



STEPTOE & JOHNSON LLP

US/EU

**Chemicals, Pesticides,
& Biocides Regulation**



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Chemicals, Pesticides, & Biocides Regulation - US

Steptoe's chemical regulation team provides services to a broad range of chemical industry clients on cutting-edge issues. Our regular interface with EPA on chemical and pesticide regulation and control issues provides us with a unique, forward-looking perspective on emerging regulatory issues and a corresponding ability to develop effective strategies with our clients.

Steptoe's active chemicals practice serves many clients in the chemical and manufacturing industries. Among our areas of practice are:

Chemical Regulation

Steptoe regularly advises chemical industry clients on a broad spectrum of regulatory programs and policy issues. Our professionals are experienced with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Food Quality Protection Act (FQPA), the Federal Hazardous Substances Act (FHSA), the Toxic Substances Control Act (TSCA), the Resource Conservation and Recovery Act (RCRA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA or Superfund) and the Federal Food, Drug and Cosmetic Act (FFDCA).

Pesticide Regulation

Steptoe has a well-known and respected practice in the regulation and registration of pesticides, with a focus on industrial biocides and antimicrobial products. Our professionals represent the interests of registrants and segments of the pesticide industry before EPA, OMB, Congress, courts, and many states. We have worked on a wide range of matters, including regulation development, registrations, pre-registrations, data call-ins, data compensation, consortium management, and enforcement issues.

The scope of products handled include, for example, drinking water and swimming pool treatment chemicals, preservatives for paints, coatings, adhesives, plastics, metal working fluids and other materials, wood preservatives, marine antifoulants, pulp and paper mill products, nanotechnology, and a wide variety of other use areas.

Toxic Substances Control Act

Steptoe attorneys regularly provide TSCA compliance advice and work with clients to resolve enforcement matters. We assist our clients in achieving compliance and provide information necessary to ensure ongoing compliance. Steptoe professionals also expect to play a role in the upcoming debate on legislative changes to TSCA's statutory provisions.

Federal Food, Drug & Cosmetic Act

Steptoe works closely with clients and FDA staff on food additive clearances, food labeling regulation, and personal care products regulation.

Hazardous Waste Regulatory Matters

Steptoe provides compliance advice on federal and state solid and hazardous waste compliance issues, including facility plans, waste classification, and permit and disposal requirements.

Steptoe's chemical regulation and control practice values its close working relationships with the relevant offices at EPA. These relationships allow us to be better informed as to how certain positions are likely to be received by EPA. It enables us to understand the objectives of the Agency and work constructively toward solutions. This integration of government relations and legal work is an additional dimension our firm brings to its work for ACC and other clients.

Chemicals, Pesticides, & Biocides Regulation - EU

Steptoe has a long history of servicing and advising the chemicals industry in Europe. We have particular experience in plant protection products (pesticides), biocides (antimicrobials), cosmetics, and commodity chemicals regulation including REACH. Our integrated team is comprised of both lawyers and technicians. This enables us to provide a comprehensive approach to compliance and deliver greater over-all efficiency and lower cost for clients.

Chemicals

Our Brussels office has provided strategic analysis and representation for clients on REACH throughout its legislative passage. Since its adoption at the end of 2006, we have been advising on the legal, regulatory and technical obligations that the new chemical legislation imposes on them. Our current activities are focused on helping clients:

- build, manage and execute internal compliance structures;
- manage their relationships with third parties (producers, importers and downstream and end users);
- classify whether they should be registering substances on their own, in preparations or in articles, understand the scope of applicable exemptions;
- evaluate likely consortia memberships;
- engage in SIEF activities, including substance sameness discussions, data gap analysis, data valuation and compensation, settling SIEF agreements and the selection of a Lead Registrant;
- comply with antitrust/competition law issues.

Biocides and Pesticides

Our Brussels office has focused on the regulation of pesticides and biocides since the directives governing each area were adopted, and has been closely involved in the review and revision process for each. With respect to biocides, our firm has represented clients in different sectors of the biocidal products industry, on issues including:

- Negotiation of consortia agreements
- Representation of clients on/in consortium meetings
- Data protection and compensation
- Negotiations with the Commission and Member States Competent Authorities

Steptoe has a substantial practice representing plant protection product registrants. We support registrants before the Commission and Member States. We have also represented clients before the European Courts of Justice defending the authorisation of plant protection products.

Our lawyers have worked to maintain cooperative relationships with Commission and Member State officials to assist us in obtaining prompt and accurate feedback on even the most difficult issues.

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United States

Seth Goldberg, sgoldberg@step toe.com

Mr. Goldberg has experience in a range of chemical regulatory issues, including FIFRA and TSCA, the HPV testing program, the Food Quality Protection Act, and the Federal Hazardous Substances Act. Clients often call on him to represent them before administrative agencies and courts in a broad range of complex matters. A substantial part of his practice involves compliance advice, agency rulemaking and license decisions, and appeals from such decisions.

Sara Beth Watson, swatson@step toe.com

Ms. Watson has more than 20 years of experience in chemical regulatory and occupational safety litigation and compliance counseling, including the integration of various regulatory requirements into a comprehensive compliance strategy for the regulated entity. Ms. Watson has provided compliance counseling to companies from small entrepreneurs to multi-national corporations and trade associations regarding a wide range of regulations, including TSCA, RCRA, CERCLA, EPCRA, CAA, CWA, FIFRA, NEPA, OSHA, FFDCA, Controlled Substances Act, site security, and various state laws such as California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65).

