businesses to receive the latest information on REACH. We answer each question during the seminar or in a follow-up written response. The anonymity of the inquirer is respected. Previous web seminars can be accessed via our dedicated online REACH Resource Center.



Step toe's REACH Team



Seth Goldberg
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Mr. Goldberg, a partner based in Washington, has over 30 years of experience in a broad range of issues centered on chemical regulation. In the US, his practice focuses on FIFRA and TSCA, and in Europe, on biocides, pesticides, and REACH. Mr. Goldberg devotes substantial time to direct advocacy before regulatory agencies. He also is heavily involved in organization and management of data generation consortia, data compensation, and advocacy on scientific issues. Clients often call on him to represent them in complex matters before administrative agencies and judicial challenges to agency decisions.



Darren Abrahams
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Mr. Abrahams is an English Barrister and a partner practicing in Step toe's Brussels office. His practice is focused on EU regulatory requirements and related commercial issues in the chemical regulatory and life sciences area. *The PLC Which Lawyer?* Yearbook consistently recommends Mr. Abrahams in EU Life Sciences and *Legal 500 EMEA* recognises his "comprehensive understanding" (2008) and "detailed expert knowledge" (2009) of EU environmental regulation. *Chambers & Partners Europe* him as one of the "leading individuals" in EU environmental regulation and reports the market's assessment that he is "exceptionally hard-working and diligent" (2009). His clients are leading companies and associations in sectors including chemicals (REACH, biocides, cosmetics and pesticides), agricultural biotechnology, electronics, food and feed, metals, and mining. An important part of his practice is helping clients to shape their legislative and policy environments, representing them before EU institutions, EU Member States, and in the European Court of Justice.



Dr. Anna Gergely
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Dr. Anna Gergely, is the firm's Director, EHS Regulatory in Step toe's Brussels office and a partner. She is our Principal Scientist with a PhD in analytical chemistry and in quantum chemistry and is a registered European

patent attorney. She has more than 15 years of international law firm experience in Brussels, counseling companies on European environment, health and safety regulatory strategies. In addition to REACH and food contact compliance, Anna specializes in nanotechnologies in relation to a broad spectrum of industry sectors. Her involvement in this field ranges from scientific and patent considerations to issues of corporate regulatory compliance and regulatory governance.



Jean Russotto
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Mr. Russotto is a partner based in Brussels. He advises US, European, and Asian clients across a broad range of matters involving EU law. He assists clients with policy advice and strategic representation before the various Directorates of the European Commission. Mr. Russotto works extensively on chemicals and life sciences regulatory issues. He is a director of the Swiss Chamber of Commerce and chairman of the EU-Swiss Committee. He is regularly cited in the *Legal 500*.



Jim Searles
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Mr. Searles is a partner in our Brussels office. His work concentrates on EU and international law, focusing on the fields of environmental regulation and trade. Mr. Searles has significant experience in substance regulation, at both Member State and EU levels. He is actively advising on the regulatory and international trade aspects of REACH, as well as developing compliance strategies. He also assists industry clients concerning EU sectoral chemical regulatory measures, climate change policy, and CO2 emission initiatives. He works with businesses and trade associations in the agricultural, chemicals, motor vehicle, information technology, steel, textiles, and general consumer goods sectors.



Nancy Russotto
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Ms. Russotto is European Affairs Advisor in Step toe's Brussels office following 18 years as head of the plastics manufacturing industry's pan-European trade



Step toe's REACH Team

association, PlasticsEurope. She assists companies in developing strategies for effectively interfacing with European regulators; adapting corporate strategy and activities in the European Union to the local culture; identifying sectors and/or businesses with shared interests and establishing relationships that will maximize the impact of advocacy activities; encouraging and aiding corporate participation in relevant European sectoral trade associations; and advising on methods for successfully advocating on industry-specific issues.



Sajid Ahmed
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Mr. Ahmed is an English Solicitor practicing in Step toe's London office. He advises major non-EU based manufacturers on REACH compliance efforts with a particular

emphasis on the interface between REACH and trade issues. Sectors in which he has advised companies on REACH include petroleum, petrochemicals, chemicals, textiles and life sciences. He also provides advice on international trade and regulatory issues.



Laura Atlee
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Ms. Atlee is a member of the New York Bar who practices in Step toe's Brussels office. Her practice focuses on both EU regulatory and international law, with emphases

on environment, trade, and competition law. She is acknowledged by the Legal 500 for her regulatory advice in the environmental field. Recent representative matters in which she has been involved include: advice on REACH for the metals sector and for downstream users, state aid specific to the chemicals sector, trade measures (i.e. anti-dumping and subsidies), customs, intra-EU market access, and climate change legislation.



Craig Simpson
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Mr. Simpson is an English Solicitor practicing in Step toe's Brussels office. His practice is focused on chemicals registration

and authorisation under REACH, biocides, pesticides, pharmaceuticals, and medical devices. Recent experience has included representing a biotechnology company and a major trade association as interested third parties in high

profile litigation before the European Courts of Justice and preparing Task Force and Data Sharing Agreements for collective dossier notification under the Biocidal Products Directive. Mr. Simpson is consistently recommended in *PLC's Life Sciences Handbook*.



Denis Mottet
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Mr. Mottet is project manager at Step toe's Brussels office for the REACH team. He is a Belgian chemical engineer who

has experience in the pharmaceutical industry and as project manager of European funded research projects in the field of biotechnology. Before joining Step toe, he worked at the European Commission on topics related to the competitiveness of the chemical sector.



Tanja Ehnert
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Ms. Ehnert is a legal assistant in Step toe's Brussels office. She works closely with firm attorneys to advise clients on the REACH

Regulation, Biocidal Products Directive, on the EU regulatory framework for GMOs and the emerging issue of nanotechnology regulation. Prior to joining Step toe, Tanja completed a traineeship with the European Commission's Environment Directorate General, during which time she assisted on the revision of the Biocidal Products Directive.

In addition, Step toe provides integrated services with RCL, Limited, a scientific and regulatory consultancy based in the UK and led by Graham Lloyd.

Graham Lloyd, glloyd@regcs.co.uk

Mr. Lloyd is a scientific and regulatory consultant with more than 25 years experience in European regulation of the chemical industry; he works directly on a broad range of EU, UK, and other national regulatory programs. Mr. Lloyd counsels clients in all aspects of chemical regulatory affairs, with a particular focus on REACH compliance. Working with Step toe, Mr. Lloyd and RCL provide a comprehensive set of skills to assist clients in compliance with the many EU directives and regulations applicable to the chemical industry.

We will be pleased to discuss our REACH services with you. To contact our REACH team please call +32 2 626 0572 or email REACH@step toe.com

STEPTOE & JOHNSON LLP

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