Cynthia Taub, ctaub@step toe.com

Ms. Taub has practiced at Steptoe for over five years. Her experience encompasses a wide range of environmental regulatory issues, with an emphasis on pesticide and hazardous chemical

regulation and the National Environmental Policy Act (NEPA). Ms. Taub's practice includes compliance counseling, regulatory development, judicial challenges to EPA regulations, and handling administrative actions. She also has focused on federal preemption, enforcement and NEPA in litigation and appellate work.

Sue Crescenzi, screscenzi@step toe.com

Ms. Crescenzi has more than 25 years of experience in the chemical regulatory arena. She is a non-attorney regulatory specialist who works closely with clients on all aspects of their relationship with the EPA. Additionally, Ms. Crescenzi has handled other chemical regulatory matters involving various programs of US EPA, US FDA, OSHA, California EPA, and state pesticide and food regulatory agencies.

Ms. Crescenzi acts as manager of several data development consortia under FIFRA, and also has been involved in a broad range of pesticide policy issues, working closely with EPA and industry representatives on various pesticide regulatory proposals. She participated in the negotiations that led to the creation of PRIA and is assisting with the development of PRIA II. Ms. Crescenzi assists clients in developing and presenting training programs to bring pesticide and chemical regulatory registration and compliance functions in-house and is a frequent speaker at pesticide conferences.

Elizabeth Brown, eabrown@step toe.com

Ms. Brown is a non-attorney technical and regulatory specialist in the Washington office.

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She has over 25 years of experience in pesticide registration, regulation, data development, and project management. She works closely with clients and EPA staff on issues relating to conventional, biochemical, microbial, and antimicrobial pesticides.

Eric Dubé, edube@steptoe.com

Mr. Dubé is a non-attorney technical and regulatory analyst in the Washington office. He has over 17 years of technical and scientific experience. He focuses on assisting clients in developing regulatory strategies to meet data generation and risk assessment requirements.

Juliana Mann, jmann@steptoe.com

Ms. Mann is a non-attorney paralegal specialist in the Washington office. She has over 10 years experience assisting clients on federal and state environmental regulatory matters, primarily antimicrobial pesticide regulatory and registration issues.

European Union

Darren Abrahams, dabrahams@steptoe.com

Mr. Abrahams is an English Barrister and a partner in Steptoe'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* identifies 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). Recent representative matters in which he has been involved include: strategic advice on the business impact of the proposed revision to the biocidal products directive; defending the authorisation of plant protection products before the Court of First Instance; strategic advice on compliance with REACH; protecting data, establishing consortia, and drafting supply agreements and letters of access for biocidal products; and managing environmental liabilities associated with manufacturing processes and product sales.

Dr. Anna Gergely, agergely@steptoe.com

Dr. Anna Gergely, is the firm's Director, EHS Regulatory in Steptoe'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.

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Jim Searles, jsearles@steptoe.com

Mr. Searles is a partner in Steptoe's Brussels office. His work concentrates on EU and international law, focusing on the fields of trade and environment. 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 the EU's REACH regulation, as well as developing REACH compliance strategies. He also assists industry clients concerning EU sectoral chemical regulatory measures and the European Union's climate change policy and CO2 emissions initiatives. He works with companies and trade associations in the agricultural, chemicals, motor vehicle, information technology, steel, textiles, and general consumer goods sectors.

Jean Rusotto, jrusotto@steptoe.com

Mr. Rusotto is a partner in Steptoe's Brussels office. 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. Rusotto 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 directory.

Craig Simpson, csimpson@steptoe.com

Mr. Simpson is a UK-qualified solicitor with experience in chemicals registration and authorisation under REACH, biocides, pharmaceuticals, medical devices, EU regulation

of food and feed, and related competition issues. In the biocides and pesticides areas, Mr. Simpson's work includes advice on challenging Commission active substance non-inclusion Decisions and notification issues for existing active substances under the Biocidal Product Review Regulations. Regular clients are leading multinational companies and trade associations operating at both European and international levels. 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, preparing Task Force and Data Sharing Agreements for collective dossier notification under the Biocidal Products Directive, and advising on related horizontal cooperation competition issues. Mr. Simpson regularly lectures and publishes on matters affecting the Life Sciences industries and is consistently recommended as a leading lawyer by PLC's Life Sciences Handbook. Before joining Steptoe, Mr. Simpson trained with the European Commission's Directorate-General Internal Market, dealing with actions against EU Member States for infringement of EC Treaty rules on free movement of goods.

Laura Atlee, latlee@steptoe.com

Ms. Atlee is a member of the New York Bar who practices in our 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

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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. In addition, Steptoe provides integrated services with the following experienced independent consultants.

Graham Lloyd, glloyd@regs.co.uk

Steptoe provides integrated services with RCL, Limited, a scientific and regulatory consultancy based in the UK and led by Graham Lloyd. Mr. Lloyd is a 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, from ensuring compliance with the many EU directives and regulations applicable to the chemical industry, to comprehensive monitoring and analysis of emerging regulatory initiatives. In addition, he is widely recognized for his leading role in the industry response to the Biocidal Products Directive.

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